

Building Better: India's Path to Superior Quality Infrastructure



Preface

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India is on the fast track to issuing Quality Control Orders (QCOs) and Compulsory Registration Orders (CROs). To fully capitalize on these initiatives, it is crucial to comprehensively strengthen India's Quality Infrastructure. This will ensure that small firms are not overburdened, quality imports are not unfairly penalized, and adequate field infrastructure, such as testing labs, are in place. Additionally, harmonizing our standards with global practices is essential.

This report highlights the key issues and provides insights into how India can enhance its Quality Infrastructure to support sustainable economic growth and competitiveness. We would be happy to receive feedback at ajay@gtri.co.in

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1. India is on the fast track to issuing Quality Control Orders

India is on the fast track to issuing Quality Control Orders (QCOs) and Compulsory Registration Orders (CROs). This rapid issuance became possible through the introduction of the new BIS Act in October 2017, which simplified the process of notifying products, systems, and services that must meet specific standards.

Since introduction of the Act in 2017, over 140 QCOs have been issued for more than 550 products, compared to just 14 QCOs covering 106 products up to 2014.

QCOs and CROs are regulatory measures used globally to ensure that products meet specific quality, safety, and performance standards before they are marketed and sold. By enforcing strict adherence to quality criteria, they help mitigate risks associated with substandard products, enhance consumer trust, and facilitate international trade by aligning domestic products with global expectations.

Over 140 QCOs covering over 550 products have been implemented in the past 7 years. This rapid pace has created implementation challenges for the firms, importers and the Government agencies alike. There is urgent need to upgrade India's quality infrastructure and conduct a matter of fact study on performance of the QCOs and to know if there is need for any course correction.

2. Examples of latest orders

Recent examples of QCOs include:

- The **Toys** (Quality Control) Order of 2020; the **Footwear** made from Leather and other materials (Quality Control) Order of 2024; the **Pneumatic Tyres and Tubes** for Automotive Vehicles (Quality Control) Order of 2009- all three orders issued by DPIIT, Ministry of Commerce and Industry;
- The **Steel and Steel Products** Quality Control Order of 2018 by the Ministry of Steel; and
- The Compulsory Registration Order of 2012 for **Electronic & IT Products** (including mobiles, mobile batteries, and laptops) by the Ministry of Electronics & IT.

Product Category	Order	Ministry
Toys	Toys (Quality Control) Order (QCO) of 2020	DPIIT, Ministry of Commerce and Industry
Shoes	Footwear made from Leather and other materials (Quality Control) Order, 2024	
Automotive tyres	Pneumatic Tyres and Tubes for Automotive Vehicles (Quality Control) Order, 2009	
Steel and Steel Products	Steel and Steel Products Quality Control Order, 2018	Ministry of Steel
Electronic & IT Products	Compulsory Registration Order, 2012 (Mobiles, Mobile batteries, laptops etc.)	Ministry of Electronics & IT

3. Impact of QCOs and CROs

The enforcement of QCOs and higher import duties has significantly reduced the import of substandard toys, with India's global toy imports dropping from US\$ 304.1 million in FY 2019 to US\$ 64.9 million in FY 2024, and imports from China decreasing from US\$ 264.6 million to US\$ 41.5 million in the same period.

Additional reported benefits include a noticeable decrease in consumer complaints and product recalls related to safety issues, a 15% increase in domestic electronics production following the implementation of CROs, a 20% increase in R&D spending by companies in sectors affected by QCOs, and annual growth rates of 8-10% in industries impacted by these regulations, compared to 4-5% growth before their enforcement.

- A noticeable decrease has been seen in consumer complaints and product recalls related to safety issues in categories regulated by QCOs and CROs. For instance, the recall rate for electrical appliances reduced by 25% after the implementation of relevant QCOs.
- The domestic production of electronics saw a 15% increase in the year following the implementation of CROs in the electronics sector. This shift indicates higher compliance and improved production standards among domestic manufacturers.
- Companies in sectors affected by QCOs have increased their spending on research and development by 20% on average. This investment aims to meet and exceed the required standards, fostering innovation and quality improvements.
- Industries affected by QCOs and CROs, such as electronics, textiles, and toys, have experienced growth rates of 8-10% annually post-implementation, compared to 4-5% growth before the regulations were enforced.

- CROs issued for various electronics and IT products, ensure that only items meeting specific safety and quality standards are imported.

The above is based on anecdotal evidence/reporting and has no data backup, a rigorous study is needed to ascertain both benefits and challenges of QCO.

4. Recommendations for Improving Quality Systems in India

India's national quality infrastructure includes (i) standardization, QCO, CROs led by BIS (ii) conformity assessment through third-party inspections and (iii) certifications and accreditation coordinated by the Quality Council of India (QCI). India has fast tracked issuance of QCO, CROs, but it needs to augment each leg of the quality system.

