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Decoding QCOs: Do We Need a Rethink?

Rajeev Kher and **Anil Jauhri**

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Abstract: India's expanding use of Quality Control Orders (QCOs) under the BIS Act is projected as a consumer safety measure but increasingly functions as a non-tariff trade barrier. The current framework centralises regulatory and certification authority within BIS, lacks mandatory Regulatory Impact Assessment, and disproportionately burdens MSMEs while offering limited global credibility due to weak international accreditation. Without structural reform, QCOs risk undermining competitiveness rather than safeguarding quality. This paper proposes global best-practice benchmarks such as institutional separation of roles, risk-based conformity assessment, and third-party accreditation to transition QCOs from protectionist instruments to credible regulatory tools.

Keywords: QCOs, BIS Act, Technical Regulation, MSME compliance, Conformity Assessment, Accreditation

1. Introduction

Standardisation, though rooted in the very fabric of nature- from biological symmetry to structured language, has taken on a critical new role in modern governance. While ancient societies inherently relied on uniformity, it is only in recent decades that standards, certification, and regulation have become formal tools for managing risk, enabling trade, and protecting public interest.

It is now a globally accepted practice to regulate products and services with implications for health, safety, and the environment. India has followed this trend, initially focusing on vital sectors such as pharmaceuticals and food through laws like the *Drugs and Cosmetics Act, 1940*[1] and the *Prevention of Food Adulteration Act (PFA), 1954.*[2] The PFA remained the cornerstone of food safety regulation in India until it was subsumed by the *Food Safety and Standards Act (FSSA), 2006,*[3] which sought to unify and modernise various fragmented laws under a single

regulatory framework. However, rapid industrialization, technological advancement, and rising trade volumes have created an urgent need to expand regulatory coverage across a broader range of products as risks to health and safety increased - including toys, medical devices, electronics, chemicals, textiles, and construction materials.

In a trade environment increasingly shaped by standards and other non-tariff measures, India's domestic framework will play a decisive role not only in protecting consumers but also in enhancing export competitiveness, negotiating power, and long-term industrial resilience.

The World Trade Organization's Agreement on Technical Barriers to Trade (TBT)[4] provides an international framework for such regulations, allowing member countries to impose technical standards on legitimate grounds like health, safety, environmental protection, and prevention of deceptive practices. In India, this regulatory mandate is now primarily exercised through the Bureau of Indian Standards (BIS) Act, 2016,[5] which expanded the scope for issuing Quality Control Orders (QCOs).

- Under Section 16 of the 2016 Act, the government can mandate compulsory standards for goods, systems, and services on broader grounds including national security and unfair trade practices,[6] and authorise BIS or other accredited bodies to enforce compliance.[7]

- Previously, the BIS Act of 1986 enabled the central government under Section 14 to mandate conformity to Indian Standards for articles or processes in scheduled industries, requiring the use of the Standard Mark under license[8]

This expanded mandate has led to an exponential rise in the issuance of QCOs, with over 800 product categories now subject to compulsory regulation.[9] This growth is not merely an outcome of consumer protection objectives, but stems primarily from the government's realisation around 2017 of India's regulatory deficits in technical regulations (TRs), especially when compared to major trading partners. While the drive to close critical gaps is welcome, it also raises key policy questions:

- Are QCOs being designed and implemented proportionately?
- Are they unduly burdening domestic manufacturers, especially MSMEs?
- Do they align with India's international trade commitments under the WTO-TBT framework?
- This paper investigates these questions by tracing the evolution of India's technical regulation regime, assessing the current BIS-led model of QCOs, and exploring policy reforms to balance regulatory objectives with economic competitiveness and global integration.

2. India's Regulatory Evolution

A suitable legislative instrument is indispensable for any government to effectively regulate products. In the Indian context, this typically takes the form of a statute. While comprehensive laws exist for sectors such as food and pharmaceuticals- most notably the *Drugs and Cosmetics Act, 1940*[1] and the *Food Safety and Standards Act, 2006,*[3] there remains a conspicuous absence of comparable legislation for a wide spectrum of industrial and consumer products.

