OVERVIEW OF INDIA'S QUALITY INFRASTRUCTURE

A Guide to Standardisation, Conformity Assessment, Accreditation, Market Surveillance, and Metrology

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About this Publication

This publication was funded by the German Federal Ministry for Economic Affairs and Energy as part of its Global Project Quality Infrastructure (GPQI). The Global Project Quality Infrastructure facilitates political and technical dialogues with partner countries. wIts goal is to reduce technical barriers to trade, enhance product safety, and strengthen consumer protection. The dialogues focus on opportunities and challenges related to standardisation, conformity assessment and accreditation, and market surveillance. They include relevant line ministries, regulators, public agencies, accreditation and standards bodies, industry associations, companies, technical and scientific institutions. The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH – the German Agency for International Cooperation – has been commissioned by the German Federal Ministry for Economic Affairs and Energy to support the implementation of GPQI in Brazil, China, India, and Mexico.

In India, the German Federal Ministry for Economic Affairs and Energy and the Indian Ministry for Consumer Affairs, Food & Public Distribution have established the *Indo-German Working Group on Quality Infrastructure* to strengthen bilateral collaboration. The Working Group brings together representatives from relevant ministries, including the Ministry of Commerce and Industry (MoCI), Ministry of Electronics and Information Technology (MeitY), Ministry of Heavy Industries and Public Enterprises (MoHI), Ministry of Road Transport and Highways (MoRTH), Ministry of Power (MoP) as well as experts from the Bureau of Indian Standards (BIS), industry, associations including the Confederation of Indian Industry (CII), and accreditation bodies including the Quality Council of India (QCI). The mutually agreed work plan reflects key areas of the economic relations between both countries. It covers topics ranging from automotive, electric vehicle and charging infrastructure, machinery safety, Industry 4.0, IT security and data protection to market surveillance. The Indian country component of GPQI supports the implementation of the mutually agreed annual work plan of the Working Group.

This publication is a result of the activities of the *Indo-German Working Group on Quality Infrastructure*. It was prepared with support of Aaditech Inspections and Services Pvt. Ltd and Dr. Kari Hiepko-Odermann. It is the first volume in a series of publications on quality infrastructure.

Foreword

Quality infrastructure fulfils essential tasks in a country's economy. It enhances the competitiveness of industry and facilitates international trade, contributes to ensuring the safety of products, and the protection of consumers.

Secretary Mr A. K. Srivastava (r) and Director-General Mr S. Schnorr (l) at the 5th Annual Meeting of the *Indo-German Working Group on Quality Infrastructure* on 16th January 2018 in New Delhi, India.

India and Germany have come together to support the development of each other's national quality infrastructures, and to grow closer together as economic partners. In 2013, the Ministry of Consumer Affairs, Food & Public Distribution, Government of India, and the German Federal Ministry for Economic Affairs and Energy initiated a bilateral Working Group on Quality Infrastructure. The Working Group aims to reduce technical barriers to trade, strengthen product safety, and ensure consumer protection. The political and technical dialogue involves relevant ministries – including the Ministry of Commerce and Industry, Ministry of Electronics and Information Technology, Ministry of Road Transport and Highways, and Ministry of Heavy Industries and Public Enterprises – as well as regulators, industry associations, companies, and technical and scientific institutions.

An important step in collaboration is understanding one another's approaches. This study provides an overview of the quality infrastructure landscape in India, covering standards development, technical regulation, conformity assessment and accreditation, and market surveillance.

We are optimistic that this publication will contribute to further deepening the Indo-German industrial collaboration, for the benefit of all stakeholders and the citizens in both countries.

Stefan Schnorr

Director-General
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Germany

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Secretary to the Government of India
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Ministry of Consumer Affairs, Food & Public Distribution
India

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3GPP	3rd Generation Partnership Project
AIMED	Association of Indian Medical Device Industry
APEDA	Agricultural and Processed Food Products Export Development Authority
APLAC	Asia Pacific Laboratory Accreditation Cooperation
APMP	Asia Pacific Metrology Programme
ARAI	Automotive Research Association of India
ASME	American Society of Mechanical Engineers
ASSOCHAM	Associated Chambers of Commerce of India
AYUSH	Ayurveda, Unani, Sidha & Homoeopathy
BEE	Bureau of Energy Efficiency
BIS	Bureau of Indian Standards
BMTPC	Building Materials and Technology Promotion Council
BND	Bhartiya Nirdeshak Dravya (Indian Reference Material)
BRC	British Retail Consortium
CAB	Conformity Assessment Body
CASCO	ISO Committee on Conformity Assessment
CED	Civil Engineering Division (BIS)
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CII	Confederation of Indian Industry
CIMFR	Central Institute of Mining and Fuel Research
CIML	International Committee of Legal Metrology
CMC	Calibration Measurement Capability
CoC	Certificate of Conformity
COPOLCO	ISO Committee on Consumer Policy
CRS	Compulsory Registration Scheme
CSIR	Council of Scientific and Industrial Research
DIPP	Department of Industrial Policy & Promotion
DoT	Department of Telecommunications
EIC	Export Inspection Council
EMC	Electro Magnetic Compatibility
ETSI	European Telecommunications Standards Institute
FICCI	Federation of Indian Chambers of Commerce and Industry
FMCS	Foreign Manufacturers Certification Scheme
FSSAI	Food Safety & Standards Authority of India
GAP	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GFCP	Good Field Collection Practices
GFSI	Global Food Safety Initiative
GHTF	Global Harmonisation Task Force
HACCP	Hazard Analysis and Critical Control Points

IAF	International Accreditation Forum
IAPMO	International Association of Plumbing and Mechanical Officials
ICT	Information & Communication Technology
IEC	International Electrotechnical Commission
IECEE	IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components
ILAC	International Laboratory Accreditation Cooperation
INSS	Indian National Strategy for Standardization
IOT	Internet of things
ISI	Indian Standards Institution
ISO	International Organisation for Standardisation
ISQua	International Society for Quality in Health Care
IST	Indian Standard Time
ITES	Information Technology enabled Services
ITU	International Telecommunications Union
LF, HF	Low Frequency, High Frequency
LITD	Electronics & Information Technology Division (BIS)
LVDC	Low Voltage Direct Current
MDR	Medical Devices Rules
MED	Mechanical Engineering Division (BIS)
MeitY	Ministry of Electronics and Information Technology
MLA	Multilateral Recognition Arrangement
MNRE	Ministry of New and Renewal Energy
MORTH	Ministry of Road Transport and Highways
MoU	Memorandum of Understanding
MoUD	Ministry of Urban Development
MRA	Mutual Recognition Agreement
MSME	Medium, Small and Micro Enterprises
NABCB	National Accreditation Board for Certification Bodies
NABET	National Accreditation Board for Education & Training
NABH	National Accreditation Board for Hospitals
NABL	National Accreditation Board for Testing & Calibration Laboratories
NAPC	National Action Plan for Chemicals
NB	Notified Bodies
NCTCF	National Coordination of Testing and Calibration Facilities
NGCP	National Capital Goods Policy
NMI	National Metrological Institute
NMPB	National Medicinal Plants Board
NOS	National Occupational Standards
NPL	National Physical Laboratory
NPOP	National Programme for Organic Production
NTH	National Test House
OECD	Organisation for Economic Co-operation and Development
OIML	International Organisation of Legal Metrology

PAC	Pacific Accreditation Cooperation
PASC	Pacific Area Standards Congress
PESO	Petroleum & Explosives Safety Organisation
PNGRB	Petroleum & Natural Gas Regulatory Board
PT	Proficiency Testing
QCI	Quality Council of India
QI	Quality Infrastructure
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SARSO	South Asian Regional Standards Organisation
SDO	Standards Developing Organisation
SMOI	Silk Mark Organisation of India
SPS	Sanitary & Phytosanitary
SSL	Secondary Standards Laboratory
STQC	Standardisation Testing and Quality Certification Directorate
TBT	Technical Barriers to Trade
TEC	Telecommunications Engineering Centre
VCSMPP	Voluntary Certification Scheme for Medicinal Plant Produce
WHO	World Health Organisation
WRAP	Worldwide Responsible Accredited Production
WTO	World Trade Organisation
ZED	Zero Effect Zero Defect

Executive Summary

Quality infrastructure (QI) ensures both user quality expectations and regulatory requirements are met. When coherent and aligned with international requirements, QI contributes to national competitiveness, economic growth, and the well-being of a country's citizens. Understanding the development of a country's QI and the public and private institutions that create it, offers a strong foundation for understanding how to do business there.

India sees quality as key for sustainable economic growth and its transformation to a global manufacturing hub, which is promoted through the government's *Make in India* initiative. Adopting international standards and taking leadership positions in priority areas of international standardisation has become an important focus.

This publication begins with an examination of the development of India's QI infrastructure. It continues with an overview of the QI system, its institutions, legal framework, and formal processes, with a focus on international trade.

Figure 1: Components of a National Quality Infrastructure

Standards Development

Standardisation in India is largely government-driven and led by a national standards body, the Bureau of Indian Standards (BIS), which is exclusively authorised to publish Indian Standards. The BIS develops standards through several hundred sectional committees, made-up of different stakeholder groups, and draft standards are shared for public consultation. Over 19,000 standards have already been published by BIS and around 5,000 of these are harmonised with international standards. India is also a member of several technical committees at the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). However, the international engagement of Indian experts has remained low.

Aside from BIS, several sectoral standards developing organisations (SDOs) also operate in India. These SDOs are often members of international standards organisations and two of these organisations have made arrangements with BIS to offer their standards as Indian Standards.

Under the Indo-German Working Group on Quality Infrastructure a standardisation dialogue strengthens the cooperation between the standards bodies of India, Germany and the European Union (EU). Several foreign SDOs have also established offices in India to promote their

standards. Five European bodies are represented through a Seconded European Standardisation Expert for India (SESEI), among them the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI).

Conformity Assessment and Accreditation

The BIS plays a central role in the Indian conformity assessment system. It operates several schemes for the certification of goods and articles, with more than 63,000 certifications, BIS accounts for about half of the certifications issued in India.

Private conformity assessment bodies (CABs) mainly operate in management systems and foreign certification schemes. Foreign multinational CABs provide a large complement of conformity assessment schemes addressing diverse requirements like product safety, product performance, organisational systems, and sustainable practices. A few Indian agencies offer certification schemes for specific product groups such as Indian origin tea, silk, organic products, medicinal plants, and medical devices.

The Indian accreditation system is coordinated by the Quality Council of India (QCI), a non-profit and autonomous body with four accreditation boards which is under the administrative control of the Ministry of Commerce and Industry. Despite QCI's well-established structure, overseas accreditations remain popular; especially the US National Accreditation Board (ANAB) and the Joint Accreditation System of Australia and New Zealand (JAS-ANZ). These organizations provide a significant number of accreditations in various fields, while laboratory accreditation has remained in Indian hands.

Technical Regulations

Compared to other countries, India has a relatively small number of technical regulations. This 'regulatory gap' will soon be closed by the introduction of new mandatory technical requirements. Issued by specific regulatory bodies set up by the government or line ministries, these new requirements have been motivated by expert discussions and political observations.

A majority of technical regulations refer to the product certification scheme or registration scheme of the BIS. Different from the EU, technical regulations in India always specify or reference the standards or essential requirements, leaving no options other than the notified Indian standards to demonstrate compliance.

In October 2017, the new BIS Act, 2016 entered into force. Considered a landmark regulation, it makes it easier to declare, or notify, products, systems and services for which compliance to specified standards is mandatory. This is usually done by line ministries issuing Quality Control Orders (QCOs). Currently, India has not adopted a formal code for good regulatory practices, e.g. for conducting regulatory impact assessments, risk assessment, or review of regulations. However, public consultation and notification according to requirements of the World Trade Organization (WTO) are carried out when issuing QCOs.

Market Surveillance

Market surveillance in India is mainly carried out before products are brought on the market. India does not have a centrally coordinated market surveillance system and the procedures and responsibilities depend on the products. Products covered by the mandatory certification schemes of BIS are tested in one of two ways. Either conformance is reconfirmed by BIS via market samples or directly at the production sites. For electronic and IT products, the Indian Ministry of Electronics and IT (MeitY) appointed the Software Technology Parks of India (STPI) to take random surveillance samples from the market.

Metrology

The National Physical Laboratory (NPL), an institution of the autonomous government body Council for Scientific & Industrial Research, is India's National Metrology Institute (NMI). It provides traceability for calibration of measurements across 239 Calibration and Measurement Capabilities (CMCs) in the data base of the International Bureau of Weights and Measures (BIPM) and 168 international and bilateral key comparisons. The NPL also produces and certifies reference materials.

The legal metrology framework is coordinated by the Directorate of Legal Metrology of the Department of Consumer Affairs, Ministry of Consumer Affairs, Food & Public Distribution (MoCAF&PD), which also represents India at the International Organization of Legal Metrology (OIML). India has adopted the metric system and international system of units recognised by the OIML. The Legal Metrology (National Standards) Rules, 2011 prescribe the standards of weights and measures, which are administered by the state governments.

Introduction

As the Indian economy grows in size and complexity so does the demand for quality products and services, including compatibility and performance. Since India integrates itself into international trade with *Make in India*, promoting itself as a global manufacturing hub, the safety of Indian workers and consumers becomes more and more relevant. Understanding, aligning to, and contributing to international practices and the requirements of overseas markets moves India toward these goals. And, by adopting international best practices the competitiveness of the Indian industry is strengthened.

Quality Infrastructure (QI) is playing an increasingly important role both domestically and internationally for India. QI, or the system, which ensures that user quality expectations, and regulatory requirements are met, is made up of all of the public and private institutions required to establish and implement voluntary standards and mandatory technical regulations, conformity assessment and accreditation, as well as market surveillance and metrology.[1] A QI that is coherent and aligned with international requirements and practices contributes to national competitiveness, economic growth, and the well-being of a country's citizens.

The different elements of India's QI must work well individually and together to be effective. Trust can only be created if a product meets a certain standard, if this compliance is demonstrated sufficiently, and if systems detect and sanction non-compliance effectively.

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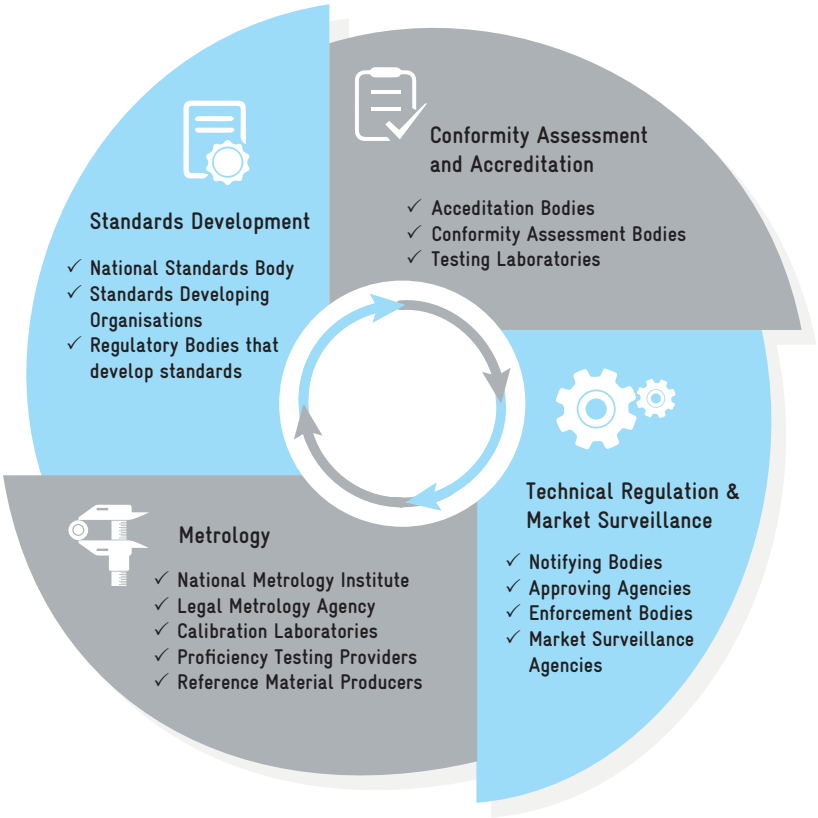


Figure 2: Bodies and Institutions in a National Quality Infrastructure

[1] Some definitions of quality infrastructure do not include technical regulations. Given their relevance for international trade, this study also considers technical regulations

Historical Evolution

QI systems take on key tasks in a country's economy. They are strong indicators of economic policies at points in the industrial development of a country. The emergence of India's own QI system closely follows the four main phases of India's economic and industrial developments since 1947 (see an overview in Table 1).

Economic Phase	Key Developments in Quality Infrastructure
1947-1965 **Phase 1: Establishment of institutions and legal frameworks**	State owned institutions established to cater to standards development, metrology, testing, export quality, essential technical regulations enacted
1965-1980 **Phase 2: Era of licensing and low economic growth**	Spread of government supported product certification, setting standards in food and agriculture
1980-1991 **Phase 3: Partial liberalisation and decontrol**	Introduction of global standards through automotive tie-ups, adoption of quality management systems by industry
1991– **Phase 4: Institutional reforms and integration into the world economy**	Setting up of national accreditation boards, setting up operations by foreign certification bodies, increase in technical regulations

Table 1: The Four Phases in the Evolution of the Indian Quality Infrastructure System

Phase 1: Establishment of Institutions and Legal Frameworks (1947-1965)

The first phase of India's economic development (1947–1965) is characterised by the creation of a strong public sector and industrial foundation made up of iron and steel, capital goods and heavy industries, and basic physical infrastructure. This period saw the establishment or modernisation of critically important public institutions that would support and guide industrial and other economic activities.

One of these was the Indian Standards Institution (ISI). Set up in 1947, ISI developed Indian Standards to aid and support industry growth. It was succeeded in 1987 by the Bureau of Indian Standards (BIS). Another noteworthy institution, the National Physical Laboratory (NPL) was established in 1950 as India's National Metrology Institute. The NPL aided the development of a testing infrastructure across sectors. With plans to set up a quality certification programme, the Central Government passed the *Indian Standards (Certification) Act* in 1952.

At the same time steps were being taken to strengthen the country's laboratory infrastructure. A programme was initiated for the improvement and modernisation of the government-owned testing laboratory, the Kolkata based National Test House (NTH) and the electrical sector saw the establishment of the Central Power Research Institution (CPRI).

One of India's earliest technical regulations, the *Prevention of Food Adulteration Act* was instituted in 1954, and is now subsumed by the *Food Safety and Standards Act, 2006*. Two years later, in 1956, the Government of India passed the *Standards of Weights and Measures Act*, which incrementally introduced the metric system, making metric weights and measures mandatory between 1958 and 1962. The following year, the Export Inspection Council (EIC) was set up by the Government of India to support Indian exports through quality control and inspection programmes.

Phase 2: Era of Licensing and Low Economic Growth (1965-1980)

The second phase (1965 – 1980) was marked by tighter governmental controls, licensing of private enterprises, and more bureaucracy. Widely believed to have significantly contributed to a decline in both economic growth and industrial development, stringent licensing created monopolies and restrictions on imports and foreign investments led to shortages of goods and a decline in their quality. The slowest rate of economic growth in the history of post-independence India marks this period.

State-owned institutions created or modernised in the previous phase, such as the ISI, NPL, and NTH, operated within a controlled environment, leading to developmental stagnation in the Indian QI system. The ISI Mark, a product certification scheme could be seen as exceptional during this phase. It slowly gained popularity in the consumer segment and remained the only widely recognised certification programme in India until the early 1990s with the advent of the management systems certification schemes led by ISO 9001.

Between 1965 and 1980 the agricultural sector experienced a large productivity increase, with India becoming self-sufficient in food grains. This 'green revolution', was the result of the introduction of high-yielding varieties of seeds after 1965 and the increased use of fertilisers and irrigation. Accordingly, a food and agriculture division was established at BIS to facilitate the growth in the agro-sector through standardisation of equipment, machinery, and processed foods.

Phase 3: Partial Liberalisation and Decontrol (1980-1991)

The third phase (1980 – 1991) can be seen as the beginning of a reform process of modest economic liberalisation. Selective de-licensing, easing of import norms, and permission for private investments in infrastructure contributed to an increase in economic growth.

Technical collaboration with Japanese car producers, and the infusion of technology and the expansion of the telecommunications sectors created important impulses for India's QI system and industrial growth. This affected the quality landscape through the introduction of high standards in automotive and telecommunications, two major sectors of the economy.

In absence of any other legal basis, some of the first technical regulations in India – such as steel tubes (1978), electrical appliances (1981), and cements (1983) – were issued under the *Essential Commodities Act, 1955*. This act was principally established to control the supplies of essential consumer goods and to mitigate shortages of goods due to hoarding and the black market. However, it lacked adequate penalty provisions making compliance low.

Most of these regulations migrated to the *Bureau of Indian Standards Act, 1986*. With this act the Central Government introduced the first comprehensive legal framework for standards development and product certification. A key objective was to enable the adoption of international standards and promote certification.

In order to set up a coordinating mechanism for the testing and calibration laboratories, the Department of Science and Technology set up a forum designated as National Coordination of Testing and Calibration Facilities (NCTCF) in 1981. This body established an accreditation programme for laboratories, and until its transition into a formal board, accredited 175 Indian laboratories.

The maturing of the automotive and engineering sector and the development of the ISO 9001 series of standards were instrumental for the introduction of overseas conformity assessment bodies and launch of other forms of certifications beyond product certification.