Recommendation summary

To further improve quality systems in India, several recommendations are proposed.

First, India should adopt and align its standards with international ones to enhance export competitiveness and seek international accreditation for BIS certifications to avoid additional costs for manufacturers. Regulations should focus on essential health, safety, and environmental parameters and use a risk-based approach to balance enforcement with industry capacity. Additionally, support for SMEs should include gradual implementation of QCOs and CROs, financial assistance, technical guidance, and phased implementation to help small firms comply.

Moreover, developing comprehensive quality infrastructure is essential for expertise, conformity assessment systems, and market surveillance. Standards and regulations should not act as non-tariff barriers, and regulatory impact assessments should be conducted to ensure regulations are effective and not burdensome. Creating high-quality, globally acceptable standards for products like Ayurveda and working towards global acceptance of Indian certifications will further improve quality systems. Finally, establishing mutual recognition agreements with key trading partners will facilitate smoother international trade.

Implementing these recommendations will enhance India's quality infrastructure, reduce burdens on small firms, and improve the global competitiveness of Indian industries.

Recommendation details

I. International Standards Adoption and Accreditation

Adopt International Standards: The Bureau of Indian Standards (BIS) should adopt international standards wherever possible, such as those for electrical safety and toys. This will reduce transaction costs for companies and enhance export competitiveness.

Systematic Alignment with International Standards: BIS and other Indian standards bodies should systematically align Indian standards with international ones by participating in organizations like ISO, IEC, ITU, Codex Alimentarius, World Organization for Animal Health (OIE), and the International Plant Protection Convention (IPCC).

Accreditation for International Acceptance: BIS should seek accreditation to ensure that its certifications are internationally accepted. Currently, many regulations under the BIS Act are based on ISO/IEC standards, but BIS certification is generally not accepted internationally due to a lack of accreditation. Achieving international acceptance will help manufacturers avoid the additional costs of seeking certification from other agencies.

II. Focused and Risk-Based Regulation

Regulate Essential Parameters only: Technical regulations should focus on health, safety, and environmental aspects, regulating only the parameters related to these concerns rather than encompassing the entire product standards. – e.g. only lead content in paints not all quality parameters of paints. However, many QCOs often regulate the entire product standard, not just the essential health, safety, and environmental parameters. This increases the cost of compliance.

Risk-Based Regulation: Use a risk-based regulation approach to balance enforcement with industry capacity. Low-risk B2B products should have different regulations compared to high-risk consumer products.

III. Support for SMEs

Gradual Implementation: Implement QCOs and CROs gradually to allow small firms to adjust to new standards.

Financial Assistance and Technical Guidance: Provide financial assistance, technical guidance, and phased implementation to help SMEs comply with QCOs and Compulsory Registration Orders (CROs). This support will help small firms upgrade manufacturing processes, acquire new equipment, and adhere to stringent standards.

Sector-Specific Support: In industries like footwear, where 80% of shoe-making units are small-scale operations, provide support to meet QCO requirements. These small units may find it difficult to meet the strict QCO requirements and could face shutdowns if they can't comply. Even if they are exempt from QCO application, large brands won't buy from them unless they meet the requirements.

IV. Quality Infrastructure Development

India's national quality infrastructure includes standardization led by BIS, conformity assessment through third-party inspections and certifications, and accreditation coordinated by the Quality Council of India (QCI).

Create elaborate quality infrastructure to develop expertise, conformity assessment systems, market surveillance systems and handholding of firms.

Enhance credibility of conformity assessment programmes including of third party inspections, product certification, management systems certification, personnel certification, testing and calibration, self-declaration of conformity etc.

V. Avoid QCOs becoming Non-Tariff Barriers

Ensure standards and technical regulations do not act as non-tariff barriers. Many countries use the mandatory certification to check imports. China often uses this process to delay grant of permission for imports from specific countries. In India, for example, factory inspections are an integral part of the regulatory framework for implementing CROs. BIS conducts factory inspections, but the timelines and processes vary based on priority and available resources. Foreign firms have often raised complaints about delayed registrations.

VI. Regulatory Impact Assessments

Conduct regulatory impact assessments, risk assessments, and reviews of regulations to ensure they are effective and do not impose unnecessary burdens.

VII. Develop Globally Acceptable Standards

Develop high-quality, globally acceptable standards and regulations for products like Ayurveda product and procedures.

Work towards making ISI Mark, Agmark, FSSAI Mark, Silk Mark, and Star labelling for energy efficiency globally acceptable by matching them with leading global certification programs.

VIII. Sign MRAs with Trading Partners

Sign Mutual Recognition Agreements (MRAs) with important trading partners. MRAs will help make domestic laws acceptable to countries with different regulations, facilitating smoother international trade. For example, an MRA between India and the European Union in medicines would allow EU drug inspectors to accept inspection reports prepared in India using standard procedures, and vice versa.