This legislative gap underscores the need for a sector-agnostic, overarching legal framework that empowers the central government to regulate products beyond those already covered under specific Acts. The Indian Constitution places "standards of weights and measures" and "goods" under the Union List,[10] thereby granting the Central Government the requisite authority to regulate products. However, this clarity does not extend to services, many of which- such as healthcare- fall within the jurisdiction of State Governments.

Historically, the government has grappled with the absence of a unified legal mechanism to regulate many classes of products. For example, medical devices continue to be regulated under the *Drugs and Cosmetics Act*, not because they were originally intended to be, but due to the lack of a dedicated law. Similarly, the regulation of gas cylinders has relied on the *Explosives Act, 1884*, often involving the Bureau of Indian Standards (BIS) or its predecessor, the Indian Standards Institution

(ISI). The *Essential Commodities Act, 1955* was also used to bring items such as steel tubes (in 1978) and cement (in the early 1980s) under regulatory oversight.[11]

Recognizing these limitations, the government introduced the Bureau of Indian Standards Act, 1986, which for the first time included an explicit provision- Section 14- to enable the regulation of products and processes:

> *"If the Central Government, after consulting the Bureau, is of the opinion that it is necessary or expedient so to do, in the public interest, it may, by order published in the Official Gazette- (a) notify any article or process of any scheduled industry which shall conform to the Indian Standard; and (b) direct the use of the Standard Mark under a licence as compulsory on such article or process.*[8] *"*
>
> *(Explanation: The term "scheduled industry" is as defined under the industries (Development and Regulation) Act, 1951.)*

This formulation, however, placed an implicit limitation on the scope of regulation by confining it to "scheduled industries" as defined under the industries (Development and Regulation) Act, 1951. As a result, several product categories-such as toys, which posed significant safety concerns - remained outside the purview of mandatory regulation despite posing public interest risks. This limitation became one of the key justifications for overhauling the regulatory framework in the 2016 amendment, which addressed these concerns more expansively. Notably, Section 25 of the 2016 BIS Act[12] further strengthens the government's power to issue directions, thereby overcoming the restrictions imposed by the older language of Section 14 and current language of Section-16.[5]

Although it could be debated whether the BIS Act was the most appropriate instrument-or whether such regulatory provisions should have been housed under the Consumer Protection Act, 1986, which was enacted in the same year, or even in a separate, standalone Act altogether - Section 14 filled a crucial vacuum in India's regulatory architecture. In the absence of this provision, the government might have faced the

impractical task of enacting separate legislations for every product category.

The BIS Act was subsequently revised in 2016, significantly expanding the scope of regulatory powers under Section 16, which states:

> *"(1) If the Central Government is of the opinion that it is necessary or expedient so to do in the public interest or for the protection of human, animal or plant health, safety of the environment, or prevention of unfair trade practices, or national security, it may, after consulting the Bureau, by an order published in the Official Gazette, notify (a) goods or article of any scheduled industry, process, system or service; or (b) essential requirements to which such goods, article, process, system or service, which shall conform to a standard and direct the use of the Standard Mark under a license or certificate of conformity as compulsory on such goods, article, process, system or service.[6]"*
>
> *Explanation.- For the purpose of this sub-Section,- (i) the expression "scheduled industry" shall have the meaning assigned to it in the Industries (Development and Regulation) Act, 1951; (ii) it is hereby clarified that essential requirements are requirements, expressed in terms of the parameters to be achieved or requirements of standard in technical terms that effectively ensure that any goods, article, process, system or service meet the objective of health, safety and environment. (2) The Central Government may, by an order authorise Bureau or any other agency having necessary accreditation or recognition and valid approval to certify and enforce conformity to the relevant standard or prescribed essential requirements under sub-Section (1)*

In addition to Section 16, the 2016 BIS Act also introduced Section 25, which empowers the Central Government to issue overarching directions to the Bureau to ensure effective implementation of the Act.

This provision further strengthens the government's capacity to steer standardisation and conformity assessment policies.