Phase 4: Institutional Reforms and Integration into the World Economy (from 1991)

The fourth phase, beginning in 1991, is characterised by the introduction of important policies for economic liberalisation, like the reduction of licensing controls, relaxed regulations for

foreign investment and technology imports, the introduction of a floating exchange rate, and the promotion of competitive markets. The phase also saw the coming of age of the Indian information technology (IT) industry which entered global markets and brought in standards in the service sector.

During this phase Indian QI consolidated. A key development was the transition of the NCTCF into an autonomous accreditation board for laboratories in 1993 that became the National Accreditation Board for Testing and Calibration Laboratories (NABL) five years later. In an unprecedented development, three main national industry associations – the Confederation of Indian Industry (CII), the Federation of Indian Chambers of Commerce & Industry (FICCI), and Associated Chambers of Commerce and Industry of India (ASSOCHAM) – all partnered with the Indian government to jointly set up the Quality Council of India (QCI). One of the first boards to be set up in the QCI was the National Accreditation Board for Certification Bodies (NABCB).

The creation of the two national accreditation boards cleared the way for recognition of other forms of conformity assessment like management systems certification, third party inspection, and laboratory testing services provided by bodies in the private and government sector. This move also facilitated the signing of mutual recognition agreements with India's trade partners. Over time, the NABCB and NABL acquired their respective international multilateral recognition arrangement (MLA) and mutual recognition arrangement (MRA) from the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the International Laboratory Accreditation Cooperation (ILAC), Pacific Accreditation Cooperation (PAC), and the International Accreditation Forum (IAF).

The spread of certification bodies in India also defines this period. It began with multinational conformity assessment bodies (CABs) setting up operations in India, followed by the opening of a number of Indian CABs. Initially, all accreditations for management systems certification were granted by overseas bodies. However, in 2000, the NABCB began accrediting certification bodies, spurred ahead when the Ministry of Micro, Small and Medium Enterprises (MSMEs) announced a subsidy for ISO 9001 certification to MSMEs that was backed by NABCB accreditation. In 2007, the QCI set up two more boards; the National Accreditation Board for Education and Training (NABET), and the National Accreditation Board for Hospitals (NABH).

Through the *BIS Act, 1986* the government had acquired powers to mandate BIS certification on products and enforce them. However, the act was restricted in terms of the product scope and in the options of conformity assessment schemes. The reviewed *BIS Act, 2016*, changed this and provides a wider scope and choices of conformity assessment options for issuing technical regulations.

India, one of the original signatories of the General Agreement on Trade and Tariffs (GATT), was an active participant in the Uruguay Round of discussions. It joined the World Trade Organization (WTO) as a founding signatory member in 1995, including the two agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS).

Standards Development

Standardisation in India is largely government-driven and led by BIS, the national standards body which is exclusively authorised to publish Indian Standards. The BIS has played an historic role in the economic development of India by providing the basic standards, product standards, test methods, and codes of practice that supported the country's industrial development. Some of its initial activities included offering support to the industry for developing company standards and running campaigns in engineering institutes about the educational use of standards.

The BIS was one of the founding members of the International Organization for Standardization (ISO) and two presidents of ISI (now BIS) served as ISO presidents. The first Director General of ISI, Mr Lal C. Verman, is regarded as one of the original thinkers and contributors to the conceptualisation of standardisation in India. The popularity of the ISI mark certification scheme served as a major incentive for the development of a large number of standards and also for the harmonisation of standards in areas where interoperability was essential.

The BIS is governed by a 27 member governing council, including representatives from the Ministry for Consumer Affairs, Food and Public Distribution (MoCAF&PD), Department of Commerce, Members of Parliament, state governments and union territories, consumer organisations, industry associations, scientific and research organisations, and national accreditation bodies.

The *BIS Act, 1986* mandated BIS with the exclusive authority to develop Indian Standards and also to oversee the harmonious development of standards in India. The act assigned the exclusive right for public claims of conformity to Indian Standards to BIS, essentially to preclude any unsubstantiated and deceptive claims. In several sectors, the Indian industry adopted overseas standards from national bodies as well as private standards bodies if there were no Indian Standards available yet.

Key Economic Benefits of Standards

The ISO has identified three key economic benefits of standards by analysing case studies of companies.

Benefit 1: Streamlining internal operations

Companies can use standards to reduce the time needed to perform specific activities, decrease waste, reduce procurement costs, and increase productivity.

Benefit 2: Innovating and scaling up operations

Standards can serve as the basis for innovating business processes, like allowing firms to introduce and manage new product lines effectively.

Benefit 3: Creating or entering new markets

Standards have been used as the basis for developing new products, penetrating new markets (both domestic and export), supporting the adoption of products, and even creating new markets.

Source: International Organization for Standardization (2014): Economic benefits of standards

Standards development process of BIS

The BIS follows the six principles for standards development from the Agreement on Technical Barriers to Trade (TBT) of the WTO, namely openness, transparency, impartiality and consensus, effectiveness and relevance, coherence, and development dimension.

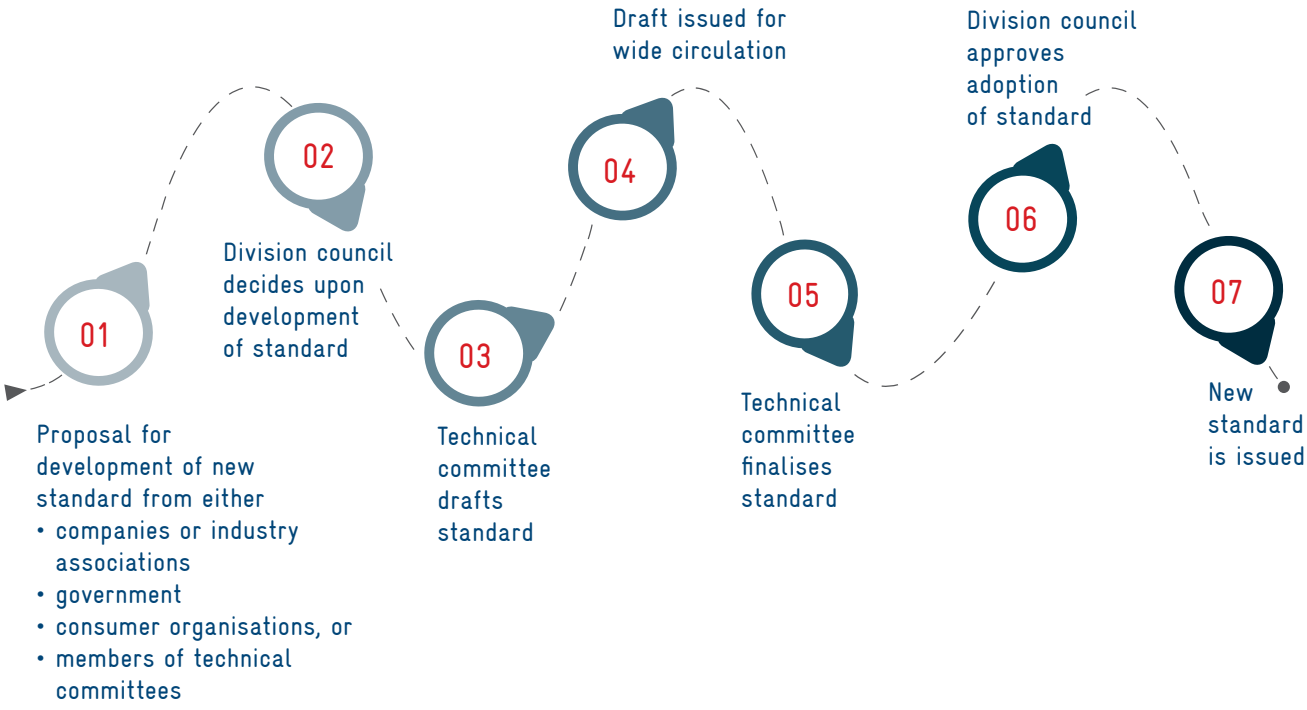


Figure 3: Standards Development Process of BIS

The proposal for a new Indian Standard can be submitted by companies or industry associations, a government ministry or department, consumer organisations, or members of the BIS Sectional Committees, referred to as Technical Committees (TCs). The proposal is considered by the respective BIS Division Council and, once accepted, assigned to the appropriate TC (see Figure 2).

A draft standard prepared and approved by the TC is issued for wide circulation for a period of no less than one month by publishing it on the website of BIS. All interested parties in India can submit their comments and suggestions using the respective templates. For standards referred to in technical regulations interested parties outside India are asked to submit their comments to the WTO-TBT Enquiry Point at BIS. The wide circulation may be waived by the TC where the matter is urgent or non-controversial, although this is rarely done.

Considering the comments received, the TC finalises the draft standard. The chairperson of the responsible Division Council approves the adoption of the standard. All established standards are reviewed periodically, and at least once in five years, to determine the need for revision or withdrawal. Standards are reaffirmed if the TC does not see the need for revision or amendment.

"Two streams of challenges need to be addressed. One relates to how India can become part of the standards setting system and increase conformity, the other relates to India's role in the global debate. Standards are not just about export promotion but also making India ready to meet its internal needs."

Ms Nirmala Sitharaman, then India's Minister of Commerce & Industry at the 4th National Standards Conclave in May 2017

BIS Committee Structure

The standards development work of BIS is distributed over 14 Division Councils with diverse technical scopes covering both manufacturing and service sectors. In 2018, a 15th Division Council on standards for services is planned. The Division Councils have established over 350 Technical Committees. Many of these act as mirror committees of their international counterparts at the ISO and IEC.

Division Councils	Number of Technical Committees	Standards Published
Electronics and Information Technology (LITD)	29	1,590
Electrotechnical (ETD)	44	1,603
Chemicals (CHD)	26	1,730
Civil Engineering (CED)	37	1,775
Food and Agriculture (FAD)	27	2,001
Management Systems (MSD)	13	351
Mechanical Engineering (MED)	29	1,236
Medical Equipment and Hospitals (MHD)	20	1,169
Metallurgy (MTD)	23	1,610
Petroleum, Coal and Related Products (PCD)	16	1,422
Production and General Engineering (PGD)	25	2,275
Textiles (TXD)	25	1,257
Transport Engineering (TED)	19	1,123
Water Resources (WRD)	18	444
Sum	**351**	**19,586**

Data as of 13 July 2018

The scope of the Division Councils and the TCs under them can be found at:
https://services.bis.gov.in:8071/php/BIS/TechnicalDepartments.php

Table 2: Division Council Structure of the Bureau of Indian Standards (BIS)

A Division Council is made up of representatives from various interests such as industry, consumers, regulatory and other government bodies, laboratories, and scientists with a BIS officer as its member secretary. While the initial composition of the Division Councils was decided by the BIS Governing Council, new members are chosen by the Division Councils themselves during the meetings, which are generally held annually. Based on the advice, the secretariat invites the organisations or individuals for their willingness to be appointed. A provision exists for the re-constitution of the Division Councils and TCs every three years. However, in most cases, the past composition is reaffirmed.

The Division Councils are authorised to set up TCs and define their scopes within their respective domains. There is no limitation to the number of TCs. The initial composition and subsequent

changes are decided upon by the Division Council after recommendations from the TC (Figure 2).

Every TC comprises representatives from various interest groups such as industry, consumers, government bodies, laboratories, scientists, and experts in personal capacity. Like the Division Councils, a BIS officer also acts as the member secretary of a TC. New nominations are mainly issued based on additional knowledge domains, and as replacement of existing members. Any organisation wishing to be nominated can write to the TC secretary with due justification, which would be decided by the committee on merit. All committees welcome actively participating members.

TCs are authorised to constitute subcommittees, panels, or working groups within their area of work as necessary, with defined scopes and composition. Panels and working groups may include organisations and individuals who are not regular members of the TCs. All work carried out by them is reviewed and ratified by the TC.

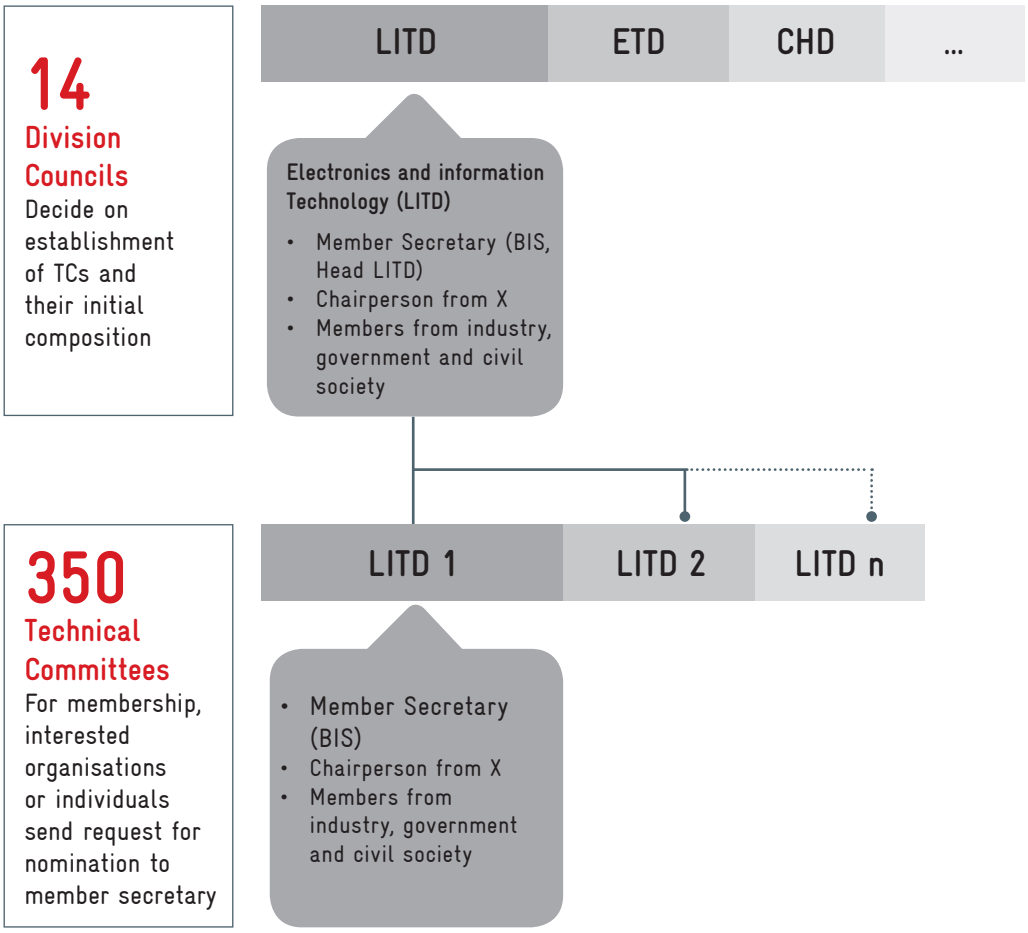


Figure 4: BIS Structure of Division Councils and Technical Committees

Published Indian Standards and International Involvement

To date, more than 19,500 standards are in place in India. Twenty-seven percent of these are harmonised with international standards. Since 2012, the overall number of Indian Standards has been rather stagnant while each year 300-400 standards have been newly developed (see Figure 3). Similarly, the total number of Indian Standards harmonised with international standards is more or less constant, although some divisions such as electrical, electronics and IT, food and agriculture, and management systems have been more active in the adoption of ISO, IEC, and WHO standards.

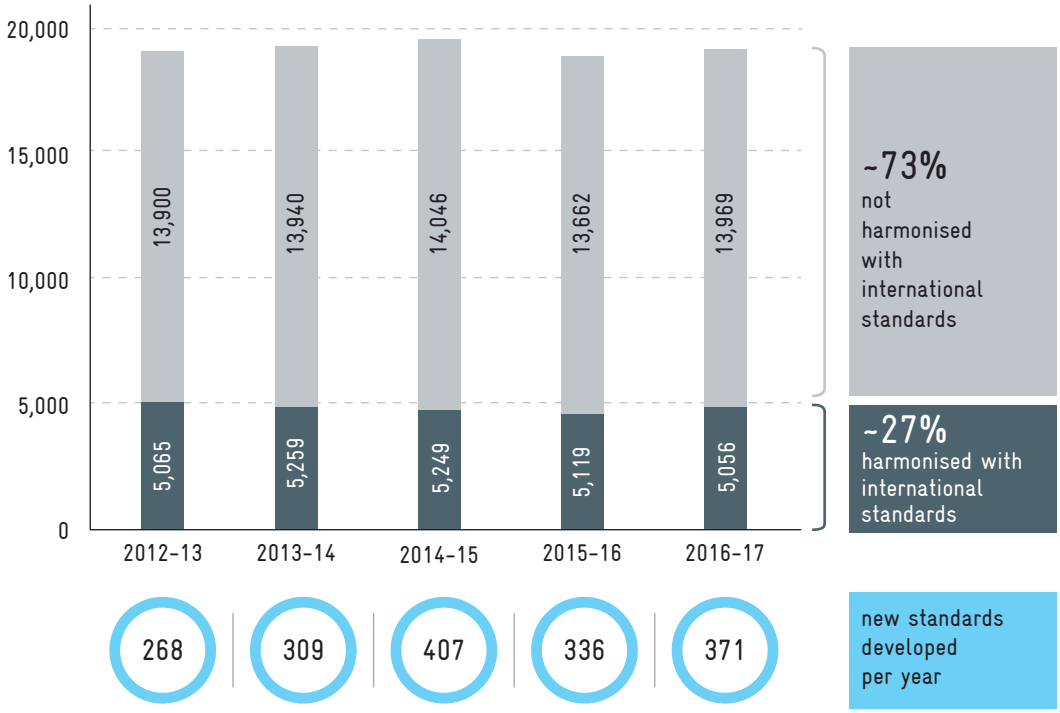


Figure 5: Number of Standards in India

It is currently being discussed by experts in India how to use policy to ensure continued participation at the working group level and financial schemes to enhance the participation of private sector members in international standardisation work. Between 2016-17 India held participating membership, or P membership, in 433 ISO committees and 86 IEC committees (see Figure 4). Even though BIS is a permanent member of a sizable number of ISO and IEC committees, actual participation in the committee meetings is relatively low. In the period 2016-17, only 24 meetings were attended.

	2013-14	2014-15	2015-16	2016-17
P membership on ISO Committees	348	416	418	433
P membership on IEC Committees	70	74	80	86

Figure 6: India's Participation in International Standards Development

The BIS holds the secretariats of two TCs and 6 subcommittees (SCs) at ISO (see Table 3). At IEC level, India holds no secretariat of TCs or SCs but is chairing a System Committee (SyC) on Low Voltage Direct Current (LVDC) and is joint-convenor with Germany of the ad-hoc group on electric vehicle and infrastructure landscaping (ahG 81).

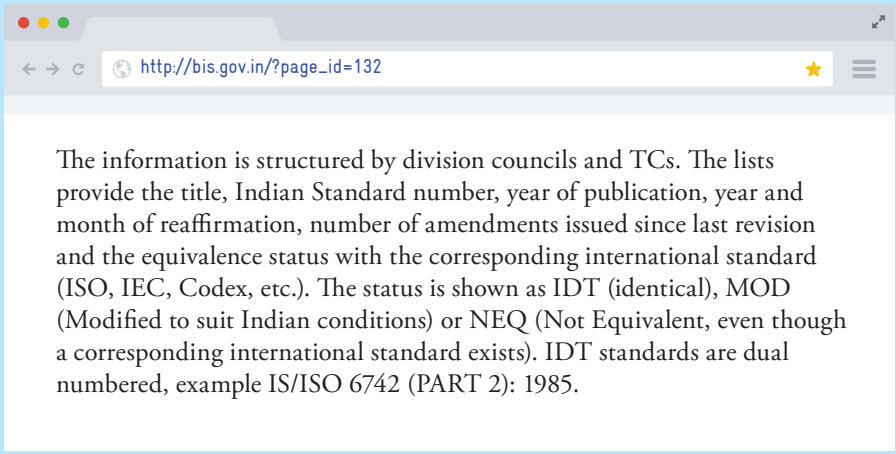
ISO/TC 34/SC 7	Spices and condiments
ISO/TC 113	Hydrometry
ISO/TC 113/SC 1	Velocity area methods
ISO/TC 113/SC 6	Sediment transport
ISO/TC 120	Leather
ISO/TC 120/SC 1	Raw hides and skins, including pickled pelts
ISO/TC 120/SC 2	Tanned leather
ISO/TC 120/SC 3	Leather products

Table 3: Secretariats at ISO Level Held by India

✓ Further information on Indian Standards

The full list of Indian Standards published and those under development can be accessed from the BIS Website:

www.bis.gov.in → *"Standardisation"*



The information is structured by division councils and TCs. The lists provide the title, Indian Standard number, year of publication, year and month of reaffirmation, number of amendments issued since last revision and the equivalence status with the corresponding international standard (ISO, IEC, Codex, etc.). The status is shown as IDT (identical), MOD (Modified to suit Indian conditions) or NEQ (Not Equivalent, even though a corresponding international standard exists). IDT standards are dual numbered, example IS/ISO 6742 (PART 2): 1985.

