



Regulations in Certifications for Indian Business

As an emerging market, India is one of the biggest and fastest growing economies in the world today. According to a report, India is cited as having the potential to become the third largest economy in the world within the next 30 years, behind only China and the USA. The “Make in India” campaign coupled with other initiatives taken by the Ruling Government, like “Skill India”, “Digital India”, etc., has stirred huge interest among various domestic and overseas stake holders. This whitepaper provides an overview of major requirements manufacturers need to address before their products can reach Indian market.

Indian Regulatory Bodies

Bureau of Indian Standards (BIS), Standardization Testing and Quality Certification (STQC), Bureau Energy Efficiency (BEE), Wireless Planning and Coordination Wing (WPC), Telecommunication Engineering Centre (TEC), Central Drugs Standard Control Organization (CDSCO), Import of Used Machinery

BUREAU OF INDIAN STANDARDS (BIS)

ISI Certification Mark: BIS is the government imparted Certification Body, which has the Voluntary scheme of 900 products and Mandatory certification for 90 products

Product Examples

- Packaged Drinking Water, Packaged Natural Mineral Water
- Cement
- Cables
- LPG Cylinders, Regulators, Valves, Oil Pressure Stoves
- Electrical Appliances
- Steel and Steel Products
- Pneumatic Tyres and Tubes

Key Steps

- Submission of application with complete test report
- Must-have of an in-house test lab for type testing covering all major tests
- BIS will perform factory inspection and pick samples from manufacturing location and same will be tested in BIS recognized labs
- Grant of approval
- Strict periodic checks at manufacturing location

BIS REGISTRATION SCHEME

A Deity (Department of Electronics and Information Technology) compulsory registration system. It is a compulsory registration scheme for 30 electronic product categories

Key Notes

- Testing must be done in BIS recognized labs (only in India)
- Reports must be submitted to BIS and obtain registration number

- Mark the product with registration number
- Market surveillance

BUREAU OF ENERGY EFFICIENCY

Assists in developing policies and strategies with a thrust on self-regulation and market principles. The primary objective of reducing energy intensity of the Indian economy

Steps to obtain BEE Certification:

- Test according to BEE recognized standards
- Submission of reports to BEE online
- Obtainment of energy label
- Visibility of energy label on product

IMPORT OF USED MACHINERY

Requirements

- At least 80% residual life is ensured
- Must be certified by Chartered engineer
- Declared value of the machine (should not be under-quoted to avoid custom duty)
- Fit to use and rest of life (scrap material required different approvals hence it is necessary to check that the machine is really fit to use)
- This inspection can be done at the departure or arrival ports. If the machine is complex then it is better to organize the inspection at the departure port itself

Following technical aspects are considered for evaluation;

- Physical Inspection & Examination of items
- Information & Documents provided by the client
- Sources of Procurement
- General Appearance & Present Condition of items
- Secondhand status & Residual Life of items
- Function, Utility & Reusability of items

WIRELESS PLANNING AND COORDINATION WING

Scope

- New Frequency Allocation: For use of wireless equipment's in a new frequency band, that needs to be allocated
- Equipment Type Approval: Import of wireless equipment's for use in the existing allocated frequency bands
- All wireless products (Transceivers, Transmitters & Receivers) entering Indian Market

Equipment Type Approval

- Obtain test results according to ETSI Standards
- Establish local representative
- Submit reports to WPC
- Obtain Equipment Type Approval

TELECOMMUNICATION ENGINEERING CENTRE

Scope

- Mandatory Certification (for IR only if the end user requests it)
- Type Approval: Required when the product is supplied to any of the DoTs
- Interface Approval: Required when the product gets directly connected to PSTN lines and when the end user calls for this certification

Checklist

- Compliance Report as per TEC "GR &/or IR" Standards
- Industrial License / SSI Registration
- Foreign collaboration copy (if applicable)
- User's Operating Manual
- Technical document for the Affidavit attested by Notary Public for each product / model

PETROLEUM AND EXPLOSIVES SAFETY ORGANISATION

Petroleum And Explosives Safety Organisation (PESO) is the department formed by Government of India to control and administer the usage of explosives, petrol stations in India. The agency issues licenses for Operation of Petrol Stations under Form XIV, Licenses to operate Petroleum Product Transportation vehicles, Licenses for Refineries, Petrochemical Complexes, etc.,

CENTRAL POLLUTION CONTROL BOARD MINISTRY OF ENVIRONMENT & FOREST

RoHS is restriction of Hazardous Substance (i.e.,) Lead, Cadmium, Mercury & Hexavalent Chromium. CPCB is driving for implementation of this regulation in Industries.