> Section 25: power of Central Government. to issue directions-*"(1) Without prejudice to the foregoing provisions of this Act, the Bureau shall, in the exercise of its powers or the performance of its functions under this Act, be bound by such directions on questions of policy as the Central Government may give in writing to it from time to time: Provided that the Bureau shall, as far as practicable, be given an opportunity to express its views before any direction is given under this sub-Section. (2) The decision of the Central Government whether a question is one of policy or not shall be final. (3) The Central Government may take such other action as may be necessary for the promotion, monitoring and management of quality of goods, articles, processes, systems and services and to protect the interests of consumers and various other stakeholders and notify any other goods, articles, processes, systems and services for the purpose of sub-Section (1) of Section 16.[12]"*

This provision also allows the government to delegate certification and enforcement powers to BIS or any accredited third-party agency, marking a significant policy shift from the 1986 framework. Complementary provisions under Section 17 establish legal prohibitions against manufacturing, selling, or claiming conformity to standards without valid certification or licenses.[13]

> *Section: 17. (1) No person shall manufacture, import, distribute, sell, hire, lease, store or exhibit for sale any such goods, article, process, system or service under sub-Section (1) of Section 16: (a) without a Standard Mark, except under a valid license; or (b) notwithstanding that he has been granted a license, apply a Standard Mark, unless such goods, article, process, system or service conforms to the relevant standard or prescribed essential requirements. (2) No person shall make a public claim, through advertisements, sales promotion leaflets,*

price lists or the like, that his goods, article, process, system or service conforms to an Indian standard or make such a declaration on the goods or article, without having a valid certificate of conformity or licence from the Bureau or any other authority approved by the Central Government under sub-Section (2) of Section 16. (3) No person shall use or apply or purport to use or apply in any manner, in the manufacture, distribution, sale, hire, lease or exhibit or offer for sale of any goods, article, process, system or service, or in the title of any patent or in any trade mark or design, a Standard Mark or any colourable imitation thereof, except under a valid licence from the Bureau.[13]"

The 2016 amendments, particularly Sections 16 and 25, thus represent a transition from a limited, industry-specific approach to a broader, more holistic regulatory regime-one that is aligned with global practices and capable of addressing public interest objectives across a much wider range of products and services.

3. Rise of QCO's in India

India's journey with mandatory product certification through Quality Control Orders (QCOs) though predates even the enactment of the BIS Act, 1986. Some of the earliest regulations involving the Indian Standards Institution (ISI), the predecessor of BIS, concerned LPG cylinders, steel tubes, and cement. These were issued under other laws such as the *Explosives Act,* and the *Essential Commodities Act, 1955*.

Following the enactment of the Bureau of Indian Standards Act, 1986, products began to be formally notified for mandatory compliance through regulatory instruments. However, even prior to the BIS Act, mandatory certification existed under other laws-for instance, steel tubes were brought under regulation through an order under the Essential Commodities Act in 1978, and cement followed in the early 1980s. While the BIS Act itself uses the term "order," the naming convention adopted in several early post-BIS notifications, such as the Oil Pressure

Stoves (Quality Control) Order, 1987, led to the widespread use of the expression "QCOs" to describe these instruments.

Throughout the late 1980s and into the early 2000s, the government continued to issue QCOs sporadically- initially covering items such as electrical appliances. However, a significant policy shift occurred around 2017, when it became evident that India faced a systemic regulatory gap across sectors that are widely regulated in other economies. Domains such as medical devices (only partially regulated at the time), telecom equipment, chemicals, textiles, and machinery had remained largely outside the purview of mandatory technical regulation in India.

This had two major consequences:

- First, it exposed Indian consumers to unsafe, substandard, or non-compliant products in the absence of legal safeguards.
- Second, it opened the Indian market to unregulated imports, adversely impacting domestic manufacturers who were expected to upgrade their quality under conditions of unfair competition. Indian producers could also continue to circulate low-quality goods in the domestic market without facing compliance pressure.

Ideally, the push for expanding the scope of technical regulations should have been led by the Department of Consumer Affairs, particularly since BIS falls under its administrative control and already had an enabling legislation in the form of the BIS Act. However, the actual momentum came from the Department of Commerce, driven by strategic trade and market access concerns.