Standards development by other Standards Developing Organisations

Besides BIS, there are 12 other bodies engaged in the development of voluntary standards in India (see Table 4). These standards developing organisations (SDOs) are largely connected to Indian ministries and develop standards in their respective subject areas. Only two of these bodies – the Building Materials and Technology Promotion Council (BMTPC), and the Automotive Research Association of India (ARAI) – have an understanding with BIS to get their standards adopted as Indian Standards. Besides the 12 SDOs a few large public-sector organisations also publish standards for their own use.

	Standards Developing Organisation	Function / Area
1	Bureau of Indian Standards (BIS)	National Standards Body – Formulation of Indian Standards (for all subjects excluding drugs and pharmaceuticals, environmental norms, grading of agricultural products) Member of ISO, IEC Product certification
2	Agricultural & Processed Food Products Export Development Authority (APEDA), Autonomous body under Department of Commerce	Standards and specifications for exports, inspection of meat and meat products in processing plants, storage premises, conveyances, organic production and systems
3	Automotive Research Association of India (ARAI) / Automotive Industry Standards Committee (AISC) (Ministry of Heavy Industries & Public Enterprises)	Research & development, certification of vehicles, standards formulation, homologation / type approval service to the Indian and overseas auto industry Representing India on WP29 – (World Forum for Harmonisation of Vehicle Regulations under UNECE)

	Standards Developing Organisation	Function / Area
4	Building Materials & Technology Promotion Council (Autonomous body under the aegis of the Ministry of Housing & Urban Affairs)	Standards development in the area of innovative and emerging building materials and technologies in the construction sector
5	Bureau of Energy Efficiency (autonomous body under the Ministry of Power)	Formulation of energy efficiency standards for appliances, operate voluntary and mandatory standards and labelling programmes
6	Directorate of Marketing and Inspection, AGMARK (attached office of the Ministry of Agriculture & Farmers Welfare)	Standardisation, grading and quality control of agricultural and allied produce. Implementing the AGMARK certification scheme of agricultural commodities for domestic trade and export
7	Indian Roads Congress (Registered Society, works in close collaboration with Ministry of Road Transport and Highways (MoRTH)	Formulation of standards and guidelines relating to roads and highways planning and construction
8	Ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy)	Pharmacopoeial standards for Indian systems of medicine and homoeopathy drugs
9	National Medicinal Plants Board (Ministry of AYUSH)	Development of Good Agricultural and Collection Practices (GACPs), development of monographs laying down standards of quality, safety and efficacy Voluntary Certification Scheme for Medicinal Plant Produce (VCSMPP)
10	Quality Council of India	Umbrella organisation for accreditation boards – NABCB, NABL, NABH, NABET and NBQP NABH – Standards for Hospital Accreditation NABET – Standard for School Accreditation besides accreditation; owner /co-owner of conformity assessment schemes
11	Standardisation Testing and Quality Certification (STQC) Directorate of the Ministry of Electronics & Information Technology	Quality assurance and conformity assessment services in the area of electronics and IT related to information security, software testing/certification
12	Telecommunication Engineering Centre (TEC), Department of Telecommunications (DOT)	Formulate standards with regard to telecom network equipment, services and interoperability, the associated conformity tests and fundamental technical plans
13	Telecommunications Standards Development Society, India (Registered Society recognised by the Department of Telecommunications)	Formulation and adoption of voluntary standards in the field of telecommunications

Table 4: Standards Development Organisations in India

A detailed list of SDOs together with their status, organisational function, and the subject areas and the number of standards published can be found in Annex 1 and 2.

Several standards development organizations, or SDOs, develop standards in their specialisation areas. In India there is currently no regulation or restriction on the development of voluntary standards other than that SDOs cannot claim their standards are Indian Standards. These SDOs use some form of stakeholder consultation, though they have not been reviewed for full compliance with the *Code of Good Practice for Standardisation* (Guide 59) of the ISO/IEC nor the six principles of TBT Agreement of the WTO.

The revised *BIS Act, 2016* includes a provision for the accreditation of SDOs. The BIS has not launched any scheme for SDO accreditation, and there is no information available whether this will happen in the near future. In the interim, the QCI has announced a voluntary programme for accreditation, which, by looking at the number of participants, has not been actively embraced by the SDOs.

The convergence of all standards development activities in India was set as a key goal by the Department of Commerce, Ministry of Commerce and Industry in June 2018 in their *Indian Strategy for Standardization* (INSS). This national strategy further details setting up a recognition scheme for SDOs and the goal to adopt SDO standards as national standards when required. The capability of SDOs will be enhanced in order to make standards development in India more dynamic, especially in emerging technologies.

Standards notified by regulatory bodies

Technical regulations brought out by regulatory bodies either specify technical requirements developed through their own consultative processes or adopt the relevant Indian or other standards. Wherever Indian Standards have been adopted, the regulatory body is involved as a member of the TC responsible for the development of the standards. Regulatory bodies involve stakeholders in the development of technical regulations or adoption of standards either through structured committees or through wide stakeholder consultation. Public notifications of the draft regulations according to the WTO TBT and SPS provisions is practised by all technical regulators. In some areas, such as food safety, scientific risk evaluation is carried out by the relevant committees.

Nine regulatory bodies or ministries are engaged in the development of standards or specifications that are used for regulatory purposes. A list of these bodies together with their status, organisational function, the subject areas, and the nature of standards notified is available in Annex 2.

Foreign Standards Developing Organisations in India

Several foreign SDOs whose standards are widely used by the industry have established support and marketing divisions in India. Prominent among these are the American Society of Mechanical Engineers (ASME), UL, Institute of Electrical and Electronics Engineers (IEEE), NACE (initially the National Association of Corrosion Engineers), the International Association of Plumbing and Mechanical Officials (IAPMO), and the British Standards Institution (BSI). While IAPMO has developed an understanding with its Indian counterpart, the Indian Plumbing Association, and has brought out the India Plumbing Code, others operate independently and have created a significant membership base in India. Indian experts in individual capacity are also members of the TCs of the bodies that are responsible for developing the relevant standards and codes.

Five European bodies, including the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) have opened an office of the Seconded European Standardisation Expert for India (SESEI) with the objective of aiding the harmonisation of standards with the EU and ISO/IEC.

Regional and International Affiliations

As India's National Standards Body, BIS represents India at the ISO and has set up national mirror committees to shadow the work of the ISO Committee on Conformity Assessment (CASCO) and the ISO Committee on Consumer Policy (COPOLCO). Likewise, the IEC National Committee of India is constituted at BIS and represents India at the International Electrotechnical Commission (IEC). The BIS is also a member of the Pacific Area Standards Congress (PASC) and the South Asian Regional Standards Organisation (SARSO). India is officially represented at the International Telecommunications Union (ITU) through the Department of Telecommunications (DoT) under the Indian Ministry of Communications. In addition, several other Indian bodies and associations are also members of the ITU.

The Food Safety and Standards Authority of India (FSSAI) under the Indian Ministry of Health & Family Welfare (MoHFW) represents India as the National Codex Contact Point (NCCP) in the Codex Alimentarius system (Codex) of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The FSSAI coordinates and promotes Codex activities in India in association with the National Codex Committee and facilitates India's input to the work of Codex through an established consultation process.

The group WP.29 (World Forum for Harmonisation of Vehicle Regulations) of the United Nations Economic Commission for Europe (UNECE) works towards the harmonisation of automotive regulations. A National Standing Committee on WP.29 matters has been set up by the Ministry of Road Transport and Highways (MoRTH) to establish national policy and guidelines for the harmonisation of automotive regulations. The ARAI represents India in the Working Parties of WP.29. Six mirror groups have been created under the WP.29 that work on pollution and energy, general safety provisions, brakes and running gear, lighting and light-signalling, noise, and passive safety.

Indian Organisation	International Organisation	Membership Status
Bureau of Indian Standards	ISO	Member
	IEC	Member through the Indian National Committee
	PASC	Member
	SARSO	Member
National Physical Laboratory of the Council of Scientific & Industrial Research	BIPM	Member
	Asia Pacific Metrology Programme (APMP)	Member
Telecommunication Engineering Centre	ITU	Member
Telecommunications Standards Development Society, India	OneM2M	Partner Type 1
	Global Standards Collaboration	Member
	3GPP	Organisational partner
Automotive Research Association of India (ARAI)	WP.29 (World Forum for Harmonisation of Vehicle Regulations) of UNECE	Member of Working Parties

Table 5: Regional and International Affiliations of Indian Standards Development Organisations

Conformity Assessment

The BIS plays a central role in the Indian conformity assessment system. It operates several schemes for the certification of goods and articles such as the ISI certification mark ('Standard Mark'), a registration scheme on the basis of self-declaration of conformity, hall-marking of gold jewellery, and management systems. A Foreign Manufacturers' Certification Scheme (FMCS) is an extension of the domestic scheme that requires pre-evaluation of manufacturing capabilities and product conformance and post certification surveillance inspections and testing.

By early 2018 over 63,000 BIS certifications had been issued, this shows that the Bureau of Indian Standards accounts for around half of all the certifications issued in India. Of these, approximately 50% were domestic product certifications, around 30% hallmarking of gold and silver, 13% registrations under self-declaration, a small share of 2% for management system certification and, 1% for foreign product certification (see Figure 6).

Definition of Conformity Assessment as per the TBT Agreement of the WTO

"Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. (…) Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations."

Source: Annex 1 of the Agreement on Technical Barriers to Trade by the World Trade Organization

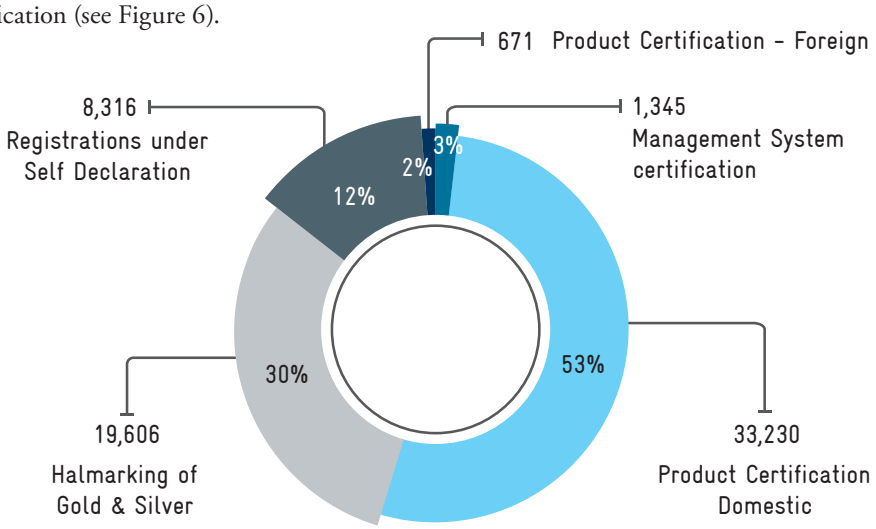


Figure 7: Number of BIS Registrations Granted and Licences Issued (until 31 March 2017)

Private conformity assessment bodies mainly operate in the field of management systems and foreign certification schemes. Foreign multinational conformity assessment bodies complement Indian conformity assessment schemes by addressing diverse requirements such as product safety, product performance, organisational systems, and sustainable practices. A few Indian agencies offer certification schemes for specific product groups such as Indian origin tea, silk, organic products, medicinal plants, and medical devices.

India has been a member of the IEC Conformity Assessment for Electrotechnical Equipment and Components (IECEE CB Scheme) for more than 20 years. The BIS acts as India's member body and is registered as national certification body. However, the scope of standards is limited (covering IEC 60947-3:1999, Low Voltage Switchgear and Control Gear) and BIS has only the role as recognising certification body without testing laboratories linked to it. Therefore, the implementation of the IECEE CB Scheme has been limited in India.

Growth of Conformity Assessment in India

Until the early 1990s, conformity assessment in India was dominated by the product certification scheme of BIS and a few prominent inspection bodies such as the Directorate General of Supplies and Disposals and Export Inspection Agencies, and laboratories like the National Test House (NTH). With the introduction of management systems conformity assessment schemes in the early 1990s and the setting up of accreditation boards in the early 2000s, the Indian conformity assessment system broadened its scope. The MLA/MRA memberships of the accreditation boards with the international forums have significantly assisted in the development and proliferation of conformity assessment activities and bodies.

Multinational CABs have brought in various conformity assessment schemes to India, covering requirements such as product safety, product performance, organisational systems, social norms, sustainable practices, process compliances, service level agreements, personnel competence, and others. CABs of European origin are active in India in the area of CE Marking – a manufacturer's declaration indicating that a product meets all the technical regulatory requirements for sale throughout the European Economic Area.

While product certification and quality management systems certification continue to be the two most popular streams of conformity assessment, others such as laboratory testing and calibration, and third-party inspections have seen high growth in the past 10 years, catering to wide and diverse segments of industrial activity. The adoption of conformity assessment principles and schemes by regulators such as PESO, the FSSAI, the PNGRB, and the Bureau of Energy Efficiency have also been key contributors to their growth in numbers and diversity.

Other forms of certification such as food safety, environmental, energy and social streams have gained wide acceptance and are contributing to the competitiveness of Indian businesses. These developments conform to the global trends that are witnessing increased levels of conformity assessment schemes both by regulatory bodies as well as private consortiums. However, India is yet to adopt national schemes for private sustainability standards, a trend that has become quite popular globally and is impacting trade.

More recently, personnel certification is being promoted by the government and private sector alike. Skills certification schemes are being jointly developed by the Ministry of Skill Development and Entrepreneurship, and the National Skills Development Corporation.

Contractual conditions by overseas buyers for compliance have been drivers of certification in several sectors – like IT enabled services, textiles, food, and agriculture. International buyers require adherence to standards such as Worldwide Responsible Accredited Production (WRAP), Sedex, GlobalGAP, and the Global Food Safety Initiative (GFSI). Current trends lean towards process certification within frameworks such as the National Aerospace and Defence Contractors Accreditation Program (Nadcap), organic and halal certification for food products, and green certification for buildings, products and companies. A majority of the foreign origin certification schemes are being offered by multinational certification bodies backed by their global understanding and experience.

Overview of BIS Certification Schemes

Almost all of BIS certification is for products, although there is a small segment for management systems. The four main BIS product certification schemes lead to the use of one of three certification marks.

The most common and best-known scheme is the Product Certification Scheme for domestic manufactures, which awards the licence to use the ISI Certification Mark, or Standard Mark. The Foreign Manufacturers Certification Scheme (FMCS) allows overseas manufacturers to use the ISI Certification Mark and sell their products in India once granted the required license.

The ISI Certification Mark or Standard Mark

Both the Product Certification Scheme and FMCS include initial capability assessment of the manufacturing unit, pre-licensing testing of the product to Indian Standards, and post-licensing surveillance that includes reassessment of factory capabilities periodically and re-testing of the product samples taken from the factory or from the market. As of July 2018, the Standard Mark is mandatory for 116 products. For products without mandatory certification, manufacturers may still choose the Product Certification Scheme due to demands from the market or to fulfil requirements in tenders of public procurement.

The Standard Mark for Registration

In 2012, the BIS introduced the (Compulsory) Registration Scheme, a simpler certification scheme for both domestic and overseas manufacturers, importers, and brand owners that awards the right to use the Standard Mark for Registration. The Registration Scheme allows products to be marked after registering the product and the company with BIS. Registration requires submission of a test report of the product demonstrating conformance to the applicable Indian Standard. These test need to be conducted in a BIS approved laboratory and are currently limited to laboratories located in India. Often, foreign manufactures with products that fall under this scheme need to have their products re-tested and certified in India. As of July 2018, the Registration Scheme is mandatory for 44 electronics and IT products as well as 6 goods related to solar photovoltaics (the list of products can be found under the same link as in the info box below).

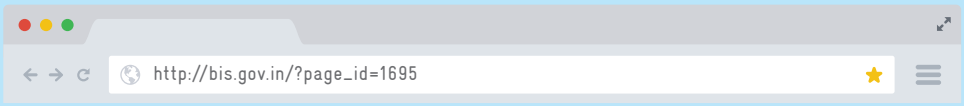
The Hallmark

The BIS Hallmarking Scheme permits the use of the Hallmark as a mark of purity on gold jewellery. It requires the testing of each batch of gold jewellery in BIS approved assaying centres which are authorised to laser engrave the jewellery with the Hallmark logo and other essential details, if the purity is found conforming to the mark. The license is given to the jeweller, who submits the jewellery batches they produce or purchase for getting it hallmarked and maintain records.

✓ Further Information Online

The list of products for which certification is mandatory can be found on the BIS website:

www.bis.gov.in → *"Conformity Assessment"* → *"Products under compulsory certification"*



BIS Product Certification Scheme

The BIS Product Certification Scheme awards the popular ISI Mark to manufacturing units under a licensing procedure that includes all activities under the Type IV (ISO 17067) certification scheme. Any manufacturer can apply for certification provided an Indian Standard exists for the product and there is at least one independent laboratory that can test the product. In most cases, the manufacturing unit should have in-house testing facilities for routine tests. The scheme is not accredited but has market presence and wide domestic recognition in public procurement and for regulatory purposes.

The BIS has offices in almost all Indian state capitals and further industrial towns. Applications are required to be filed in the nearest office and are processed by the same office, including licensing and post-licensing operations. A licence is given for one year initially and subsequently renewed for two years. BIS officials conduct factory inspections, with or without prior intimation, to ascertain compliance with the agreed scheme requirements and to reconfirm conformance of the product certified by sending samples to laboratories owned or approved by BIS. In instances

where product conformance or compliance to scheme requirements are found deficient, BIS uses discretion to issue warnings or suspend or withdraw certification rights.

The scheme comprises a normal procedure, a simplified one, and a combination of both. Under the normal procedure, the applicant submits the application to the responsible BIS branch office. BIS officers then carry out a preliminary factory evaluation during which, they assess the capabilities of the manufacturer and quality assurance facilities in place. The licensed unit is required to implement a scheme of testing and inspection which is provided by BIS. Product samples are drawn and either tested in the in-house laboratory or sent for independent testing. A license is granted if all steps have shown compliance (see Figure 7).

The simplified procedure permits an applicant to submit a test report of the product from a BIS approved laboratory together with the application. While the initial assessment of the manufacturing facility would still take place, the test report is accepted for grant of licence. However, if the confirmatory test sample taken by BIS is reported as non-conforming, BIS immediately suspends the marking rights.

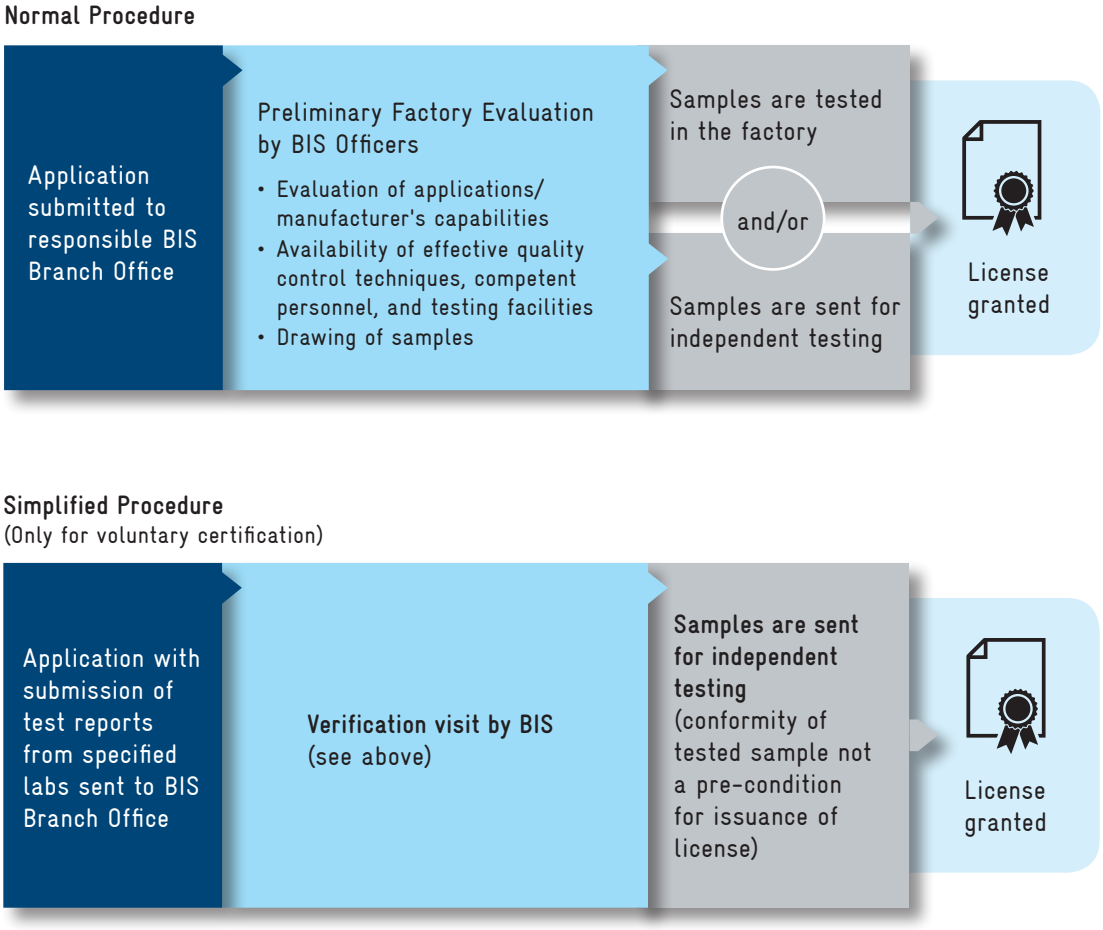


Figure 8: Procedure of Granting a License for the use of the Standard Mark

The number of licences issued under the BIS Product Certification Scheme reached more than 33,000 by the end of 2017 (see Table 6). This trend can largely be attributed to an increase in mandatory certification of products notified by different ministries, for example, steel and electrical products (see chapter on Technical Regulations).