Examples

E-Waste generated from;

- Information Technology and Telecommunication Equipment

- Consumer electrical and electronics

Environmental Standard

- Ambient Air Quality
- Water Quality / Pollution
- Auto Fuel Quality
- Generator Set Emissions
- Noise Level
- Soil

The Ministry of Environment, Forest and Climate Change (MoEFCC) is the nodal agency in the administrative structure of the Central Government for the planning, promotion, co-ordination and overseeing the implementation of India's environmental and forestry policies and programmes.

The broad objectives of the Ministry are:

- Conservation and survey of flora, fauna, forests and wildlife
- Prevention and control of pollution
- Afforestation and regeneration of degraded areas
- Protection of the environment and
- Ensuring the welfare of animals

STANDARDIZATION TESTING AND QUALITY CERTIFICATION (STQC)

A Safety Certification Scheme, provides voluntary 'S' – Mark. STQC offers this certification under the CB Scheme (an NCB) and also under its general S – Mark Certification Scheme, this scheme has lost its popularity by its target group.

EUROPEAN REGULATION SYSTEM

CE marking based on directives, covers many parameters but mainly limited to safety. Major product categories are under self declaration and Limited products like medical devices are under notified body CE marking scope. The Voluntary scheme GS mark covers many product categories with production surveillance.

INDIA REGULATION SYSTEM

BIS certification scheme covers safety and performance parameters. Strong production control with periodic sample verification and market surveillance. In BIS Registration Scheme (CRS), testing is possible only for recognized labs and grant still issued by BIS. The disadvantages are; it covers only limited products, parameters like EMC and other regulations not always taken into consideration



CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Existing

- Covered under Drugs act
- 28+ products are listed
- Approval process is similar to Drugs

Proposed

- Draft revised regulation is due for approval
- Model is based on European Scheme
- Would be made independent of drugs
- Proposed to cover all medical devices in phases

New proposed system is comparable with European union's medical device directive and in-vitro diagnostic device directives. A public workshop has been organized under this forum to bring the awareness to the industry in the month of November 2014 in New Delhi.

INDIAN BOILER REGULATIONS

The finished boilers and its associated components for shipping and selling in the Indian market, need to make sure that they are certified to the Indian Boiler Regulations.

- The India Boiler Authorities strictly enforce the requirements of IBR-1950 with amendments, refusing site installation or assembly of any materials that are not correctly certified to the India Boiler Regulations
- The regulations would cover not only inspections, but also the conditions for material procurement. The Central Boilers Board was formed as a result of an amendment in 1937
- The latest version of the law is known as the India Boiler Regulation, 1950. Amendments are issued from time to time

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled food related issues in various Ministries

and Departments. FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

Highlights of the Food Safety and Standard Act, 2006:

Various central Acts like Prevention of Food Adulteration Act, 1954, Fruit Products Order, 1955, Meat Food Products Order, 1973, Vegetable Oil Products (Control) Order, 1947, Edible Oils Packaging (Regulation) Order 1988, Solvent Extracted Oil, De-oiled Meal and Edible Flour (Control) Order, 1967, Milk and Milk Products Order, 1992 etc will be repealed after commencement of FSS Act, 2006. FSSAI Approve laboratories to perform analysis for the Act established in ensuring the quality of products for the prescribed parameters

- 5.4.1 Packaging materials shall provide protection for all food products to prevent contamination, damage and shall accommodate required labelling as laid down under the FSS Act & the Regulations there under
- 5.4.2 Only Food grade packaging materials to be used. For packaging materials like aluminum plastic and tin, the standards to be followed are as mentioned under the FSS Regulations and rules framed there under
- 5.4.3 Packaging materials or gases where used, shall be non-toxic and shall not pose a threat to the safety and suitability of food under the specified conditions of storage and use

Compliance Certification

Rule 126: Prototype of every motor vehicle to be subject to test

Every manufacturer or importer of motor vehicle other than trailer and semi trailer shall submit the prototype for test by the Authorised Test Agency for granting a CMVR Compliance Certification. (Procedure for Type Approval shall be as per AIS 017-2000 as amended from time to time.)

Rule 126 B

Prototype of every Construction Equipment Vehicle to be subject to test....

Rule 126A : Conformity of Production

The testing agencies referred to in Rule 126 shall in accordance with the procedures laid down by the Central Government also conduct test on vehicles drawn from the production line to verify conformance to the exhaust emission requirements (Rule 115).

Rule 127: Quality certificate by manufacturer

The sale of every motor vehicle manufactured shall be accompanied by a certificate of road-worthiness issued by the manufacturer in Form 22

Rule 124 Safety Components

- Type Approval and Conformity of Production as per AIS 037
- Applicable in phased manner for notified components



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