The Department of Commerce recognised that:

- India's lack of domestic regulations weakened its negotiating position in bilateral and multilateral trade talks- since trading partners faced no technical barriers entering the Indian market, they had little incentive to address India's regulatory challenges abroad.
- In the context of Free Trade Agreements (FTAs), even when India reduced tariffs, its exporters derived limited benefit, as Indian goods

continued to face stringent technical regulations and SPS (sanitary and phytosanitary) measures in other countries, while foreign goods entered India with minimal compliance requirements.

- QCOs could serve as a non-tariff trade tool to help manage the growing trade deficit.
- Adoption of domestic technical regulations aligned with international standards could prepare Indian products to access advanced markets generating greater value for producers from their exports.

This strategic realisation triggered a concerted effort to identify and regulate critical product sectors using the BIS Act- then and now, one of the few cross-sector instruments available for technical regulation. As a result, the country has witnessed a surge in QCOs across diverse industries. As of 2025, over 800 product categories are under compulsory BIS certification through QCOs, with the list continuously updated on the BIS website.[14]

4. Why QCOs Matter: Are Regulations Necessary?

The preceding Sections make it evident that technical regulations are not optional- they are a core responsibility of the state. Governments across the world are expected to protect their citisens from unsafe, substandard, or deceptive products, and India is no exception. The need for regulation must be rooted in public welfare, as well as in broader objectives such as environmental protection, fair trade practices, and national security.

However, while the justification for regulation is sound, the method and process of implementation are equally critical. Regulatory frameworks should be designed in consultation with industry stakeholders, especially regarding the technical feasibility of compliance and the timeframes required for adaptation. In sectors where standards evolve rapidly or the compliance burden is high, the government should also consider providing technical and financial assistance, particularly to micro, small, and medium enterprises (MSMEs).

It is also important to highlight a major institutional gap in India's current regulatory rollout. While the Ministry of Skill Development

and Entrepreneurship (MSDE) has built a vast skilling ecosystem, the implementation of technical regulations has not been aligned with sector-specific skill planning. Recent regulations affecting sectors such as medical devices, pharmaceuticals (GMP upgradation), toys, and machinery have been introduced without engaging the relevant Sector Skill Councils. As a result, industries are being asked to meet new compliance benchmarks without parallel development of a qualified workforce-leading to systemic friction and delayed adaptation.

This gap is further compounded by the fact that regulators themselves cannot-and should not-take on the responsibility of manpower development, as this may create a conflict of interest with their core function of oversight and enforcement. Instead, the skill ecosystem is ideally placed to address this critical need. However, there is currently no structured mechanism through which industry, especially MSMEs, can reliably access competent manpower for implementing regulatory standards. Bridging this disconnect is essential for ensuring that compliance is not only mandated but also practically achievable across the value chain.

This reveals a deeper lack of coordinated action across ministries, where regulatory mandates are being executed in isolation, rather than as part of a synchronised industrial and governance strategy. For QCOs to be truly effective, India's approach must combine regulatory intent with institutional preparedness and stakeholder participation.

4.1 Standards and QCOs in the larger scheme of India's economic growth

While product regulation is often viewed through the lens of consumer protection or trade policy, its economic benefits are equally significant. Standards improve the intrinsic and perceived value of goods, foster market trust, reduce transaction costs, and enable access to domestic and international markets. Products that comply with recognised standards-whether for safety, performance, or sustainability-often command higher

prices, face less regulatory friction, and enjoy broader market access.

A compelling domestic example is the Indian toy industry. Prior to 2020, the market was flooded with low-cost, substandard imports. The introduction of QCOs under the BIS Act mandated safety standards for all toys, including imports. Initially met with resistance, these standards which are based on international standards have since helped compliant Indian manufacturers gain access to large retail chains and e-commerce platforms, which now insist on BIS certification. This has improved product credibility, curbed unsafe imports, and enabled MSMEs to scale operations for formal markets[17].

Similarly, India's gold hallmarking system, made mandatory in phases starting 2021, led to increased consumer confidence in purity, helped formalise a fragmented industry, and positioned hallmarked jewellery as a benchmark of fair trade and authenticity in quality-sensitive markets such as the UAE and Singapore[18].