Despite an increased use of the scheme, there has been a decline in the number of surveillance inspections, batch inspections, and samples drawn for testing in the period from 2012 to 2017. An arrangement to outsource inspection activities to other bodies was launched in 2008, but terminated in 2015.

	2012-13	2013-14	2014-15	2015-16	2016-17
Indian Standards under certification	1,065	908	938	941	927
New licences issued	2,964	3,580	3,202	3,155	4,098
Number of licences (year-end)	26,357	27,796	29,516	31,347	33,230
Surveillance inspections carried out	25,092	18,614	19,660	11,763	10,162
Batch inspections carried out	11,811	11,213	6,358	6,665	8,256
Samples drawn for testing	32,492	22,541	20,959	22,288	21,384

Table 6: Key Numbers on the BIS Product Certification Scheme (2012-17)

BIS Foreign Manufacturers Certification Scheme

Since 2000, BIS has been operating a Foreign Manufacturers Certification Scheme (FMCS) to ensure imported products comply with mandatory Indian Standards which are also applicable to domestic goods. All manufactures or exporters of these regulated products to India are required to apply for certification of their products with BIS for exports to India. The FMCS applies to all regulated products except for electronics and IT goods covered by the Compulsory Registration Scheme.

The FMCS is based on the domestic Type IV Scheme format described above. All pre-certification and surveillance inspections are conducted by BIS inspectors on site. The foreign manufacturer is required to designate an authorized Indian representative who is responsible for compliance to the necessary provisions on their behalf. The scheme is voluntary in nature and any foreign manufacturer can apply for certification of their products to BIS before placing it on the Indian market. However, in practice almost all FMCS certifications are used for regulated products.

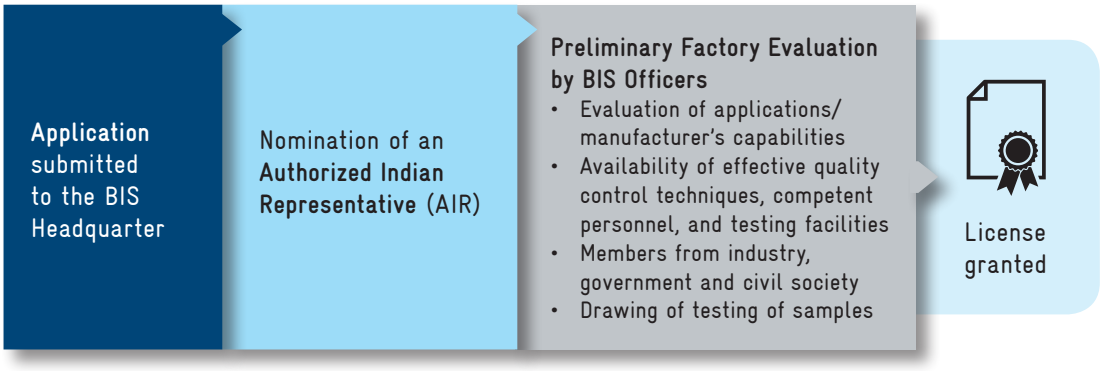


Figure 9: Procedure of Granting a License for the Use of the Standard Mark under the Foreign Manufacturers Certification Scheme

By the end of 2017 the FMCS was available for 83 Indian Standards, more than 670 licences had been granted in 48 countries (see Table 7).

	2012-13	2013-14	2014-15	2015-16	2016-17
Indian Standards under certification	43	60	71	73	83
New licences issued	49	147	111	68	190
Number of licences (year end)	263	379	470	511	671

Source: Annual reports of the Bureau of Indian Standards (BIS)

Table 7: Key Numbers on the Foreign Manufacturers Certification Scheme (2012-17)

BIS (Compulsory) Registration Scheme

With a view to provide a simpler option to the Type IV certification scheme, BIS introduced a Registration Scheme that relies on self-declaration of conformity which is backed by a third-party test report submitted by the applicant. The BIS does not conduct any factory or sample evaluation, but registers the manufacturers based on the legal documents submitted, thereby permitting them to apply the BIS Registration Mark.

The scheme was first adopted by the Ministry of Electronics and Information Technology (MeitY) for notifying compulsory registration of electronic products placed on the Indian market and is popularly referred to as CRS (Compulsory Registration Scheme). The first Compulsory Registration Order was issued by MeitY in 2012 and covered 15 categories of electronic products. Until 2018, a total of 44 product categories have been listed for mandatory registration.

In 2017, the Ministry of New and Renewal Energy (MNRE) has declared 6 product categories covering solar photovoltaics, systems, devices and components for Compulsory Registration (with effect from July 2018).

	2013-14	2014-15	2015-16	2016-17
Indian Standards under certification	15	30	30	30
Registrations (end of year)	742	1,428	4,279	8,316

Table 8: Key Numbers on the Registration Scheme (2013-17)

For grant of registration, applicants need to submit a test report from a third-party testing laboratory recognised by the BIS. So far, only laboratories located in India are recognised. Manufacturers have to apply for a separate registration number for products being manufactured at different locations. All foreign applicants without liaison or branch office in India have to appoint an authorised Indian representative. After approval of the application by the BIS, registration is granted for two years and needs to be renewed subsequently.

The Scheme includes random surveillance testing of products placed in the market by the responsible regulatory body, as of now, MeitY or MNRE. The BIS does not carry out any surveillance for registered products. In 2015-16, MeitY had appointed private agencies to draw samples from the market and send them for testing to the approved laboratories. This arrangement was terminated and MeitY has now assigned market surveillance to the Software Technology Parks of India (STPI). Set up by MeitY in 1991, STPI is an autonomous society with the objective to promote software exports from India. Fifty-seven STPI centres and sub-centres have been established across India and provide consulting, training, and implementation services.

Hallmarking of Gold Jewellery

The BIS Hallmarking Scheme is a purity certification scheme that was launched in 2000. The scheme is aligned with international criteria on hallmarking according to the *Vienna Convention, 1972*. The BIS grants licenses to the jewellers to use the Hallmark on gold jewellery. The certified jewellers can get their jewellery hallmarked from any of the assaying and hallmarking centres recognised by BIS. Assaying and hallmarking centres are recognised based on international criteria in line with the marking and control of precious metals.

Despite being purely voluntary, the scheme has gained popularity nationwide (see Table 9). The revised *BIS Act, 2016* has a provision for making hallmarking compulsory if the Central Government chooses to do so.

	2012-13	2013-14	2014-15	2015-16	2016-17
Hallmarking Licenses in operation	11,281	12,743	14,058	15,887	19,606
Recognised Assaying Centres	210	285	331	370	454

Table 9: Key Numbers on the Hallmarking Scheme (2012-17)

BIS Laboratory Network

The BIS has established a network of eight laboratories to support its Product Certification Scheme and also recognises accredited laboratories for testing of product samples. The BIS laboratories are located at Sahibabad (near Delhi), Mumbai, Chandigarh, Kolkata, Chennai, Bengaluru, Patna, and Guwahati.

In addition, BIS operates a laboratory recognition scheme under which it has recognised more than 200 external laboratories. These laboratories supplement BIS certification schemes by testing surveillance samples sent by BIS or for pre-testing product samples submitted by applicants under the Registration Scheme or the simplified procedure of product certification. In some cases, such as for packaged drinking water, the licensees of BIS can also use the recognised laboratories for routine testing.

All BIS laboratories are accredited by the NABL. The qualification criteria for recognised laboratories also requires NABL accreditation, although BIS also carries out prior and periodic evaluation of the laboratory facilities.

The full list of the BIS recognised laboratories can be accessed at:

http://bis.gov.in/?page_id=1819

Other Domestic Certification Schemes

Besides the certification schemes run by BIS, there are sectoral certification schemes operating in India. Below is a selection of some major sectoral certification schemes.

Tea Certification

The Tea Board India – a state agency of the Government of India – certifies varieties of teas grown in India as genuine and permits the use of the certification marks (logos) for each tea identified by region e.g. Darjeeling, Nilgiri Orthodox under the *Geographical Indications of Goods (Registration and Protection) Act, 1999*. No tea can be exported unless covered by a licence or a permit issued by or on behalf of the Board. The Board also empanels certification bodies for Food Safety Management System Standards Certification (e.g. ISO 22000, RVA Dutch HACCP, BRC, FS 22000).

Medicinal Plants

The National Medicinal Plants Board (NMPB) in collaboration with the Quality Council of India (QCI), has launched a voluntary certification scheme for medicinal plant products. The scheme relates to Good Agricultural Practices (GAP) for cultivated medicinal plants, and Good Field Collection Practices (GFCP) on different aspects for harvesting and post-harvest management of medicinal plants.

Organic Products

The Agricultural and Processed Food Products Export Development Authority (APEDA) operates an accreditation scheme for organic production and laid down related standards and regulations governing the use of the National (India Organic) Logo. The standards and procedures are in line with international standards regulating the import and export of organic products. The Indian standards for organic production have been recognised by the European Commission and Switzerland as equivalent to their respective standards. Similarly, the United States has recognised the conformity assessment procedures as equivalent to those of its country.

Silk Mark

The Silk Mark is a quality assurance label which signifies a product contains 100% pure silk in its base fabric. The product certification scheme is promoted and operated by the Silk Mark Organisation of India (SMOI), an initiative of the Ministry of Textiles. The scheme prescribes pre-qualification criteria, quality assurance system, and training requirements.

Alternative Medicines

A voluntary certification scheme for traditional products and alternative medicines, bundled under the acronym AYUSH, has been launched by the Department of Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy, Government of India, in collaboration with the Quality Council of India. Certifications are provided by CABs accredited by the NABCB.

ZED Certification

The Zero Effect Zero Defect (ZED) Certification Scheme has been launched in India with the objective to raise the capability and competitiveness of the Indian manufacturing industry. Developed by the Quality Council of India, the ZED Scheme has been promoted by the Ministry of Medium, Small and Micro Enterprises with an initial outreach of more than 20,000 MSMEs. The scheme is based on a maturity model for incremental development of the manufacturing units through improvement in processes like quality planning, product and process designing, resource management, environmental compliances, inventory management, supplier development, customer engagement, intellectual property governance, improved efficiencies, and reduced waste and carbon footprint. The units are assessed through a qualified process and rated on the maturity grid. Currently, about 60 MSME units have been rated under the scheme.

Indian Certification for Medical Devices Scheme

The Indian Certification for Medical Devices (ICMED) Scheme has been set up by the Association of Indian Medical Device Industry in collaboration with the QCI and the NABCB as a voluntary certification programme to enhance patient safety and consumer protection. Moreover, it aims to reduce trading of sub-standard products or devices, which represents a serious problem in the Indian health system. Launched in 2016, the programme includes three schemes of which, two are based on management systems standards (ISO 9001 and ISO 13485), while the third is a product certification scheme for devices.

Even though there is no recognition of the schemes by any international regulator or buyer, five leading certification bodies – TÜV SÜD, TÜV InterCert, TÜV Rheinland, UL India, and Intertek India – are recognised for ICMED. These schemes were launched prior to the publication of the *Indian Medical Devices Rules, 2017* that also includes compliances to ISO 13485 as well as product standards and the use of accredited conformity assessment bodies. Due to the new Medical Device Rules there is the possibility of changes to the ICMED Scheme in the near future.

Conformity Assessment by other bodies

While an exact count is unavailable, based on accreditations issued by three major accreditation boards dominant in India, there are an estimated 70-80 conformity assessment bodies providing certification and inspection services in India. All major multinational CABs have set up operations in India and provide conformity assessment services required by overseas regulatory requirements or private consortium standards. An illustrative list of the Conformity Assessment schemes being serviced is given in Annex 5.

The prominent bodies among these are Bureau Veritas, SGS, DNV, TÜV SÜD, TÜV NORD, TÜV Rheinland, UL, Intertek, LRQA, and BSI. All European-origin bodies utilise their status as Notified Bodies under EU Directives and Regulations to provide CE Marking services for various product groups.

Some of the Indian origin bodies providing conformity assessment services are IRClass, STQC, Tata Projects Ltd, RITES Ltd, CEIL, and ERDA.

Accreditation

The Indian accreditation system is coordinated by the QCI, a non-profit and autonomous body under the administrative control of the Department of Industrial Policy and Promotion (DIPP), which is a part of the Ministry of Commerce and Industry. It is governed by a council composed of representatives from government, civil society, and the private sector (CII, FICCI and ASSOCHAM). Founded in 1997, the QCI was commissioned to establish an accreditation structure and to promote overall quality in India.

Under the umbrella of the QCI, four accreditation boards are set up and function with a high degree of independence:

» National Accreditation Board for Certification Bodies (NABCB)
» National Accreditation Board for Testing & Calibration Laboratories (NABL)
» National Accreditation Board for Hospitals and Healthcare Providers (NABH)
» National Accreditation Board for Education & Training (NABET)

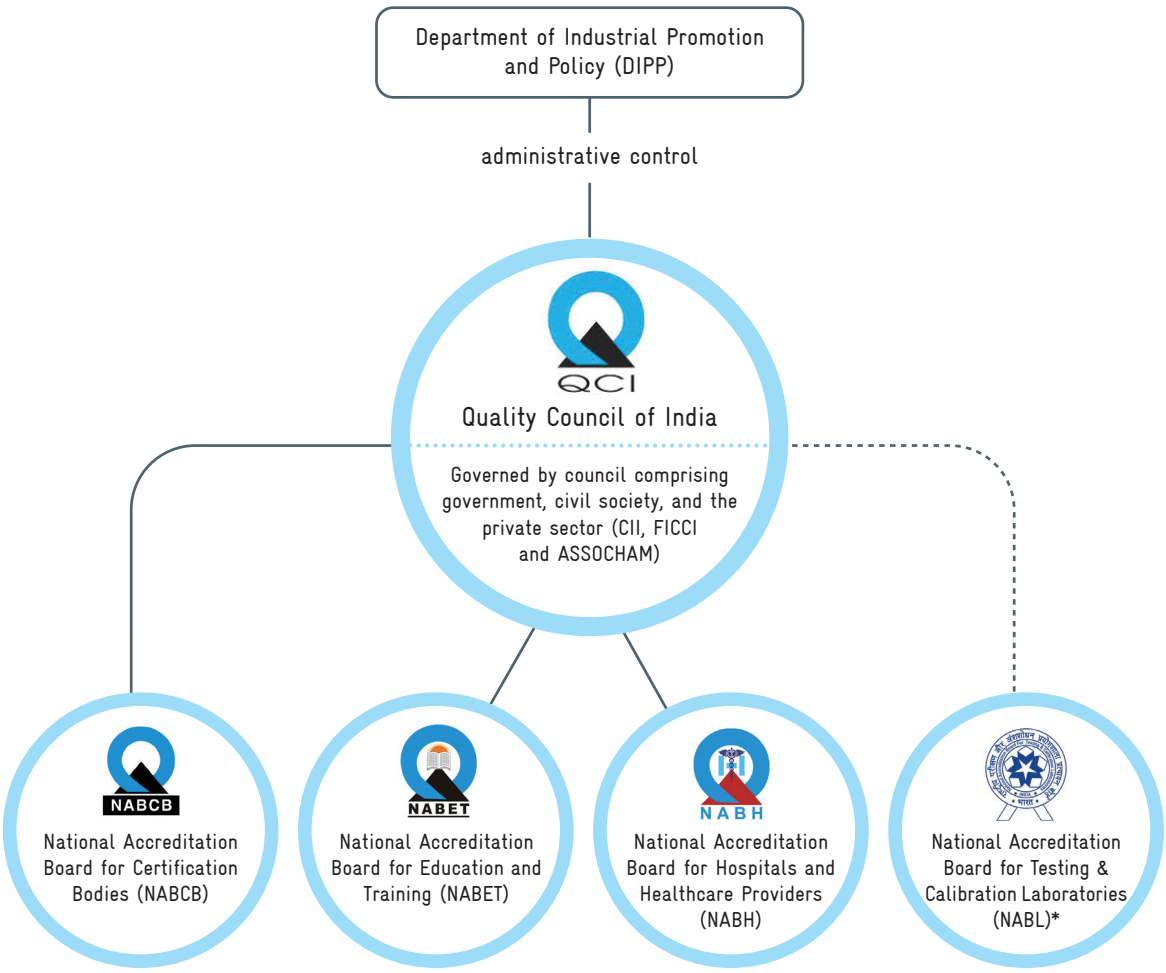


Figure 10: The Indian Accreditation Bodies

The NABCB and NABL operate under the framework of ISO 17011, the international standard for accreditation bodies that accredit conformity assessment bodies. The other two boards, NABH and NABET, operate under self-regulating norms. The NABH is a member of the Accreditation Council of International Society for Quality in Healthcare (ISQua).

The NABCB and the NABL are members of international multilateral arrangements coordinated by the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC). Parties involved in these mutual or multilateral recognition arrangements (MRA) agree to recognise the results of each other's conformity assessments and accreditations. However, similar to current regulatory approaches worldwide, some technical regulations in India overrule these international arrangements in practice and lead to duplicate testing and certification of products when imported to India.

National Accreditation Board for Certification Bodies (NABCB)

The NABCB, created in 2000, is responsible for providing the national accreditation system for all conformity assessment bodies, except those in metrology activities. Given the strong presence of BIS in product certification, most of the accreditation schemes operated by the NABCB are for inspection bodies and in the field of management systems (see Figure 9).

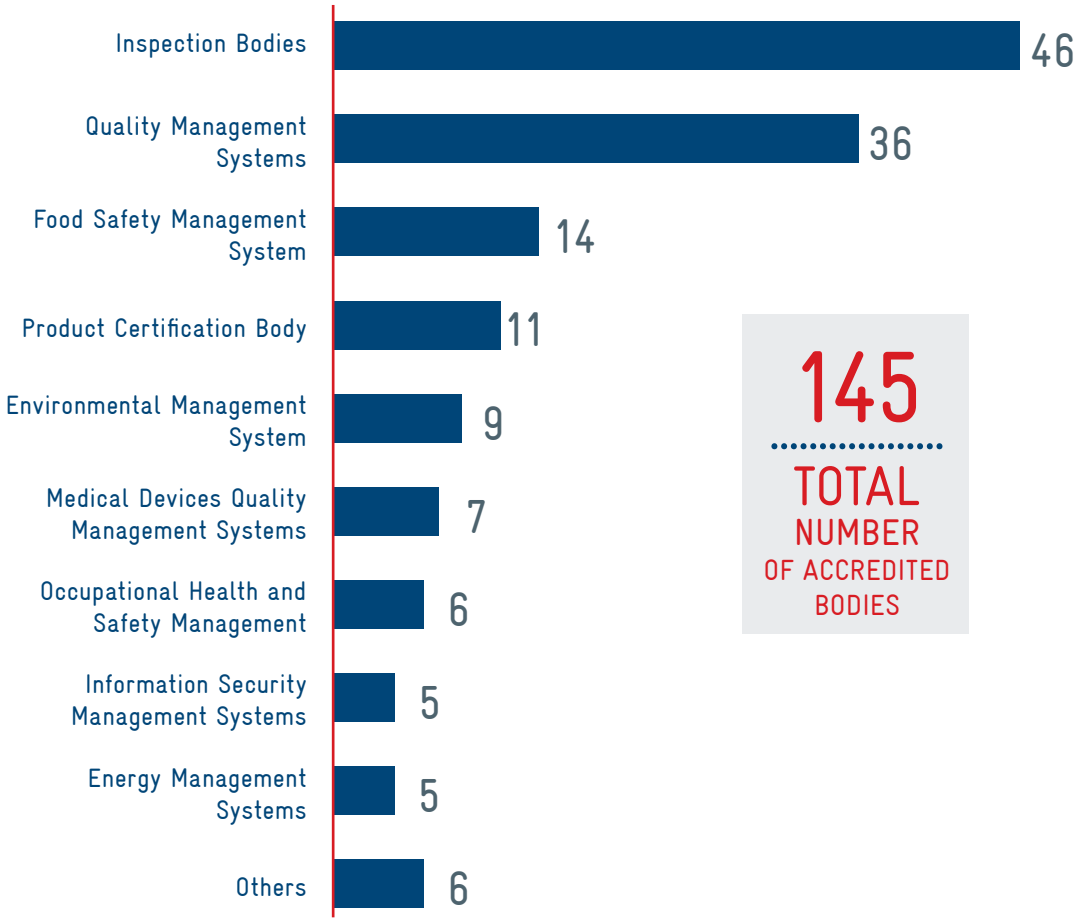


Figure 11: Number of bodies currently accredited by the NABCB (July 2018)

In India, unlike the EU, there is more than one accreditation body permitted. Besides the Indian NABCB, accreditations from overseas bodies are accepted. Most prominent are the US-accreditation board ANAB and the Joint Accreditation System of Australia and New Zealand (JAS-ANZ). Both of these provide a significant amount of accreditations. Of the estimated 50,000 management system certificates issued in India, 14,000 certificates, or about 28% were issued by NABCB accredited bodies. Foreign boards mostly accredit multinational bodies which operate in India. For their exports-oriented business, management systems certificates from globally popular accreditation bodies such as ANAB are commonly preferred.