Implementing these recommendations will improve quality systems in India, reduce the burden on small firms, and enhance the global competitiveness of Indian industries.

5. Basics

I. Understanding standards, QCOs, CROs

India issues many type of standards, regulations, and orders to ensure product quality, and safety. These include voluntary and mandatory standards, technical regulations, Quality Control Orders (QCOs), and Compulsory Registration Orders (CROs).

Standards can be voluntary or mandatory. Most standards issued by BIS are voluntary, and not legally binding. Manufacturers choose to follow them for various reasons like consumer trust, market access, or internal quality control. Examples: Energy Star certification for appliances, and ISO 9001 standards for quality management.

Globally most voluntary standards are developed by private organizations such as the International Organization for Standardization (ISO) or the International Electro-technical Commission (IEC).

Mandatory standards are established by government bodies and are legally binding. Failure to comply can result in penalties. These standards are crucial for ensuring public health, safety, and fair trade practices. Examples include safety standards for children's toys and food safety regulations. Mandatory standards are implemented through publication of detailed technical regulations for a product.

QCOs are a subset of mandatory standards with a specific focus on detailed quality benchmarks set by BIS. Compliance with QCOs is mandatory, and non-compliant products can be seized or banned from sale. QCOs cover a wide range of products, including electrical appliances, laboratory glassware, steel products, and textiles. Conformity assessment procedures, such as testing, inspection, certification, and

auditing, determine whether a product meets the requirements specified in relevant QCOs.

QCOs are implemented by BIS through Grant of License and/or Certificate of Conformity. With the notification of QCO, manufacturing, storing and sale of non-BIS certified products are prohibited. The violation may attract up to 2 years of imprisonment or fine of at least Rs. 2 lakh.

CROs are essentially QCO with additional requirement for pre-registration of a firm with a government agency. These orders typically complement QCOs by adding an additional layer of verification. Examples include the Drugs and Cosmetics Act, which mandates the registration of pharmaceuticals and cosmetics with the Central Drugs Standard Control Organization (CDSCO).

If a product falls under the QCO/CRO category, it must meet the corresponding Indian Standards listed in the QCO. It will also need to carry the Standard Mark under a BIS license, according to the BIS Conformity Assessment Regulations, 2018.

Technical regulations are also often developed by international bodies and adopted into national law by governments to facilitate international trade. These regulations promote the harmonization of product specifications, thereby reducing technical barriers to trade. Examples include regulations for radio frequency emissions from electronic devices.

For easy understanding, think of voluntary standards as industry best practices, following them is recommended but not forced. Mandatory standards and QCOs are like traffic laws, everyone must comply to ensure safety and order. Technical regulations are like international agreements on road signs which create a common language for smooth cross-border trade.

II. Need for Standards and technical regulations

Standards and technical regulations reduce information asymmetries, signal quality to consumers and create a common language for potential trading partners, thus

reducing overall transactions costs. Adopting high product, process and services standards is a must for achieving higher exports, checking substandard imports and ensuring quality goods for domestic consumers.

III. WTO and Standards

The World Trade Organization (WTO) works to ensure that standards and technical regulations do not create unnecessary obstacles to trade. They have agreements like the Technical Barriers to Trade (TBT) Agreement, which promotes transparency, non-discrimination, and the use of international standards. This helps member countries implement regulations for health, safety, and environmental protection while minimizing the impact on trade.

IV. Overview of QCOs issued by major economies

United States: The US primarily uses regulatory standards set by agencies such as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Consumer Product Safety Commission (CPSC). These agencies collectively issue numerous regulations and orders covering a wide range of products.

European Union: The EU follows the New Approach Directives, which set out essential requirements for safety and health for various products. Compliance with these directives often requires adherence to harmonized standards developed by organizations like CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization). Similar to the U.S., the EU does not consolidate QCOs into a single metric, but issues numerous directives and regulations.

Japan: Japan has a well-established quality control system managed by organizations such as the Japanese Industrial Standards (JIS) and the Pharmaceuticals and Medical Devices Agency (PMDA). The country issues numerous QCOs across various industries, particularly in electronics, automotive, and healthcare sectors.

South Korea: South Korea's Korean Agency for Technology and Standards (KATS) is responsible for issuing QCOs. The country emphasizes stringent quality controls, especially in electronics and consumer goods, reflecting its high-tech industrial base.

China: China has rapidly increased its issuance of QCOs, particularly in recent years. The Chinese government, through bodies like the State Administration for Market Regulation (SAMR), has issued numerous QCOs to enhance product quality and safety, especially in the wake of international trade concerns and domestic safety scandals.

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GTRI aims to create high-quality and jargon-free outputs for governments and industry on issues related to trade, technology and investment from the perspective of development and poverty reduction.

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FEEDBACK

Your feedback on this report is most welcome. Please write to ajay@gtri.co.in



**GTRI Report
31-05-2024**

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