On the global front, the non-acceptance of Indian certification for tyres by Ecuador-despite technical compliance with international standards- faced rejection due to BIS certification lacking ISO/IEC 17065 accreditation-highlighting how absence of international recognition imposes tangible economic costs[19].

Internationally, the ISO[20] and OECD[21] have found that standardisation contributes between 0.3% and 1.0% of GDP growth annually in advanced economies by improving productivity, enabling interoperability, and fostering innovation. In India, sectors like pharmaceuticals (WHO-GMP) and food processing (HACCP) have shown significant export growth after adopting such standards[22] further validating the economic case for quality compliance.

As India moves toward its *Viksit Bharat* vision, standardisation must be seen not just as a regulatory necessity, but as an instrument of value creation, industrial upgrading, and global competitiveness. A quality-conscious economy builds not just safer products, but also stronger markets.

5. Problems in India's approach

While the intent behind India's Quality Control Orders (QCOs) is sound, their current implementation reveals several systemic and structural challenges. These problems not only weaken the efficacy of the regulatory regime but also risk undermining India's broader industrial, trade, and MSME competitiveness goals. Followings are the problems in India's approach:

5.1 Absence of Regulatory Impact Assessment (RIA)

While India's move toward a stronger regulatory framework is well-intentioned, it suffers from a critical procedural gap: the absence of a Regulatory Impact Assessment (RIA) mechanism. Globally, RIAs are considered a best-practice tool to ensure that regulations are justified, balanced, and do not impose disproportionate burden on stakeholders. The European Union, for instance, mandates RIAs before adopting any technical regulation. These assessments help governments evaluate the likely economic, operational, and social impacts of a proposed regulation, identify viable alternatives, and ensure that the overall benefits outweigh the compliance costs.

India currently lacks an institutionalised framework for RIAs across ministries and regulators. As a result, Quality Control Orders (QCOs) and other technical regulations are often issued without structured cost–benefit analysis, stakeholder consultation, or implementation feasibility assessments. This can lead to regulatory overreach, duplication, or inefficient resource allocation, especially affecting MSMEs and sectors with limited technical readiness.

The OECD's guidance on RIAs offers a robust model that India can adapt to its context. However, equipping every ministry or regulator to independently conduct RIAs may not be feasible in the short term. A more practical approach would be for the Government of India to designate or establish a central technical body, with domain expertise and institutional independence, to provide RIA services on demand. This agency could

support ministries and regulators in designing smarter, evidence-backed regulations.

India's current **over-reliance on the Bureau of Indian Standards (BIS)** - essentially a voluntary standardisation body as per the global model- as the hub for issuing QCOs also highlights the lack of regulatory institutional differentiation. In most developed economies, regulatory functions are clearly separated from National Standards Bodies (NSBs), which operate primarily in a consultative and support capacity. By contrast, India's model of using BIS as both the certifier and de facto regulator resembles practices in least-developed and low-capacity countries in parts of South Asia, Africa, and the Middle East.

This model requires an urgent rethinking. A more future-ready approach would involve either:

- Creating a dedicated legal instrument empowering ministries to issue technical regulations under a common legal framework (e.g., via amendments to the IDR Act or Consumer Protection Act), or
- Establishing a **National Authority for Technical Regulations**, similar to South Africa's National Regulator for Compulsory Specifications (NRCS), which was set up in 2008 with a comparable mandate separating it from the national standard body.

5.2 BIS as Both Regulator and Certifier

A critical structural flaw in India's current regulatory approach lies in the dual role assigned to the Bureau of Indian Standards (BIS) under the Quality Control Order (QCO) regime. As per existing provisions, BIS is empowered not only to issue conformity certificates but also to enforce compliance and conduct market surveillance. This consolidation of roles within a single entity is increasingly being questioned in international trade forums and negotiations.