The following table presents a comparison of accreditations of certification and inspection bodies issued under various schemes by NABCB, and ANAB and JAS-ANZ which have a significant presence in India.

Scheme	NABCB	ANAB	JAS-ANZ
Quality Management Systems	36	21	45
Environment Management Systems	9	18	37
Quality Management for Medical Devices	7	8	4
Occupational Health and Safety	6	10	34
Food Safety Management Systems	14	4	22
Information Security Managements Systems	5	8	13
Energy Management Systems	5	6	4
Aerospace	0	17	
Information Technology Systems	1	4	3
Business Continuity Management Systems		3	
TL 9000 (Telecom)		9	
Inspection Bodies	46		2
Product Certification Bodies	11		15
Others	5		
Total	**145**	**108**	**179**

Table 10: Comparison of Accreditations in India by NABCB, ANAB and JAS-ANZ

The number of NABCB accreditations for management systems programmes have remained stagnant over the past 5 years. However, the schemes for accreditation of inspection bodies and product certification bodies has grown steadily (see Table 11).

Scheme	2013-14	2014-15	2015-16	2016-17	As on 15-Feb-18	Applications in progress
Quality Management Systems (QMS)	41	42	38	33	35	9
Environmental Management Systems (EMS)	13	12	10	10	9	3
Inspection Bodies (IB)	18	25	30	35	41	29
Food Safety Management Systems (FSMS)	14	15	14	13	13	3
Occupational Health and Safety Management Systems (OHSMS)	5	7	6	5	5	5

Scheme	2013-14	2014-15	2015-16	2016-17	As on 15-Feb-18	Applications in progress
Product Certification (PCB)	3	5	6	7	9	8
Information Security Management Systems (ISMS)	1	3	3	3	4	4
Energy Management Systems (EnMS)	1	2	3	4	5	5
Information Technology Service Management Systems (ITSMS)	-	1	1	1	1	1
Trustworthy Digital Repositories Management Systems (TDRMS)	-	-	-	-	1	1

Table 11: Number of NABCB Accreditations by Area

International Recognition and Cooperation of the NABCB

The NABCB is a member of the International Accreditation Forum (IAF) and the Pacific Accreditation Cooperation (PAC) as well as signatory to their MLAs related to management systems for quality, environmental, and food safety and Global GAP. The NABCB is also a full member of the International Laboratory Accreditation Cooperation (ILAC) and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) as well as signatory to its MRAs for inspections (see Table 12).

Scheme	Accreditation Standard	MLA / MRA Status
Quality Management Systems (QMS)	ISO 17021-1	PAC / IAF
Environmental Management Systems (EMS)	ISO 17021-1	PAC / IAF
Inspection Bodies (IB)	ISO 17020	APLAC /ILAC
Food Safety Management Systems (FSMS)	ISO 17021-1	PAC / IAF
Product Certification (PCB)	ISO 17065	PAC / IAF
Information Security Management Systems (ISMS)	ISO 17021-1	PAC
Energy Management Systems (EnMS)	ISO 50003	PAC
Global GAP		PAC / IAF

Table 12: NABCB's status of MLAs / MRAs

The NABCB has granted 7 accreditation licences to bodies outside of India. Accreditations for quality management systems have been granted in (1) Nepal and (2) Mauritius, inspections in (3) Qatar, product certification in (4) Bangladesh, (5) Nepal, and (6) Bhutan, and Trustworthy Digital Repositories management systems in (7) the UK.

The NABCB has signed 17 cooperation agreements or Memorandums of Understanding (MoU), with other accreditation bodies for different purposes. These include conducting assessments on behalf of the other bodies or taking part in joint assessments. The arrangement helps in reducing costs and efforts for maintaining accreditation. The NABCB provides accreditation services in Bhutan and Nepal as they have yet to establish their own accreditation bodies (see Table 13).

Cooperation Arrangement	MOU Partner
Conduct assessment on behalf of partner AB	SANAS, UKAS, SAS, COFRAC, SNAS, DAkkS
Joint assessments	JAZ-ANZ, IAS
Mutual recognition of results of assessment carried out by both parties.	CGCRE/INMETRO
Provide NABCB accreditation services	BSB (Bhutan), NBSM (Nepal)
Technical cooperation on accreditation	Mauritius Accreditation Service Federal Accreditation Service (RusAccreditation) Russian Federation GCC Accreditation Centre BSCA, Belarus NCA, Kazakstan

Table 13: International Cooperation of the NABCB

National Accreditation Board for Testing and Calibration Laboratories (NABL)

In 1981, Laboratory accreditation services in India began under the umbrella of the National Coordination of Testing and Calibration Facilities (NCTCF), a programme set up by the Department of Science and Technology. The NCTCF was renamed the National Accreditation Board for Testing and Calibration Laboratories (NABL) in 1993 and aligned to the ISO Guide 25. The NABL operated as an independent autonomous society reporting to the Department of Science and Technology until 2016. Then it was brought under the leadership of QCI as part of the Central Government's move to consolidate all accreditation activities in India.

Up until December 2017, the NABL provided almost 4,200 accreditations, of which, testing laboratories accounted for 59%, calibration laboratories for 19%, medical laboratories for 21%, and proficiency testing providers and reference material providers for less than 1% each (see Table 14). The laboratories belong to diverse sectors and interests such as those providing commercial services, owned by government and regulators, captive laboratories of industries as well as laboratories doing research and academic work.

Major certifiers such as BIS and EIC mandate NABL accreditation for all laboratories performing tests or calibration for their schemes. The NABCB has prescribed the use of NABL accredited laboratories for all accredited third-party inspection and product certification schemes.

Scheme	Accreditations granted until 31.12.2017	Applications received from 01.04-31.12.2017
Testing Laboratories	2,469	391
Calibration Laboratories	804	80
Medical Laboratories	898	124
Proficiency Testing Providers	24	4
Reference Material Producers	7	4
Total Accreditations	**4,197**	

Table 14: Accreditations by the NABL

International Recognition and Cooperation of the NABL

The NABL is a full member of ILAC and APLAC and is signatory to their MRAs on accreditation of testing laboratories, including medical and calibration laboratories. The NABL is also signatory of the APLAC MRA for proficiency testing providers and reference materials producers (see Table 15).

Scheme	Accreditation Standard	NABL MLA Status
Testing Laboratories	ISO/IEC 17025	APLAC / ILAC
Calibration Laboratories	ISO/IEC 17025	APLAC / ILAC
Medical Laboratories	ISO/IEC 15189	APLAC / ILAC
Proficiency Testing Providers	ISO/IEC 17043 ISO/IEC 13528:2015	APLAC
Reference Material Producers	ISO Guide 34 / ISO/IEC 17034	APLAC

Table 15: International Recognition of the NABL

Under a MoU signed with Nepal's National Bureau of Standards and Metrology (NBSM), the NABL grants accreditation to laboratories in Nepal for which NBSM operates as National Accreditation Focal Point (NAFP).

New Projects on Laboratory Accreditations

NABL has recently undertaken several special projects to augment accreditation of testing laboratories in the following areas:

- drugs and pharma testing: programme on accreditation (specifically focused on pharmaceutical industry for Ministry of Health & Family Welfare)
- water testing for Ministry of Drinking Water and Sanitation and Central Water Commission food testing for Food Safety and Standards Authority of India, focused on government food laboratories environment testing for the Central Pollution Control Board
- collection centres of medical labs
- public health laboratories of districts for Ministry of Health & Family Welfare
- weights and measures for the accreditation of all state-level and working standard laboratories
- bio medical equipment test and calibration for Association of Indian Medical Device Industry
- software testing in collaboration with STQC
- solar technology and systems for National Institute of Solar Energy
- toys certification and testing to support the amended notification issued by the Directorate General for Foreign Trade mandating testing of all imported toys in NABL accredited laboratories and the shortly expected technical regulation for compulsory certification of toys

Technical Regulations

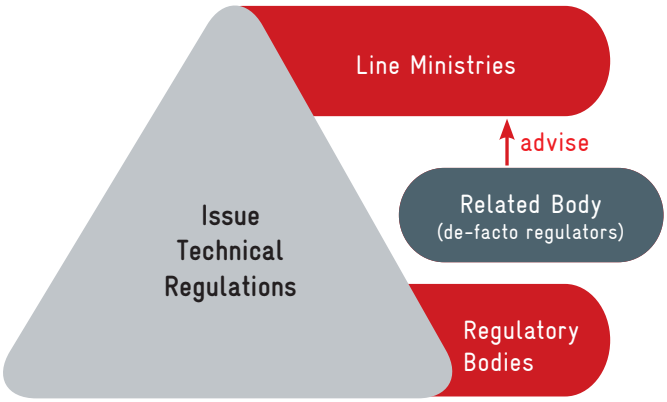
Technical regulations in India are either issued by specific regulatory bodies set up by the government, or by responsible ministries, also known as line ministries. Usually these bodies are under the jurisdiction of the Central Government, however in some areas such as weights and measures, prevention of food adulteration, personnel protective gear, and road safety, they are issued by the state governments.

Special regulatory bodies in India were established for a few sectors such as drugs, insecticides, explosives, pressure vessels, boilers, mines safety, and nuclear energy. In the last ten years, several new regulatory bodies have been set up, the most notable being the Food Safety & Standards Authority of India (FSSAI) which consolidated different regulatory functions being performed across several ministries. Other new prominent technical regulatory bodies include the Bureau of Energy Efficiency (BEE) and the Petroleum & Natural Gas Regulatory Board (PNGRB).

In all other sectors such as environment, chemicals, electrical and electronic products, telecommunications, machinery, construction material, healthcare, and automotive and road safety, the respective line ministries as well as the Departments of Industrial Promotion and Policy (DIPP), and Consumer Affairs (DoCA) have a double role as policy maker and regulator (notifying body). A few other bodies work closely with their respective ministries and act as de-facto regulators like the Central Pollution Control Board under the Ministry of Environment & Forests, the ARAI under the Ministry of Road Transport and Highways, the TEC under the Ministry of Communications (see Figure 10).

Technical Regulations according to the TBT Agreement of the WTO

"Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."



- Department for Industrial Policy and Promotion (DIPP)
- Department of Heavy Industries (DHI)
- Ministry of Steel
- Ministry of Electronics & Information Technology (MeitY)

- Automotive Research Association of India (ARAI)
- Central Pollution Control Board (CPCB)
- Telecommunication Engineering Centre (TEC)

- Food Safety & Standards Authority of India (FSSAI)
- Petroleum and natural Gas Regulatory Body (PNGRB)
- Bureau of Energy Efficiency (BEE)
- Central Boilers Board (CBB)
- Petroleum and Explosives Safely Organisation (PESO)

(Institutions on the right are just exemplary)

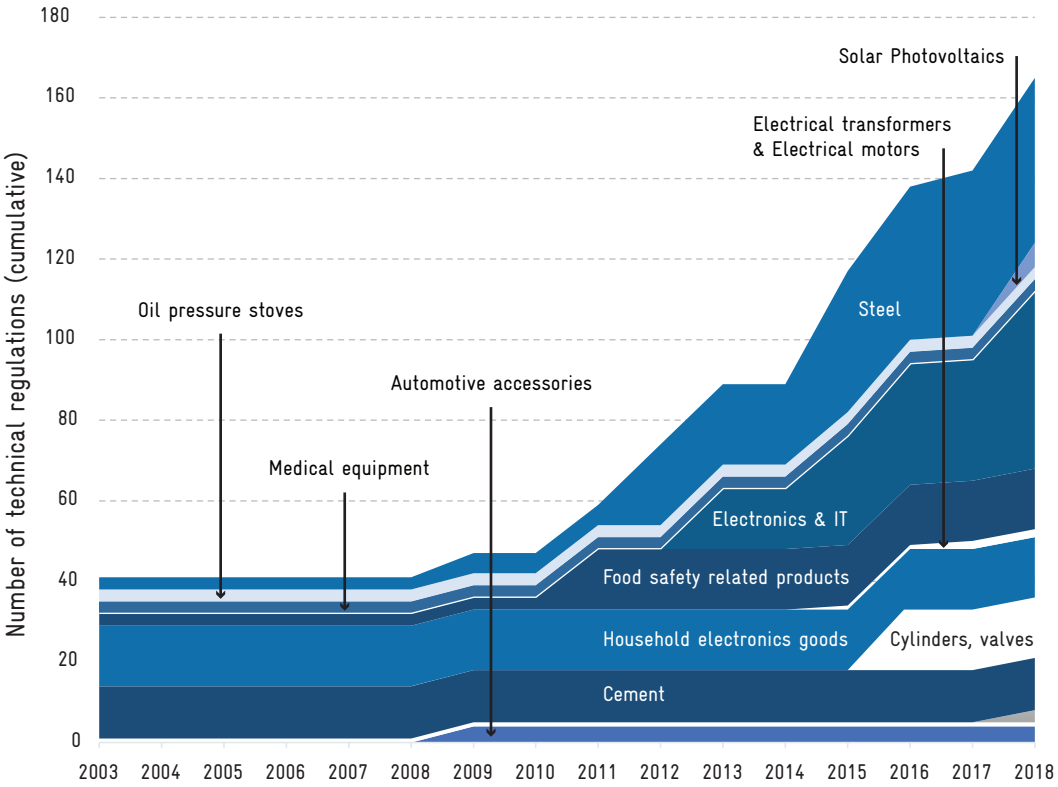
Figure 12: Issue of Technical Regulations in India

A major difference between formal regulatory bodies and ministries is that the regulatory bodies tend to have a more detailed technical understanding of the regulations. They are familiar with relevant standards and the selection of the compliance procedures, such as conformity assessment regulations. In most cases, the regulatory bodies also have their own infrastructure for checking conformance, carrying out market surveillance, and other enforcement activities. Line ministries, on the other hand, usually rely on the general enforcement machinery of state governments, which is limited.

A key difference between Indian and EU technical regulations is that the EU allows the demonstration of compliance through routes other than the notified (harmonised) standards, which can be used for presumption of conformity. Indian technical regulations always specify or reference the standards or essential requirements. Moreover, while the BIS registration scheme is a first step, self-declaration of conformity has not been widely adopted in India.

Regulated Sectors

India has a small number of technical regulations in comparison to markets like the EU. India lacks provisions in machinery safety, electrical products, including equipment in hazardous areas, chemicals, construction products, and telecom products (see Annex 4). Based on several discussions at national expert forums and within the Indian government, it becomes clear that India intends to close these 'regulatory gaps' by issuing a larger number of technical regulations. In recent years the number of products regulated through mandatory certification has increased, covering a larger number of sectors (see Figure 12).



New or amended mandatory certification for products since 2003.
* 2018 includes announced mandatory certification, which have not yet entered into force.

Source: Grinsted/Kesari/Singh. 2018. Quality Rules in India: Trade, Technical Regulations and Consumer Protection, ORF Issue Brief No 245, p. 4.

Figure 13: Number of Products under Mandatory Certification in India (2003–18)*

Body	Scope of Regulation
Food Safety and Standards Authority of India	All food products for human consumption
Ministry of Steel	Notified steel products
Department of Heavy Industries	Notified steel tubes

Body	Scope of Regulation
Department of Industrial Policy & Promotion (DIPP)	- Ductile (cast) iron pipes - Notified industrial electrical products - Notified electrical wires & accessories - All types of cements - Notified tyres and tubes for automotive - Oil pressure stoves
Petroleum and Explosives Safety Organisation (PESO)	- Gas cylinders, valves & regulators - Ex equipment - Pressure vessels
Bureau of Energy Efficiency	Notified appliances and equipment
Ministry of Electronics & information Technology (MeitY)	Notified electronic products
Department of Health and Family Welfare/ (Drugs Controller General of India)	- Drugs - Notified medical devices
Department of Consumer Affairs	- Clinical thermometers - Multipurpose dry batteries
Ministry of Textiles	Textiles, cotton bales
Central Boilers Board	Boilers, heat exchangers, converters, evaporators and related fittings, components, materials
Petroleum & Natural Gas Regulatory Board	Petroleum, petroleum products and natural gas, including the construction and operation of pipeline and infrastructure projects

Table 16: Regulatory agencies and the scope of their technical regulations

The detailed description of each regulated sector, the regulatory authority, the approvals required, and the mode of compliance assessment is given in Annex 3.

The Process of bringing out Technical Regulations

There is no clearly defined process in India that determines which products should be covered by technical regulations. In most cases, recommendations are made by concerned ministries or by BIS. New technical regulations are created in reaction to either similar technical regulations in other countries, such as with electrical products, medical devices, or when dangerous or low-quality products by domestic producers or importers flood the Indian market.

Usually, technical regulations would refer to the BIS certification scheme or lately the BIS registration scheme. However, areas where regulators are formally designated such as food safety, medical devices, energy efficiency, the respective regulator notifies essential requirements and uses its own approval processes. Annex 2 gives the standards used by the regulators and Annex 3 the details of the approval process or use of conformity assessment procedures.

Act	legal framework and general principles ('statute')	passed by the Parliament
Rules	details related to an Act	passed by a ministry
Regulations	technical details related to the implementation of an act	passed by a ministry

Table 17: Hierarchy of Government Documents in India

The Revised BIS Act, 2016

To give a legal framework to standardisation and conformity assessment activities in India, the *Bureau of Indian Standards Act 1986* was issued that gave Government powers to notify goods for compulsory BIS certification while BIS was given powers to prosecute against misuse of BIS marks. The conformity assessment activities however were restricted to a single product certification scheme (ISI Mark Scheme), later extended to the Compulsory Registration Scheme.

The importance of the BIS Act can be gauged from the fact that it is the only legal instrument available to the government to declare technical regulations, barring a few sectors such as food, pharma, boilers and pressure vessels, petroleum products, explosives etc. where specific acts are in place.

With the realisation that quality requirements for goods and services have assumed a much larger significance both with respect to consumer protection and competitiveness of the Indian industry, the BIS Act was amended in 2016.

The amended act empowers the government to declare technical regulations for any article, service, process, or system which it considers necessary from the point of view of health, safety, environment, prevention of deceptive practices and security based on essential requirements or standards other than BIS standards. The act also permits using other forms of conformity assessment, besides BIS certification.

The revised BIS Act has been enforced with the notification of the BIS Rules with effect from 13 October 2017. Based on this several ministries are evaluating the need for technical regulations on products and services and have begun holding public consultations.

Technical regulations are issued under various formats in various acts and are notified by the Central Government and passed by the Parliament. Statutory provisions are included that establish the authority for administering the Act (see Table 17). Examples are the *Bureau of Indian Standards Act, 2016; the Food Safety & Standards Act, 2006; the Drugs and Cosmetics Act, 1940; and the Energy Conservation Act, 2001*. Technical regulations may appear in the form of rules under an act, such as the *Medical Device Rules, 2017* (under the *Drugs and Cosmetics Act*) or as regulations, such as the *Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011* or as Quality Control Orders (QCO), mainly issued under the *BIS Act*.

All technical regulations invariably specify the scope, important definitions, parties to whom it applies, the need for licensing or approval, approval authority, authority responsible for enforcement, standards or essential requirements that need to be complied with, powers of the authorities to call for information, to take samples – both pre and post approval, to conduct search and seizure and the obligations of the parties to comply with the orders issued.

The Quality Control Orders (QCOs) under the *BIS Act,* are issued by the ministry responsible for the respective sector. Over the years, the format of the QCOs has become standardized and they have referred to the BIS Product Certification or Registration Schemes as the mode of conformity assessment. However, with the publication of the *BIS Act, 2016* and the issue of guidelines by the Department of Consumer Affairs in March 2018, future QCOs may include provisions of conformity assessment by other conformity assessment bodies.

The procedure issued by the Department of Consumer Affairs advises the line ministries to follow the following process for issuing technical regulations (see Figure 14).

Figure 14: Process of Issuing Technical Regulations in India

In case an agency other than BIS is chosen for conformity assessment (i.e. 3 b), it needs to be either accredited by the NABCB or by BIS for carrying out conformity assessment activities.

The following chart depicts the typical sections incorporated in a QCO and a brief description of what each clause contains. The sections in yellow are those that may appear in future QCOs.

Opening Paragraph	Describes the enabling Act and its section, under which the QCO is issued
Short Title and Commencement	Describes the products covered and the date on which the QCO will become operational
Definitions	Typically include the definitions of parties impacted such as manufacturer, dealer and 'Appropriate Authority', i.e. the authority empowered to implement the provisions of the QCI
Prohibition of manufacture, import, storage, sale and distribution etc.	Stipulates the conditions regarding licensing, approval and labelling etc. without which prohibitions will apply
Obligation for Certification / Registration / Certificate of Conformity	Describes the requirement for conformity assessment including testing requirements, and usually the short procedure for applying, obligations post certification
Authorised CABs, Laboratories	Provides reference for using authorised Conformity Assessment Bodies and Laboratories for issue of Reports or Certificate when not under BIS Certification route
Power to call for information, search and seizure	Describes authority of Appropriate Authority to call for information, conducting inspection of records and search and seizure
Testing of samples	Provides information regarding post certification testing by BIS or Appropriate Authority and the related standards
Market Surveillance	Describes authority of Appropriate Authority to call for information, conducting inspection of records and search and seizure
Power to issue direction to manufacturers, dealers or sellers	Describes authority of Appropriate Authority to issue directions for compliance that may be necessary but not specifically stated in the order
Compliance of directions	Creates obligations on the parties involved to comply with directions
Obligations to furnish information	Creates obligations on the parties involved to maintain and provide information when called for in relation to the products
Optional clauses are in yellow, mandatory ones in blue.	

Figure 15: Structure of a Typical Quality Control Order issued under the BIS Act

In the Indian National Strategy for Standardization, the Government of India outlined the goal to develop a sound understanding of good regulatory practices and regulatory impact assessments, for which so far, no formal code is in place. Furthermore, coordination among agencies responsible for notifying technical regulations shall be strengthened. Whereas no guideline for good regulatory practices exists yet, public consultations are invariably carried out before issuing notifications. By this the regulatory authority gives due consideration for the time required to implement the regulation, and there have been many instances of where timelines have been extended based on justifications. Proposed technical regulations are notified to the WTO TBT and SPS platform (the notifying authorities for TBT and SPS notifications are given in Annex 6).

Market Surveillance

Market surveillance ensures that products on the market comply with applicable regulations. As a result, it helps to protect consumers and workers, as well as contributes to meeting other public interests such as safeguarding the environment and adhere to aspects of national security. To achieve this, a country's market surveillance commonly comprises aspects such as gathering market intelligence, applying risk assessment, drawing and testing product samples, recalling non-conforming products from the market, and imposing sanctions.

In India, market surveillance is mainly a part of conformity assessment for regulated products. Unlike the EU, India does not have a centrally coordinated market surveillance system and procedures and responsibilities depend on the regulated products.

For products covered by the mandatory certification of BIS, market surveillance takes place in two ways:

1. **Certification surveillance:** As a certification body that follows the Type IV (ISO 17067) Certification Scheme, BIS is responsible for taking samples of certified products from the market and testing them in BIS recognized labs to reconfirm their conformance to the relevant Indian Standard.

2. **Enforcement surveillance:** Quality Control Orders specify the appropriate authority which is responsible for securing compliance. In most cases the appropriate authority is the relevant regulator or line ministry and the state governments. The appropriate authority is responsible for ensuring that products are not being manufactured, stored or supplied without the required certification.

If products or commodities are regulated by other acts, joint enforcement operations are sometimes undertaken by the state government authorities with the help of local police. This applies to cement, gas cylinders, packaged drinking water, and other examples.

The Petroleum & Explosives Safety Organisation (PESO) has a nation-wide network of offices and carries out surveillance operations directly. The Food Safety & Standards Authority (FSSAI) Act empowers the food departments of state governments which regularly conduct surveillance operations. A similar arrangement exists for the *Weights and Measures Act*, where each state government has set up legal metrology divisions. The new regulators such as the Bureau of Energy Efficiency, Petroleum and Natural Gas Regulatory Board do not have an established market surveillance mechanism.

MeitY does not have any direct resources for market surveillance for the electronic products covered by the Compulsory Registration Scheme it is responsible for. In May 2018, MeitY notified a modified surveillance process for electronics and IT goods. For its implementation, MeitY appointed the Software Technology Parks of India (STPI) to take random surveillance samples from the market. The STPI was set up by MeitY in 1991 as an autonomous society with the objective to promote software exports from India. A total number of 57 STPI centres and sub-centres have been established across India and provide consulting, training, and implementation services.

According to this procedure, MeitY initiates the surveillance process for notified goods through its portal. Upon receiving this request, the STPI executes the surveillance by collecting samples for testing and counter samples for storage from a local market. The manufacturer or local representative shall be informed about the sample pickup date, time and location of the market so that authorised personnel of the manufacturer or local representative can be present. In case the product is not available on the market, as in the case of industrial products, the STPI

representative enquires with the manufacturer or local representative about its availability. The packaged and sealed sample is then sent to a laboratory empanelled under the surveillance process by MeitY. STPI reviews the test reports and sends them to MeitY, which initiates necessary action.

If the test report shows non-compliance with technical regulations, MeitY issues a call to the manufacturer or local representative asking for explanations. If no sufficient explanation is given, MeitY informs BIS to take necessary action, e.g. withdrawal of license.

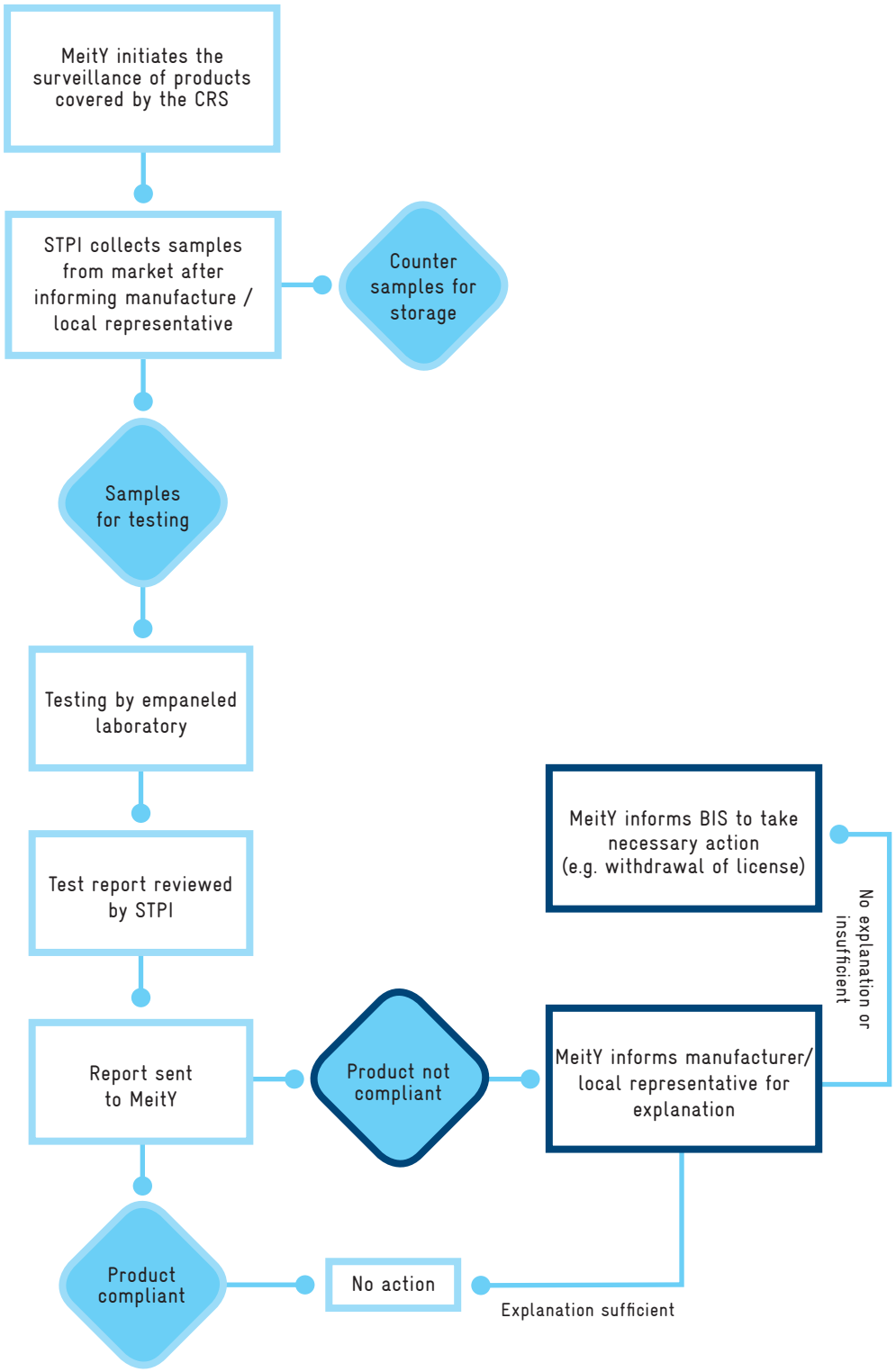


Figure 16: Process of Market Surveillance for the Compulsory Registration Scheme for Electronic and IT Products

MeitY's surveillance scheme includes a provision that each registered manufacturer deposit the annual estimated cost of one surveillance operation in advance. The surveillance cost includes the maximum retail price of required quantities of the test and counter samples (the number of samples would be as required for testing as per notified IS standards), logistics and packaging charges, laboratory test charges, and charges for storage of counter samples.

In another development, on May 29, 2018, the Bureau of Energy Efficiency signed an MoU with the NABCB as per which NABCB would make available accredited product certification bodies as Independent Agencies for Monitoring and Evaluation (IAME) under the BEE Standard and Labelling program. The product certification bodies will carry out surveillance activities to support implementation of the labelling program.

The development of an effective market surveillance mechanism is one of the objectives of *India's National Standardization Strategy* (INSS), published in June 2018. The strategy declares that preference shall be given to self-declaration of conformity schemes, which are based on adequate prior and post-market surveillance. Market surveillance is currently carried out primarily by federal agencies and customs authorities, but they lack the necessary technical expertise and sufficient resources. Therefore, a coordinating market surveillance authority should be established which can establish an effective system of aftermarket surveillance. This also includes a provision for cross-border exchange of information.

"The regulatory authority should be responsible for any pre-market approvals if necessary, conduct market surveillance to ensure that suppliers meet the technical requirements, and implement sanctions in the event of product failures. The regulatory authority should, as a matter of principle, not be involved in the conformity assessment service provision."

Source: UNIDO, 2018, Quality Policy. Technical Guide, Vienna, Austria, p. 25

Metrology

National Physical Laboratory

Established in 1950, the National Physical Laboratory (NPL) of the Council of Scientific & Industrial Research (CSIR) is the National Metrology Institute of India. It is a member of the International Bureau of Weights and Measures (BIPM) and the Asia Pacific Metrology Programme. The NPL is also a research laboratory in the field of physical sciences.

The NPL has 239 Calibration and Measurement Capabilities (CMCs) in the BIPM data base, and 168 international or bilateral key comparisons. The CMCs provide national traceability through a series of calibrations, and in turn are traceable to the International System of Units. They also assist in the development of reference materials and reference equipment. The NPL offers commercial services for calibration of test equipment in the areas it holds CMCs.

In 2017, the NPL re-launched its certified reference materials under a branded series titled *Bhartiya Nirdeshak Dravya* (BND). The first certifications have been granted to the Government of India Mint for high purity (9999) reference gold standard and to the Central Institute of Mining and Fuel Research (CIMFR) for bituminous coal. It is in the process of developing certified reference materials for high purity metals, quartz, and elemental solutions.

As the National Accreditation Board for Testing and Calibration Laboratories (NABL) operates the accreditation scheme for reference material producers, it is expected NPL and NABL would set up a cooperation arrangement for the development of certified reference materials in India. The NABL would be responsible for the capacity assessment of the reference materials producers and NPL would evaluate the technical characterisation of the individual reference materials to certify them at the required accuracy and uncertainty levels.

Legal Metrology

The Standard of Weights and Measures Act, 1976 established national standards of weights and measures and regulates the trade of goods that are sold or distributed by weight, measure or number. It is based on the metric system and the International System of Units recognised by the International Organisation of Legal Metrology (OIML). This act was replaced in 2009 by the *Legal Metrology Act*, with the aim to protect consumer interests and serve other stakeholders including the industry.

The legal metrology division of the Department of Consumer Affairs (DoCA) adopts the recommendations of the OIML, of which India is a member. The director responsible for legal metrology of DoCA is member of the International Committee of Legal Metrology (CIML) and other technical committees of the OIML.

The entire regulatory and conformity assessment framework for weights and measures has been notified through these acts and rules:

- *Legal Metrology Act 2009*
- *Legal Metrology (Packaged Commodities) Rules 2011* which prescribe mandatory declarations on the pre-packaged commodities, such as packer's, manufacturer's, or importer's addresses, commodity name, quantity filled, date of packing, maximum retail price
- *Legal Metrology (Numeration) Rules, 2011,* which prescribe the standards for numeration

- *Legal Metrology (General) Rules, 2011,* which cover specifications including clinical thermometers, standard weights for testing higher capacity weighing machines, blood pressure measuring instruments, and compressed natural gas (CNG) dispensers
- *Legal Metrology (National Standards) Rules, 2011,* which prescribe the standards of weights and measures, their hierarchy, maintenance and custody etc.
- *Legal Metrology (Government Approved Test Centre) Rules, 2013,* which recognise non-governmental establishments to undertake verification and stamping of weight and measures used in trade and commerce

The functions under the *Legal Metrology Act* are divided between the Central and State Governments (see Figure 5). Matters of national policy and other related functions such as uniform laws on weights and measures, technical regulations, training, precision laboratory facilities, and implementation of international recommendations are governed by the Central Government. State governments and union territory administrations are responsible for the enforcement of the laws. Offices of the Controller of Legal Metrology (Weights & Measures) have been established in all 36 states and union territories of India.

As the administration of the *Legal Metrology Rules* is the responsibility of state governments, many states have legislated their own rules for enforcement. The enforcement activities typically include:

- verification of weights and measures,
- inspection to check whether weights and measures verified and stamped are being properly used by the commercial operator (traders),
- checking that deliveries made using weights and measures are verified and stamped,
- ensuring mandatory declarations and Maximum Retail Price (MRP) on the pre-packed commodities, and
- registration of offences detected during inspections.

The laboratory network for weights and measures includes regional reference standard laboratories, secondary standards laboratories at the state level, and working standards laboratories at the inspectorates established at the district level.

Five regional reference standard laboratories situated at Ahmedabad, Bangalore, Bhubaneswar, Faridabad, and Guwahati are working as central agencies between the NPL and state government laboratories for traceability of standards. These laboratories are responsible for the testing of models of weights and measures, verification of secondary standards of state governments, calibration of sophisticated weighing and measuring instruments, and consumer awareness programmes. The reference laboratories use national standards, maintained at the NPL in New Delhi for direct traceability.

The Secondary Standards Laboratory (SSL), set up by state governments, are third in the hierarchy of standards after regional standards, maintained at regional reference standards laboratories. The secondary standards maintained at SSLs are used for verification and ascertaining accuracy of working standards, maintained at working standards laboratories in inspectorates of different districts.

The following illustration below describes the legal metrology framework in India, with responsibilities allocated at the different levels.

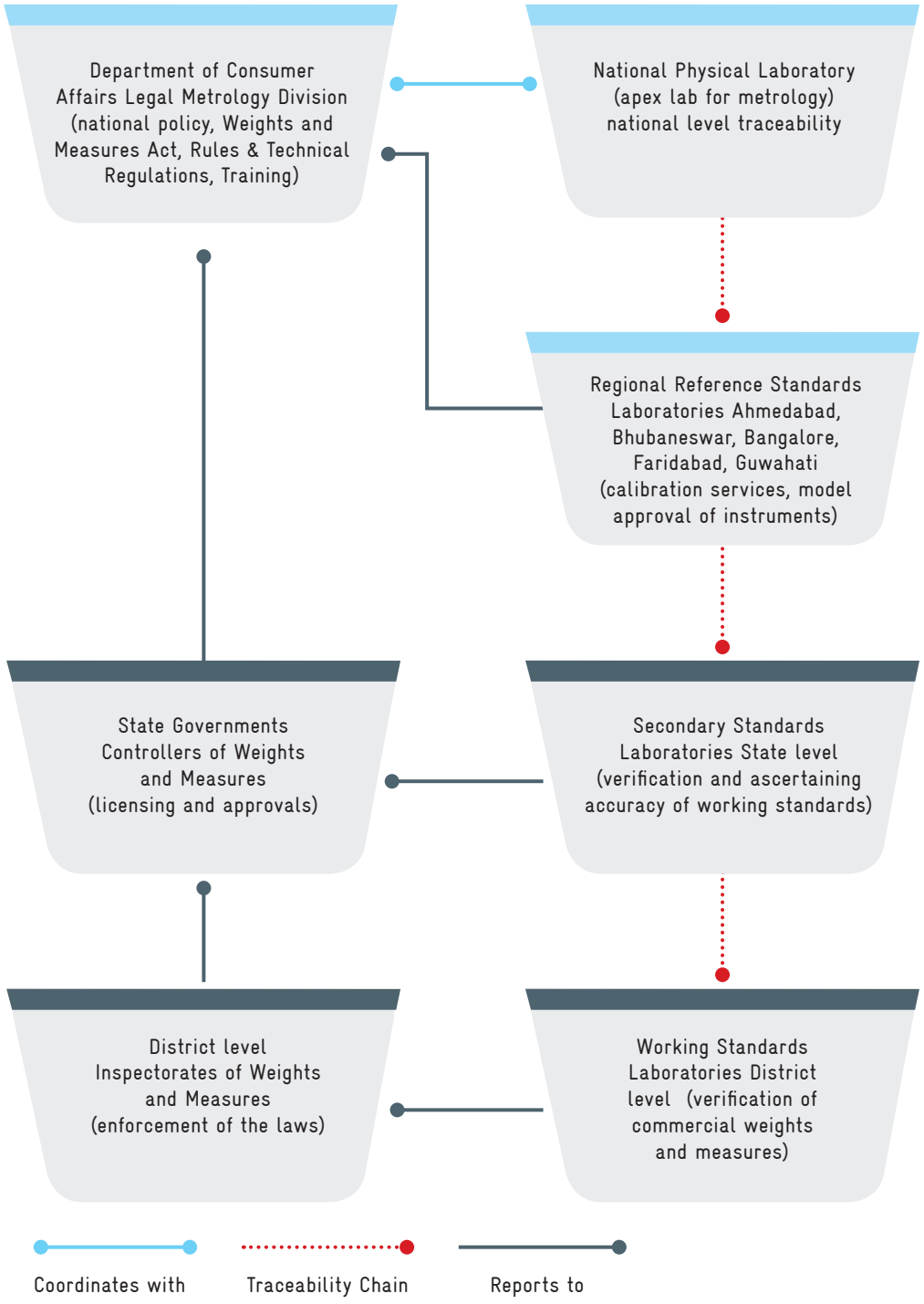


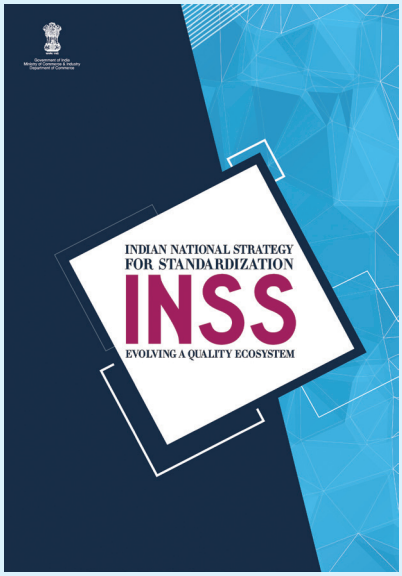
Figure 17: The Legal Metrology Landscape in India

The Indian National Strategy for Standardization

In June 2018, the Department of Commerce (DoC), Ministry of Commerce and Industry, published its first comprehensive strategy for India's quality infrastructure. The Indian National Strategy for Standardization (INSS) addresses standards development, conformity assessment and accreditation, metrology, technical regulations, and market surveillance.

The INSS captures the outcomes of consultations held over a four-year period from 2014 to 2017 through national and regional standards conclaves that attracted wide participation of experts and stakeholders from union and state governments, industry, regulatory bodies, national and overseas standards and conformity assessment bodies, academics, and international forums.

The INSS frames specific recommendations in the form of 23 goals and is intended to be implemented over a five-year period (2018-2023), monitored by a high-level committee with quarterly reviews.



India's first comprehensive strategy on quality infrastructure: The Indian National Strategy for Standardization (released in June 2018)

The key objectives of this draft strategy are:

- Positioning standards as a key driver of all economic activities relating to goods and services.
- Developing a comprehensive ecosystem in India for standards development considering the diversity of interests and expertise available.
- Using standards for providing a level playing field to domestic industry and enhancing the competitiveness of Indian goods and services in domestic and international markets.
- Adopting best practices in standardisation, conformity assessment, and technical regulations, and creating an integrated infrastructure, roadmaps, and institutions for their effective management.
- Playing an active role and taking leadership positions in apex international forums in the related areas.
- Creating response mechanisms to global developments on standards, technical regulations, and conformity assessment practices that impact market access of Indian goods and services.
- Aligning the strategy with other national policies related to trade and industry, consumers and environment.

"Propelled by the aspirations and enterprise of our people, a New India is emerging which confidently and constructively engages the global economy and trade. It is appreciable that a new framework of standardisation is being adopted which can provide far reaching benefits to economy and will raise the credibility of 'Made in India' brand in the global market."

Prime Minister Narendra Modi in the Indian National Strategy for Standardization (INSS)

Developments of Quality Infrastructure in selected Indian Sectors

Standardisation in the area of Low Voltage Direct Current

India has taken the global lead on preparing standards for Low Voltage Direct Current (LVDC) infrastructure. The relevance of LVDC has increased along with the increased use of solar power. Solar power, which is inherently DC, has spurred growing interest in appliances that work directly out that current.

As a result, BIS has set up the TC ETD 50 - LVDC Power Distribution Systems. The committee has taken up the development of Indian Standard Guidelines on 48V LVDC distribution systems. This standard is applicable to domestic units, commercial units either single or multiple, guest rooms or guest suites of hotels, motels or similar occupancies, mobile homes, and in building applications in general. The standard is also applicable to locations where electrical utility service is not available and power is derived from single or multiple renewable energy sources.