The WTO TBT (Technical Barriers to Trade) Guidelines on Conformity Assessment Procedures, issued in March 2024, clearly recommend the separation of regulatory oversight from conformity

assessment functions. The rationale is simple: combining standard-setting, certification, and enforcement creates a concentration of authority that risks undermining impartiality, due process, and stakeholder trust. Most developed regulatory systems maintain institutional separation between the regulator and the certifier to ensure objectivity, prevent conflicts of interest, and uphold transparency in enforcement.

Indeed, India has recognised the global practice and importance of separation and documented its intent in the Indian National Strategy for Standardization (INSS)[15] issued by the Department of Commerce in 2018.

India's current model stands in contrast to this best practice. Under QCOs, BIS functions as:

- The standard setter (through Indian Standards),
- The certifying authority (through its licensing and inspection schemes), and
- The enforcement agency, including powers to conduct factory raids search and audits, impose penalties, and seize non-conforming goods.

This accumulation of authority raises legitimate concerns in global trade circles, especially in the context of mutual recognition, WTO compliance, and fair competition. For example, a foreign manufacturer seeking BIS certification may perceive the lack of institutional independence as a barrier to market entry, and rightly so under WTO norms.

Moreover, India's market surveillance architecture remains underdeveloped. Surveillance functions across regulators and sectors are inconsistent, underfunded, and lack the professional capacity found in mature regulatory regimes. Given this unsatisfactory baseline, assigning such surveillance responsibilities solely to BIS- an agency already overstretched with certification duties- risks both ineffective enforcement and undue procedural power.

A modern regulatory ecosystem should follow the principle of institutional decoupling, where:

- The regulator sets the rules,
- Accredited third parties assess compliance, and
- Market surveillance is normally the responsibility of the regulator, while conformity assessment should be kept independent. In India's federal setup, this role could also be undertaken by state authorities or a coordinated network. Alternatively, the government may explore a dedicated body for market surveillance to ensure objectivity and consistency.

India must therefore revisit the BIS-centric model and adopt a structure that aligns with WTO norms, OECD recommendations, and global best practices, ensuring transparency, accountability, and trust- both domestically and in international trade.

5.3 Disproportionate Compliance Burden on MSMEs

While QCOs aim to raise product quality and consumer safety, the implementation model adopted under the BIS Act-especially Scheme I (Type-4 certification)-has imposed significant compliance burdens on Indian manufacturers, particularly micro, small, and medium enterprises (MSMEs). Originally developed in the 1950s as a voluntary certification scheme, this model involves factory inspections and product sampling, which should be distinguished from market surveillance (MS), a regulatory function. While it has helped build quality culture in Indian industry over time, its mandatory imposition under QCOs has had unintended consequences.

The requirement for in-house laboratories, embedded in BIS certification from its inception, is particularly problematic when extended to MSMEs under regulatory compulsion. Establishing and maintaining an in-house lab- including skilled personnel, calibrated equipment, consumables, and quality control systems- represents a fixed cost MSMEs can barely absorb. While some QCOs have diluted this requirement over time, it continues to feature prominently in many regulations and often results in industry pushback and requests for exemptions post-notification.

To address these challenges, alternatives such as external or third-party labs and common testing facilities in industrial clusters should be promoted. These models are more inclusive and cost-effective, particularly in sectors like toys, textiles, or light engineering where in-house testing infrastructure is not economically viable. Ministries issuing QCOs must factor this into regulatory design to avoid post-notification compliance distress. A visible movement in this direction has already been made.

Although BIS has, in recent years, introduced less burdensome conformity assessment procedures-such as product registration-these are not widely utilised. Scheme I continues to dominate QCO implementation, with little differentiation based on product risk. This uniform approach raises a legitimate question: should high-infrastructure commodities like cement or transformers be subject to the same compliance rigour as consumer-facing items intended for children or households? A more risk-calibrated framework could enhance regulatory efficiency without compromising safety

Another concern is the royalty-based pricing model embedded in the BIS framework. Under QCOs, manufacturers are required to pay usage fees for the ISI mark based on production output (e.g., per ton of steel or per bag of cement). This model, designed for voluntary certification to promote self-sustenance, becomes counterproductive when made mandatory- it directly increases production costs and undermines competitiveness, particularly when regulators in other sectors (e.g., FSSAI, CDSCO) or even globally do not follow such practices. In some cases, high compliance costs have led smaller players to exit manufacturing entirely or pivot toward lower-risk activities, such as contract bottling for multinationals.