This standard covers the essential requirements for installations powered from an Extra Low Voltage 48 V DC power source. Power sources include interconnected or stand-alone batteries, solar photovoltaic systems, other distributed renewable generation systems, or generators. All sources defined in IEC 60364-4-41 Clause 414.3 are applicable but with a nominal voltage of 48V. Safety isolation transformer or Class II power converters shall be used if the voltage at any point in the power conversion system exceeds 60V from generation to the output.

Based on this experience, India became the convenor of IEC Systems Evaluation Group (SEG) 4 on *Low Voltage Direct Current Applications, Distribution and Safety for use in Developed and Developing Economies.* The purpose of SEG 4 was to evaluate the status of standardisation in the field of low voltage direct current (LVDC) applications and products and to recommend the architecture of any future standardisation work program that the IEC may undertake. The SEG evaluated the usage of LVDC in different integration environments in developed and developing economies with the objective to enhance energy efficiency and to develop new ways to utilise LVDC power.

India is now the chair of the IEC Committee SyC LVDC *Low Voltage Direct Current and Low Voltage Direct Current for Electricity Access* and convenor for its WG 1 *LVDC Standards for Electricity Access.*

Standards on Smart Cities

Concurrent with the Smart Cities Mission launched by the Ministry of Urban Development (MoUD) to develop 100 smart cities in India, various BIS divisions have taken up standardisation projects that will provide technical assistance in developing the core infrastructure as well as the modules for them. The ministry has released a concept note on Smart Cities that identifies social, physical, institutional, and economic infrastructure as the four pillars of a smart city.

The Civil Engineering Division of BIS has set up a Smart Cities TC, i.e. CED 59. The TC is currently developing a standard on smart cities indicators based on ISO 37120: 2014 ("Sustainable Development of Communities: Indicators for city services and quality of life").

The Electronics and Information Technology Division (LITD) of BIS had constituted a technical 'Smart infrastructure Panel' (LITDC/P2) for exploring the work being pursued on smart cities standardisation at the international level, and to identify the need for standardisation in the national context in the area of smart cities, active assisted living, smart manufacturing, and smart energy. The panel served as the national mirror committee for IEC SyC Smart Cities, IEC

SEG 7 Smart Manufacturing, and JTC 1/WG 11 Smart Cities. The Panel has published a pre-standardisation study report on *Unified, Secure & Resilient ICT Backbone for Smart Cities/Smart Infrastructure* covering the technical requirement analysis report on areas which are crucial in enabling optimisation of the ICT infrastructure in any Smart city:

a. ICT Reference Architecture for Smart Cities/Infrastructure
b. Last Mile Communication for M2M/IoT Applications
c. Common Service Layer Requirements in ICT Architecture for Smart Infrastructure

The Panel has also identified the need for additional allocation of spectrum in the sub-GHz range in India. As a large number of devices are expected to be connected in near future, present allocation of frequency band (865-867 MHz) may not be sufficient for the entire M2M/IoT/Smart Cities space. Currently only 2 MHz is available as un-licensed spectrum which can be used for low power wireless applications. Even if the additional 1 MHz in the 433-434 MHz band available for indoor applications is considered, India would not be able to cater to the billions of devices that would be installed in the IoT/M2M/Smart Cities initiatives.

The BIS has set up a TC LITD 28 on Smart Infrastructure, which had its first meeting in January 2018. The Committee shall take up standardisation in the field of Smart Cities (Electro-technical and ICT aspects) and related domains including smart manufacturing, active assisted living and shall be the liaison for IEC SyC Smart Cities, IEC SyC Smart Manufacturing, IEC SyC AAL, and JTC 1/WG 11 Smart Cities.

Technical Regulations for Medical Devices

On January 31, 2017 the Ministry of Health & Family Welfare introduced the Medical Devices Rules 2017, with effect from 1 January 2018. These rules defined medical devices to be considered separate from drugs. Both drugs and devices had been regulated in the identical manner under the *Drugs and Cosmetics Rules, 1945*.

The term medical device includes specific devices that help in diagnosis and treatment, specific substances that affect the human body, surgical dressings, bandages, blood collection bags and any other substance or device used in diagnosis or treatment of any disease or disorder of any human being or an animal. The specific devices and substances will be notified by the government from time to time.

The new rules have been framed in conformity with the Global Harmonisation Task Force (GHTF) framework and conform to best international practices and classify medical devices based on risk. Accordingly, the medical devices are categorised as Class A (having low risk), Class B (having low to moderate risk), Class C (having moderate to high risk), and Class D (having high risk).

A list of 351 medical devices and 247 in-vitro diagnostics medical devices along with their risk classes were notified on November 1, 2017 by the Drugs Controller General under provisions of the Medical Devices Rules, 2017. This list is the elaboration of the 15 categories of medical devices and 8 substances that were earlier notified under the Drugs and Cosmetics Act.

The rules provide for the product standards to be maintained by the manufacturers. They may be summarised as follows:

- Every manufacturer must follow a standard prescribed by the Central Government for the medical device specifically or which has been laid down by BIS.
- In the absence of the above, the standards laid down or prescribed by IEC or IEC or any other pharmacopoeia standards shall apply.
- In the absence of the above-mentioned categories for standards, validated manufacturers' standards shall be applied.

The rules introduce third party conformity and certification by notified bodies. The NABCB has been identified to accredit certification bodies that will be designated as Notified Bodies (NBs) by the Central Licensing Authority (CLA). These NBs will undertake verification and assessment of Quality Management Systems of the medical device manufacturers of Class A and Class B category and – if required – also be called upon to render assistance for regulation of Class C and D medical devices. As per the rules, the quality management system of all manufacturing units must be in conformity with ISO 13485.

The NABCB has constituted a task force to finalise the audit requirements based on the MDR 2017 and prepare a common report format to be used by NBs for the purpose. A network of NABL accredited laboratories for testing medical devices will be set up by the Government and by other entities.

Technical Regulations for Telecom Equipment

The Department of Telecommunications (DoT) has issued a notification on September 5, 2017 to amend the Indian Telegraph Rules for mandatory testing and certification of telecom equipment in India before sale. The rules are planned to come into effect on October 1, 2018. The Telecommunication Engineering Centre (TEC) has been notified as the implementing agency for the mandatory testing and certification of telecom equipment. The certification is for equipment design and can be obtained by original equipment manufacturers in India, or overseas or by the importer. The certificate shall be valid for five years from the date of issue.

The testing is to be carried out by Indian laboratories accredited in India and based upon their test reports, certificate shall be issued by the TEC. Currently, different divisions of the TEC have set up mandatory testing consultative forums to frame the essential requirements (ERs) for the equipment.

According to draft procedures for mandatory testing and certification of telecommunication equipment, which the TEC published, two certification procedures are intended:

1) Simplified certification scheme based on self-declaration accompanied by a pre-issued test report from an approved test centre (applying to a list of 20 items initially).
2) General certification scheme based on application, payment of fee, getting a sample tested after application and evaluation of the test report by the TEC (a list of 28 items has been proposed initially).

Machinery Safety

The Department of Heavy Industry has developed the *National Capital Goods Policy* (NGCP) to promote the Indian capital goods sector and exports from Indian machinery and equipment manufacturers. India's share in global exports of capital goods is less than 1%, whereas the import content varies from 10 % for low technology and as high as 78% for high technology equipment.

The NGCP includes, among others, specific recommendations for standardisation and conformity assessment. These include the goal to define Indian standards and certification for foreign companies to participate in Indian public procurement tenders, the introduction of mandatory standards (incl. defining minimum acceptable safety, environment and performance standards for machinery), and upgrading the development, testing, and certification infrastructure.

So far, India does not have any mandatory standards for the safety of machinery or regulation that can be deemed to be equivalent to the European Machinery Directive. The BIS has developed some voluntary standards for safety of machinery, however, these were not harmonised with international standards. With a view to support the *Capital Goods Policy*, BIS has set a new committee on Safety of Machinery (MED 40). The following standards have been issued by the TC:

- adoption of ISO 12100: 2010: Safety of machinery General principles for design risk assessment and risk reduction
- adoption of ISO 13849, 13850, 13851, 13854, 13855, 13856, 13857, 14119, 14120, 14122, 14123. 14159, 29042 and their parts (Total 32 standards related to safety of machinery)
- new projects for standards development include:
- adoption of ISO 20474 Parts 1 to 13 2017: Earth-moving machinery Safety
- adoption of 9 equivalent ISO standards on building construction machinery
- development of associated test methods, performance requirements, terminology standards

It is expected, once the harmonised standards are in place, the government may consider notifying them for mandatory compliance in line with the NCGP.

Regulation of Chemicals

The Ministry of Environment & Forests has constituted a National Coordination Committee for preparation of a National Action Plan for Chemicals which are produced, imported and consumed in the country as well as new chemicals. The NAPC would include:

- policy framework where registration of chemicals is needed,
- phasing out of chemicals in the short and long term based on safety to human health and environment,
- modification required in existing legislation to facilitate the regulations, and
- formulating views on Persistent Organic Pollutants that are restricted in other countries and on hazardous chemicals and pesticides listed in Annex III of the Rotterdam Convention that have been banned or severely restricted due to health or environmental consideration by more than two parties.

It is expected the recommendations of the NAPC would lead the way towards technical regulations in India similar to the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and other regulations on chemicals.

Pressure Vessels

The revised Static & Mobile Pressure Vessels (Unfired) Rules, 2016 have extended the standards for design, construction and testing of pressure vessels to ASME Section VIII Division 1 or Division 2, PD5500, EN 13458, EN 13530, AD:2000 code as amended from time to time in addition to IS 2825.

However, specific design requirements are additionally provided in the rules for design pressure, design temperature, pressure relief valves, steel thickness, fittings, marking and painting. These rules have been further amended in 2018 to provide for LNG storage, handling, transportation, operation, maintenance and dispensing.

Annex 1: Voluntary Standards Development Organisations in India

S. No.	Organisation	Status	Organisation Function	Subject areas, number of Standards published
1	Bureau of Indian Standards (BIS)	autonomous body under the Ministry of Consumer Affairs, Food & Public Distribution (MoCAF&PD)	National Standards Body, formulation of Indian Standards, representing India at the ISO, IEC; product certification	- all subjects excluding drugs and pharmaceuticals, environmental (ambient and emission) norms, grading of agricultural products - more than 15,000 standards
2	Standardisation Testing and Quality Certification (STQC) Directorate of the Ministry of Electronics and Information Technology (MeitY)	attached office of MeitY	quality assurance and conformity assessment services in the area of electronics and information technology (IT) related to information security, software testing and certification, development of national level assurance framework in IT and software sectors	E-government standards on subjects under the aegis of the National Centre for e-Governance Standards and Technology: - network and information security - metadata and data standards for application domains - biometric standards - standards and specifications for e-authentication (e-Pramaan) - digital preservation standard - localisation and language technology standards - technical standards and e-governance architecture
3	Bureau of Energy Efficiency (BEE)	autonomous body under the Ministry of Power	- promote the use of energy efficient products and installations - formulation of energy efficiency standards, operate voluntary and mandatory standards, and labelling programmes	- energy performance standards for appliances; has issued 11 voluntary and 10 mandatory standards - has published the Energy Conservation Building Code
4	Directorate of Marketing and Inspection, Agriculture Mark (Agmark)	attached office of the Department of Agriculture, Cooperation and Farmers' Welfare under the Ministry of Agriculture & Farmers' Welfare	standardisation, grading and quality control of agricultural and allied produce prescribed under the provision of the Agricultural Produce (Grading & Marking) Act, 1937 Implementing the Agmark certification scheme of agricultural commodities for domestic trade and export	grading standards covering 164 commodities in: - pulses - cereals - essential oils - makhana (fox nut) - vegetable oils - fruits and vegetables - roasted bengal gram - vermicelli, macaroni and spaghetti
5	Indian Roads Congress	registered society, works in close collaboration with the Ministry of Road Transport and Highways (MoRTH).	formulation of codes of practices for specifications and standards, guidelines and manuals relating to roads and highways planning and construction	more than 100 standards for - roads, namely survey, investigation, equipment, design, construction, environment, maintenance, geometrics, safety, road signage, and technology - specification and codes of practice for bridges and also guidelines for their inspection, maintenance, testing, and rating

S. No.	Organisation	Status	Organisation Function	Subject areas, number of Standards published
6	Building Materials & Technology Promotion Council	autonomous body under the aegis of the Ministry of Housing & Urban Affairs	development, standardisation, mechanisation and large scale field application of innovative and emerging building materials and technologies in the construction sector	new building materials
7	Automotive Research Association of India (ARAI) / Automotive Industry Standards Committee (AISC)	research institute of the automotive industry with the Ministry of Heavy Industries & Public Enterprises (MoHI&PE)	research & development, certification of vehicles, standards formulation under the aegis of AISC, homologation/ type approval service to the Indian as well as overseas auto industry, representing India on WP29 – (World Forum for Harmonisation of Vehicle Regulations under UNECE)	Automotive Industry Standards (AIS), 187 standards published on vehicles, components, test methods, type approvals, road safety, ITS, and others
8	Agricultural and Processed Food Products Export Development Authority (APEDA)	autonomous body under the Department of Commerce (DoC), Ministry of Commerce and Industry (MoCI)	development of industries relating to export of agricultural commodities, providing financial assistance, registration of exporters, fixing of standards and specifications for exports, inspection of meat and meat products in processing plants, storage premises, conveyances, organic certification	standards for organic production and systems under the National Programme for Organic Production (NPOP): - Crop production - Livestock, poultry and products - Beekeeping - Aquaculture production - Food processing and handling
9	Quality Council of India (QCI)	registered society co-founded by the Department of Industrial Policy & Promotion (DIPP), the Confederation of Indian Industry (CII), the Federation of Indian Chambers of Commerce & Industry (FICCI), and Associated Chambers of Commerce and Industry of India (ASSOCHAM)	umbrella organisation for accreditation boards (NABCB, NABL, NABH, NABET and NBQP). besides accreditation, is owner/co-owner of conformity assessment schemes	NABH: standards for hospital accreditation NABET: standards for school accreditation standards and criteria documents for voluntary schemes - Indian Certification of Medical Devices (ICMED) - Indian Good Agriculture Practices (INDGAP) - Competence of Traditional Community - Health Practitioners (TCHPs) - IndiaGHP Certification Scheme - IndiaHACCP Certification Scheme - Competence of Yoga Professional Certification Schemes

S. No.	Organisation	Status	Organisation Function	Subject areas, number of Standards published
10	Department of AYUSH	Ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy)	provides focused attention for the development of education and research in Ayurveda, yoga and naturopathy, Unani, Siddha and homoeopathy. evolves pharmacopoeia standards for Indian systems of medicine and homoeopathy drugs.	Ayurvedic Pharmacopoeia of India issued by the Pharmacopoeia Commission for Indian Medicine & Homoeopathy; the official book of standards for substances included in the Indian traditional Ayurvedic medicines including definition, identification, quantitative parameters, assay and other requirements Good Manufacturing Practices (GMP) for Ayush drugs
11	National Medicinal Plants Board	Ministry of AYUSH	conservation and augmenting local medicinal plants and aromatic species of medical significance. Development of Good Agricultural and Collection Practices (GACPs) voluntary certification scheme for medicinal plant produce	voluntary standards for - Good Agriculture Practices (GAP) for producers - Good Field Collection Practices (GFCP) for collectors
12	Telecommunication Engineering Centre (TEC)	a division of the Department of Telecommunications (DOT)	formulates standards with regard to telecom network equipment, services and interoperability, the associated conformity tests and fundamental technical plans TEC has been appointed as the Designating Authority (DA) on behalf of DoT for conformity assessment and certification bodies located in India to perform testing and certification of telecom products	TEC has formulated 624 technical specifications that include 523 on generic requirements, 65 on interface requirements, 13 on service requirements, and 23 standards
13	Telecommunications Standards Development Society, India (TSDSI)	registered society recognised by the Department of Telecommunications (DOT)	formulation and adoption of voluntary standards in the field of telecommunications	- TSDSI has transposed select specifications from Rel 10 to Rel 13 of 3GPP specifications (comprising of 295 specifications) for IMT advanced technologies (as per ITU-R M.2012-3) and Rel 2 of oneM2M specifications (comprising of 17 specifications and 10 technical reports) - New standards development in progress for M2M, IOT, interoperability and portability of cloud services, standards for cloud computing interoperability, fiber optics products and network

Annex 2: Regulatory Bodies which have notified standards

S.No.	Organ	Status	Organisation Function	Subject areas, number of Standards published
1	Central Boilers Board	regulatory body under the Department of Industrial Policy & Promotion (DIPP), Ministry of Commerce and Industry (MoCI	regulations for - laying down the standards for materials, design, construction of boilers - registration and inspection of boilers	standards for all types of boilers and heaters, economiser, feed pipes, feed heaters and other similar vessels, boiler and super-heater tubes, headers and other pressure parts, welded and seamless forged drums, mountings, fittings and auxiliaries, feed water
2	Tea Board	statutory body under the Department of Commerce (DoC), Ministry of Commerce and Industry (MoCI)		standards for black, green, Kangra and instant tea
3	Central Pollution Control Board (CPCB)	regulatory body under the Ministry of Environment & Forests	promotes cleanliness of streams and wells in different areas of the states by prevention, control and abatement of water pollution, and to improve the quality of air and to prevent, control or abate air pollution	lays down standards for - quality of air - water quality criteria for drinking water bathing water, wild life and fisheries, irrigation, industrial cooling, controlled waste disposal - discharge of environmental pollutants - vehicular exhausts for passenger cars, diesel vehicle and 2-/3-wheelers - emission norms for vehicles, emission norms and sound levels for diesel engines and generator sets, CPCB also prepares manuals, codes and guidelines relating to treatment and disposal of sewage and trade effluents as well as for stack gas cleaning devices, stacks and ducts
4	Petroleum and Natural Gas Regulatory Body (PNGRB)	regulatory body related to the Ministry of Petroleum and Natural Gas	regulate the refining, processing, storage, transportation, distribution, marketing and sale of petroleum, petroleum products and natural gas	- technical standards and specifications including safety standards for - petroleum and petroleum products pipelines regulations - city or local natural gas distribution networks - codes of practices for emergency response and disaster management plan
5	Ministry of Environment, Forest and Climate Change (MoEFCC)			effluent and emission standards for different industry/service sectors are provided in the schedule of various rules framed by MoEFCC under the *Environment Protection Act*

S.No.	Organ	Status	Organisation Function	Subject areas, number of Standards published
6	Food Safety and Standards Authority of India (FSSAI)	regulatory body related to the Ministry of Health & Family Welfare	regulation of food safety standards, safe food practices, licensing and registration of specified categories and size of food business operators,	lays down standards for articles of food and regulates their manufacture, storage, distribution, sale and import - Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 - Compendium of Food Safety and Standards (Food Product Standards and Food Additives) Regulation - Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016 - Food Safety and Standards (Organic Food) Regulation, 2017
7	Petroleum and Explosives Safety Organisation (PESO)	regulatory body under the Department of Industrial Policy & Promotion (DIPP), Ministry of Commerce and Industry (MoCI)	regulation of explosives, petroleum, carbide of calcium, flammable and non-flammable compressed gases and other hazardous substances, pressure vessels, factories, transport, storage installations, dispensing stations, bottling plants, refineries, gas filling plants and stations, petroleum storage and retail outlets, cross country pipelines, flame proof equipment	while adopting Indian Standards, BS, EN, ISO standards as the principal specifications for the products under regulations, the respective rules lay down additional essential requirements such as labelling, colour codes, working and test pressures: - Ammonium Nitrate Rules, 2012. - Explosives Rules, 2008 - Gas Cylinders Rules, 2016 - Static & Mobile Pressure Vessels (Unfired) Rules, 2016 - Petroleum Rules, 2002 - Calcium Carbide Rules, 1987
8	Ministry of Road Transport an	Ministry of Road Transport and Highways (MoRTH)	- prepare new standards for automotive items related to safety - review and recommend amendments to the existing standards - recommend adoption of such standards to the CMVR Technical Standing Committee	laying down functional and safety requirements for automotive vehicles and components in the Central Motor Vehicle Rules, 1989 - evolves standard specifications for roads and bridges in the country - adoption of standards developed by the Automotive Industry Standards Committee set up by the MORTH

S.No.	Organ	Status	Organisation Function	Subject areas, number of Standards published
9	Central Drugs Standard Control Organisation (CDSCO)	central drug authority under the Director General of Health Services, Ministry of Health & Family Welfare	regulatory control over the import of drugs, approval of new drugs and clinical trials regulations over medical devices	lays down the standards for drugs and health care devices, technologies, approve new drugs under the Drugs and Cosmetics Act. - Standards for drugs, vaccines etc: Indian pharmacopeia, Homoeopathic pharmacopeia, standards maintained at the International Laboratory for Biological Standards, Statens Serum Institut (Denmark) and at the Central Veterinary Laboratory (UK) - Standard for disinfectant fluids (Schedule 0) - Specified in the Rules - Standards for cosmetics in finished form (Schedule S) – adoption of BIS standards) - Standards for Condoms & Contraceptives (Schedule R): Specified in the Rules - Standards for Medical devices: BIS Standards, if there are no BIS Standards then International Standards, or other International Pharmacopeia Standards, in case national or international standards are not available, manufacturer 's validated standards

Annex 3: Technical Regulations in India

Sector / Product	Statutory notifications	Body responsible for Notification	Type of Approvals	Authorities responsible for approvals / surveillance	Conformity Assessment Agency
Food Safety	- *Food Safety and Standards Act, 2006* - Food Safety and Standards Rules, 2011 - FSS (Licensing and Registration of Food businesses) Regulation, 2011 - FSS (Packaging and Labelling) Regulation, 2011 - FSS (Food product standards and Food Additives) Regulation, 2011 (part I) - FSS (Food product standards and food additives) Regulation, 2011 (part II) - FSS (Prohibition and Restriction on sales) Regulation, 2011 - FSS (contaminants, toxins and residues) Regulation, 2011 - FSS (Laboratory and sampling analysis) Regulation, 2011 - Food Safety and Standards (Food Import) Regulations, 2016 regarding standards of Melamine in Milk and Milk Products.	Food Safety and Standards Authority of India (FSSAI)	Central License State License Registration BIS certification (for 13 types of food products and 2 types of feeding bottles)	FSSAI regional offices, state government designated authorities, relevant BIS office	designated regulatory agencies, referral food laboratories, approved laboratories
Steel	Steel and Steel Products (Quality Control) Order, 2018 (This order mandating BIS certification on 38 types of steels supersedes and subsumes all previous Quality Control Orders issued for steel)	Ministry of Steel	BIS Product Certification Licence	BIS for certified products appropriate authorities listed in each order for enforcement	BIS
Steel Tubes	Mild steel tubes (excluding seamless tubes and tubes according to API specifications) (Quality Control Order, 1978 issued under *Essential Commodities Act, 1955* mandating BIS Certification on 3 types of steel tubes	Department of Heavy Industries	BIS Product Certification Licence	BIS for certified products	BIS

Sector / Product	Statutory notifications	Body responsible for Notification	Type of Approvals	Authorities responsible for approvals / surveillance	Conformity Assessment Agency
Ductile (cast) Iron Pipes	Ductile Iron Pressure Pipes and Fittings (Quality Control) Order, 2009 mandating BIS Certification on 2 types of centrifugally cast ductile iron pipes for water, gas and sewerage and fittings	Department of Industrial Policy & Promotion (DIPP)	BIS Product Certification Licence	BIS for certified products appropriate authorities listed in the order for enforcement	BIS
Gas Cylinders, Valves and Regulators	Gas Cylinders Rules, 2016 under the *Explosives Act, 1884*	Petroleum and Explosives Safety Organisation (PESO)	approval for design / manufacture/ filling and hot repair of gas cylinders approval for imported cylinders	For manufacture and hot repair of cylinders, valves and regulators relevant BIS office, final approval by the Chief Controller of Explosives	BIS for all domestic cylinders, valves and regulators For imported cylinders, recognised certification bodies as given in Schedule 1 of Gas Cylinder Rules
Ex equipment	*Petroleum Rules, 2002.* (Rule 102 for Flame Proof / Intrinsically Safe Apparatus)	PESO	approval of Ex (Electrical) Equipment for use / installation in hazardous areas	Chief Controller of Explosives, Nagpur	prior BIS Licence for domestic manufacture For imported, Ex equipment, ATEX or IEC Ex Certificate of Conformity
Pressure Vessels	*Static & Mobile Pressure Vessels (Unfired) Rules, 2018*	PESO	approval for manufacturing capability, design, fabrication, repair and modification of pressure vessels	Chief Controller of Explosives, Nagpur	competent person/ inspector recognised by the Chief Controller of Explosives

Sector / Product	Statutory notifications	Body responsible for Notification	Type of Approvals	Authorities responsible for approvals / surveillance	Conformity Assessment Agency
Energy Efficiency	Bureau of Energy Efficiency Regulations (Product wise) and Gazette Notifications under the Energy Conservation Act, 2001 Products currently covered for mandatory energy efficiency labelling: - Frost free refrigerators - Tubular fluorescent lamps - Room air conditioners / inverter air conditioners - Distribution transformer - RAC (cassette, floor standing tower, ceiling, corner AC) - Direct cool refrigerator - Electric geysers - Colour TV - LED lamps	Bureau of Energy Efficiency	company registration (online) model registration and permission to apply label	Bureau of Energy Efficiency	NABL accredited labs or ILAC member accredited labs for testing Market surveillance (verification) by designated agencies
Industrial Electrical Products	Quality Control Orders issued by the Department of Industrial Policy & Promotion (DIPP) under the BIS Act, 1986 mandating BIS Certification: - Electrical transformers (Quality Control) order, 2015 - Energy Efficient Induction Motor – Three phase Squirrel Cage (Quality Control) Order, 2017 - Electrical Capacitors (Quality Control) Order, 2017) – 3 types of capacitors	Department of Industrial Policy & Promotion (DIPP	BIS Product Certification Licence	BIS for certified products appropriate authorities listed in the order for enforcement	BIS

Sector / Product	Statutory notifications	Body responsible for Notification	Type of Approvals	Authorities responsible for approvals / surveillance	Conformity Assessment Agency
Electrical Wires and Accessories	Electrical Wires, Cables, Appliances and Protection Devices and Accessories (Quality Control) Order, 2003 under the *Bureau of Indian Standards Act, 1986,* mandating BIS Certification for 15 household electrical products including 4 types of consumer appliances, electric cables, switches, residual circuit breakers, tungsten and self-ballasted lamps and Watt hour meters	Department of Industrial Policy & Promotion (DIPP)	BIS Product Certification Licence	BIS for certified products appropriate authorities listed in the order for enforcement	BIS
Electronic Products	Information Technology Goods (Requirement for Compulsory Registration) Orders issued from 2012 to 2017, mandating compulsory registration of 44 Electronic products	Ministry of Electronics & Information Technology (MeitY)	BIS Registration Mark	BIS for registered products Appropriate authorities listed in the orders for enforcement	Market surveillance by designated agencies appointed by MietY
Cement	Cement (Quality Control) Order 2003 dated issued under *Bureau of Indian Standards Act, 1986* mandating BIS certification for 15 types of cements used for construction and masonry purposes	Department of Industrial Policy & Promotion (DIPP)	BIS Product Certification Licence	BIS for certified products appropriate authorities listed in the order for enforcement	BIS
Medical Devices	Indian Medical Devices Rules, 2017 under *Drugs and Cosmetics Act, 1951* mandating conformance to standards on 15 types of medical devices (351 medical devices and 247 in-vitro diagnostics medical devices have been notified) and 8 substances	Department of Health and Family Welfare	licensing	Central Licensing Authority (Drugs Controller General of India for class C&D devices, state licensing authorities for class A & B devices	Third party (NABCB) accredited notified bodies for class A & B devices Licensing authorities for class C & D devices
	Clinical Thermometers (Quality Control), 2001, mandating BIS certification for 2 types of clinic thermometers	Department of Consumer Affairs	BIS Product Certification Licence	BIS for certified products Director Legal Metrology, Department of Consumer Affairs	BIS
Automobile Accessories Tyres and Tubes	Pneumatic Tyres and Tubes for Automotive Vehicles (Quality Control) Order 2009, mandating BIS Certification for 3 types of tyres and 1 type of tubes	Department of Industrial Policy & Promotion (DIPP)	BIS Product Certification Licence	BIS for certified products appropriate authorities listed in the order for enforcement	BIS

Sector / Product	Statutory notifications	Body responsible for Notification	Type of Approvals	Authorities responsible for approvals / surveillance	Conformity Assessment Agency
Dry Batteries	Multipurpose Dry Batteries (Quality Control) Order, 1987, mandating BIS Certification for multi-purpose dry batteries	Department of Consumer Affairs	BIS Product Certification Licence	BIS for certified products	BIS
Oil Pressure Stoves	Oil Pressure Stoves (Quality Control) Order, 1997, mandating BIS Certification for oil pressure stoves	Department of Industrial Policy & Promotion (DIPP)	BIS Product Certification Licence	BIS for certified products appropriate authorities listed in the order for enforcement	BIS
Textiles, Cotton	Cotton Control (Amendment) Order, 1987 under *Essential commodities Act, 1955* mandating packing of cotton bales as per Indian Standard IS: 12171	Ministry of Textiles	permission to pack	Textile Commissioner	Textile Commissioner
Boilers and Accessories	*Indian Boilers Regulations, 1950* as amended from time to time specifying design, fabrication, inspection, testing and certification of boilers, heat exchangers, converters, evaporators and fittings, components, materials, etc.	Central Boilers Board	certification	Central Boilers Board	competent persons of an inspecting authority recognised by the Central Boilers Board
City Gas Distribution Networks	Technical standards and specifications including safety standards for city or local natural gas distribution networks, regulations, 2008	Petroleum & Natural Gas Regulatory Board	authorisation	Petroleum & Natural Gas Regulatory Board	approved accredited third-party inspection agency
Natural Gas Pipelines	Technical standards and specifications including safety standards for natural gas pipelines regulations, 2009	Petroleum & Natural Gas Regulatory Board	authorisation	Petroleum & Natural Gas Regulatory Board	approved accredited third-party inspection agency

Annex 4: Comparison of Regulated Sectors between the EU and India

Sector	European Union	India
Electrical Safety	Low Voltage Directive – 2014/35/EU all low voltage equipment excluding domestic switches, power meters, ATEX equipment, medical devices and Radio interference	21 products under BIS
Machinery	Machinery Directive – 2006/42/EC almost all types of machineries including components and accessories	no regulations for machinery safety. *Capital Goods Policy, 2016* contains policy to introduce mandatory standards for machinery based on ISO standards
Medical Devices	Medical Devices Directive – 93/42/EEC (Additionally in-vitro diagnostic medical devices Directive 98/79/EC) Active Implantable Medical Devices Directive – 90/385/EEC All devices	Indian Medical Devices Rules, 2017 15 device categories (351 medical devices and 247 in-vitro diagnostics medical devices) 8 substances
Gas Appliances	Gas Appliances Directive 2009/142/EC (GAD) all appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing	no regulations for gas appliances
Personnel Protective Equipment	Personal Protective Equipment Directive – 89/686/EEC all device and equipment claimed to be personal protective equipment	no regulations on PPE. use regulated for certain operations under state government rules. Standards not prescribed
Construction Products	Construction Products Regulation – Regulation (EU) No 305/2011 all construction products, building materials and accessories used in buildings	*Bureau of Indian Standards Act, 1986* 38 types of steel, 15 types of cements under BIS third party certification regulations for fire-retardant textiles under consideration
Boilers and Pressure Vessels	Pressure Equipment Directive – 97/23/EC additionally Simple Pressure Vessel Directive (87/404/EC, Transportable Pressure Equipment Directive (99/36/EC), Aerosol Dispensers Directive (75/324/EEC). pressurised Vessels, storage containers, heat exchangers, steam generators, boilers, industrial piping, safety devices and pressure accessories	Indian boiler regulations for boilers and accessories Static and Mobile Pressure Vessels (Unfired) Rules, 2016 covering pressure equipment excluding boilers - permits compliance to ASME Section VIII Division 1 or Division 2,PD5500, EN 13458, EN 13530 in addition to IS 2825

Sector	European Union	India
Equipment used in Explosive Atmospheres	ATEX Directive – 2014/34/EU all electrical components and apparatus and machinery for use in explosive atmospheres. separately supplied protective systems for controlling unavoidable explosions	*Petroleum Rules, 2002* requiring conformance of all flameproof and intrinsically safe equipment in petroleum handling and storage installations coal mines regulations requiring conformance all flameproof and intrinsically safe equipment used in mines
Toys	Toy Directive – 2009/48/EC all types of toys	DGFT Notification 2017 for pre-testing of imported toys domestic regulation under consideration
Chemicals Safety	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulations	Hazardous Waste (Management & Handling) Rules, 1989, Insecticides Rules, 1971, Explosives Rules, 1983, The Factories Act, 1948, restrict use of certain chemicals no regulation for registration. Ministry of Environment, Forest and Climate Change has set up a national coordinating committee to recommend regulations similar to REACH.
Electromagnetic Compatibility	EMC Directive all equipment liable to generate electromagnetic disturbance	no Regulations presently planned to be included in essential requirements being framed under the Indian Telegraph Rules, 2017 for mandatory testing and certification of telecom equipment
Telecom Equipment	Radio & Telecommunication Terminal Equipment Directive – 1999/5/EC all radio and telecom equipment. Low voltage and EMC directives apply. In addition compliance to spectrum allocation. Can be extended to network interoperability, data privacy, etc.	notification by the Department of Telecommunications in 2017 on mandatory testing and certification of telecom equipment under licence. List and essential requirements being drawn. Effective date 01.10.2018 mobile phones and telephone answering machines brought under MeitY Compulsory Registration Order
Restriction of Hazardous substances	RoHS – Restriction of Hazardous Substances – Directive – 2011/65/EU all electronic equipment and components	no regulations on RoHS
Plant protection and Biocidal Products	Plant protection products – Regulation – 1107/2009 Biocidal Products Regulation – 528/2012 approval of plant protection products before placing in EU markets /approval of active substances by the European Food Safety Authority (EFSA) authorisation of product / approval of active substances before placing in EU markets products being notified	Insecticides Act, 1968 requires registration of substances and license to manufacture. BIS certification obligatory for licensing 34 pesticides / formulations banned, 18 registrations declined

Annex 5: Conformity Assessment Services being offered in India

General Management Systems Certification Schemes

- ISO 9001 - Quality Management System
- ISO 14001 - Environmental Management System
- OHSAS 18001 - Occupational Health and Safety Management System
- ISO 45001:2018 - Health and Safety Management
- ISO 27001 - Information Security Management System
- ISO 22301 - Business Continuity Management (BCM) System
- ISO 55001 Asset Management System
- ISO 50001 - Energy Management System
- SA 8000 - Social Accountability Certification

Sector-Specific Management Systems Certification Schemes

- ISO 22301 - Food auditing and system certification
- ISO 13485 - Quality Management System for Medical Devices
- IATF 16949 - Quality Management System for Automotive Industry
- AS/EN 9100 - Aerospace Management System
- ISO/IEC 20000 - Information Technology (IT) Service Management System
- TL 9000 - Management System for Telecommunications Industry
- ISO 29001 - Petroleum, petrochemical and natural gas industries
- ISO 28000 - Security Management System for the Supply Chain
- ISO 39001 - Road Traffic Safety Management
- Worldwide Responsible Accredited Production (WRAP)
- IRIS (International Railway Industry Standard) - Rail Management system
- ISO 29990 - Quality Management System
- EN 15838 - Customer Call Centre Guidelines
- Global GAP

Climate Change and Business compliance

- Clean Development Mechanism (CDM)
- Carbon Footprint Certification
- Validation, Verification and Certification of Climate Change Projects
- Code of Conduct (CoC)
- Business Social Compliance Initiative (BSCI)

Product Certification Schemes

- CE Mark
- ENEC 24 (for electrical products)
- RoHS (for electronic components)
- IECQ HSPM QC 080000 (IECQ Hazardous Substance Process Management) Certification
- Body owned schemes such as KiteMark (BSI), UL Mark (UL), CSA Mark (CSA)

Third Party Inspection Schemes

- Inspection services complying with ISO 17020

Annex 6: WTO Notifying Authorities and Enquiry Points

	Notifying Authority	National Enquiry point
Technical Barriers to Trade (TBT)	Department of Commerce, Ministry of Commerce & Industry	Head, International Relations & Technical Information Services Department Bureau of Indian Standards, Manak Bhavan, 9 Bahadur Shah Marg, New Delhi-110002 – India Telephones: + (91 11) 232 30 342 / 232 31 082 Fax: + (91 11) 232 39 399 E-mail: tbtenquiry@bis.gov.in
Sanitary and phytosanitary measures (SPS) – Human Health related	Food Safety & Standards Authority of India (FSSAI)	Assistant Director SPS Enquiry Point Food Safety and Standards Authority of India (FSSAI) FDA Bhawan, Kotla Road New Delhi-110002, India Tel: +(011) 23231681 Fax: +(011) 23220994 E-mail: spstbt.enqpt@fssai.gov.in
SPS – Plant Quarantine	Department of Agriculture, Cooperation and Farmers' Welfare, Ministry of Agriculture and Farmers' Welfare	Joint Secretary, Department of Agriculture, Cooperation & Farmers' Welfare Ministry of Agriculture & Farmers Welfare, Room No. 238, Krishi Bhawan, New Delhi-110011, India. Tel/Fax: +(91 11) 23382937; E-mail: jspp-dac@nic.in
SPS – Animal Health	Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture and Farmers Welfare	Joint Secretary Department of Animal Husbandry, Dairying and Fisheries Ministry of Agriculture, Room No. 240, Krishi Bhawan, New Delhi E-mail: jslh-dadf@nic.in

Work Cited

This publication made use of several resources available online. Please consult the following websites to access further information on quality infrastructure in India.

Automotive Research Association of India
https://www.araiindia.com/

Bureau of Indian Standards
www.bis.org.in

- BIS Act, Rules and Regulations (e.g. BIS Act, 1986 and BIS Act, 2016)
  http://bis.gov.in/?page_id=2377
- Products covered by mandatory BIS certification
  http://bis.gov.in/?page_id=1695
- Annual Reports (e.g. 2016-17)
  http://www.bis.org.in/org/AnnualReport2016-17.pdf

Central Drugs Standard Control Organization (CDSCO)

- Medical Devices Rules 2017
  http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E.pdf

Department of Commerce, Ministry of Commerce and Industry
www.commerce.gov.in

- Indian National Strategy for Standardization
  http://commerce.gov.in/writereaddata/uploadedfile/MOC_636552662013452841_INSS_draft_23-2-18.pdf
- Export Promotion Councils
  http://commerce.gov.in/InnerContent.aspx?Id=6

Department of Consumer Affairs, Ministry of Consumer Affairs, Food & Public Distribution
https://consumeraffairs.nic.in/home.aspx#

- Acts and rules on legal metrology
  https://consumeraffairs.nic.in/forms/contentpage.aspx?lid=639

Department of Heavy Industry, Ministry of Heavy Industries and Public Enterprises

- National Capital Goods Policy
  http://dhi.nic.in/writereaddata/Content/NationalCapitalGoodsPolicy2016.pdf

Department of Industrial Policy and Promotion, Ministry of Commerce and Industry
http://dipp.nic.in/

Directorate General Factory Advice Service and Labour Institutes (DGFASLI)
http://www.dgfasli.nic.in/

EU-India ICT Standardisation Project

http://www.indiaeu-ictstandards.in/

Food Safety and Standards Authority of India (FSSAI)

- Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016

  http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html

Indian Council for Research on International Economic Relations (ICRIER)

- Virmani, Arvind. 1996. Economic Development and Transition: India, conference paper.

  http://www.icrier.org/pdf/Japanb.pdf

India Standards Portal

http://www.indiastandardsportal.org/

Ministry of Electronics and IT (MeitY)

- Compulsory Registration Scheme for Electronics and IT products
  http://meity.gov.in/esdm/standards
- Standardization Testing and Quality Certification (STQC) Directorate
  http://stqc.gov.in

Ministry of New and Renewable Energy (MNRE)

https://mnre.gov.in/

Ministry of Power (MoP)

https://powermin.nic.in/

National Physical Laboratory of India (NPL)

http://www.nplindia.in/national-metrology

National Skills Qualifications Framework

http://www.skilldevelopment.gov.in/nsqf.html

Petroleum and Explosives Safety Organisation (PESO)

- Static & Mobile Pressure Vessels (Unfired) Rules, 2016

  http://peso.gov.in/index.aspx/images/front/flash/flash/Hindi/PDF/PDF/SMPV_RULES_2016.pdf

Quality Council of India (QCI)

http://qcin.org/

- National Accreditation Board for Certification Bodies (NABCB)
  http://nabcb.qci.org.in/
- National Accreditation Board for Testing and Calibration Laboratories (NABL)
  http://nabl-india.org
- National Accreditation Board for Hospitals & Healthcare Providers (NABH)
  https://www.nabh.co/
- National Accreditation Board for Education and Training (NABET)
  http://nabet.qci.org.in/

Seconded European Standardization Expert for India (SESEI)

http://sesei.eu/

Telecommunication Engineering Centre (TEC) of the Department of Telecommunications (DoT)

- Mandatory Testing and Certification of Telecom Equipments (MTCTE)

http://www.tec.gov.in/certification-approval-procedure/

Telecommunications Standards Development Society, India (TSDSI)

https://tsdsi.in/

United Nations Industrial Development Organization (UNIDO)

- UNIDO, 2018, Quality Policy. Technical Guide, Vienna, Austria.

https://www.unido.org/sites/default/files/files/2018-06/QP_TECHNICAL_GUIDE_08062018_online.pdf

World Trade Organization (WTO)

- Agreement on Technical Barriers to Trade (TBT)

https://www.wto.org

https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

Ensuring Quality in India and Beyond

The ability to produce quality products is key to a strong economy. India has chosen to direct its focus on developing a strong and robust quality infrastructure (QI) system. With both the 2014 Make in India initiative and the 2018 Indian National Strategy for Standardization, India is preparing itself as a global manufacturing hub and an address for foreign investment.

This publication was created within the framework of the Indo-German Working Group on Quality Infrastructure. It gives a comprehensive overview of the different components of India's quality infrastructure system, its institutions, the legal framework, and processes, with a particular focus on international trade. It shall support the domestic and foreign industry in complying with requirements as well as encourage their active participation in standards development. In addition, it shall act as a reference for policymakers and interested stakeholders about the Indian quality infrastructure system and contribute to the expert discourse on its further development and implementation.

Overview of India's Quality Infrastructure
A Guide to Standardisation, Conformity Assessment, Accreditation, Market Surveillance, and Metrology

Indo-German Working Group on Quality Infrastructure | Knowledge Series 1

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