Further, several QCOs have mandated compliance with entire BIS standards, including quality parameters that go beyond the core regulatory objectives of health, safety, and environmental protection. This results in overregulation and inflated costs. A more balanced approach would involve selectively notifying only the essential safety elements of a standard- allowing quality certifications to remain voluntary. For instance,

in the case of paints, the Ministry of Environment, Forest and Climate Change (MoEFCC) initially referenced BIS standards in draft notification but eventually limited regulation to a lead content cap (90 ppm), dropping broader BIS requirements in the final notification.

5.4 Overregulation of Raw Materials and Intermediates

A growing concern in India's regulatory landscape is the expansion of QCOs beyond final consumer goods to include raw materials, intermediate inputs, and components. While the principle that all products placed in the market should be safe is valid, in practice, the blanket regulation of upstream components has led to disruptions in domestic manufacturing and export-linked supply chains.

Many Indian industries depend on imported raw materials or intermediate components that are either not produced domestically or are not available at the required specifications and scale. When these inputs are brought under QCOs, importers are required to obtain BIS certification - often without access to BIS-recognised laboratories abroad or adequate domestic testing capacity. This creates delays, compliance uncertainty, and operational bottlenecks, even for firms that manufacture high-quality final goods. In some cases, when the volumes required in India are relatively small, foreign manufacturers may find the BIS compliance process too burdensome and opt out of the Indian market entirely - thereby disrupting critical supply chains and hurting domestic production.

A notable example is the air conditioner industry, which faced regulatory constraints following the notification of a QCO covering components such as hermetic compressors above 7000W (2TR). In response to industry concerns over disrupted production, the Department for Promotion of Industry and Internal Trade (DPIIT) was compelled to temporarily relax the QCO for certain components. This underscores the risk of regulating industrial inputs without adequately assessing downstream implications- a gap that could be addressed through Regulatory Impact Assessment (RIA).

In the absence of such assessments, the inclusion of inputs under mandatory certification can create cascading compliance burdens, delay time-to-market, and adversely impact India's export competitiveness. It also discourages the adoption of global supply chain integration practices, especially in sectors like electronics, chemicals, automotive, and industrial machinery.

To ensure a balanced and trade-compatible regulatory framework, India must prioritise the regulation of final products- where the consumer safety risk is most direct- and adopt a risk-based, tiered approach to regulating inputs. Regulatory instruments should clearly distinguish between:

- Consumer-facing goods, which merit stricter conformity protocols, and
- Industrial or intermediate components, where voluntary standards, supplier declarations, or import documentation may suffice-or a less burdensome form of conformity assessment procedure is used. In the European Union, for instance, Self-Declaration of Conformity (SDOC) is used to demonstrate compliance for an estimated 70% of products bearing the CE Mark, guided by the protocol laid out in ISO 17050. While adopting SDOC for final consumer products in India remains risky-given the weak enforcement and limited legal deterrence-it could serve as a pragmatic alternative for raw materials and intermediates, especially in supply chains dependent on rapid, flexible sourcing, given that user or consumer is more enlightened industry rather than common man.

Such an approach would not only reduce compliance friction but also align India's regulatory framework with global practices that emphasise proportionality, risk, and supply chain integrity.

5.5 Lack of Coordination with Sectoral Institutions

a) Need for technical manpower - A significant weakness in India's current approach to technical regulation is the absence of institutional coordination, particularly between regulatory authorities and the

country's extensive skill development ecosystem. While India has made substantial investments in workforce development- most notably through the Ministry of Skill Development and Entrepreneurship (MSDE) and its network of Sector Skill Councils (SSCs)- this capacity has not been leveraged in the rollout of Quality Control Orders (QCOs).

Recent regulatory mandates across sectors such as medical devices, pharmaceuticals (GMP compliance), toys, and industrial machinery have highlighted this gap. New QCOs and compliance requirements have been introduced without consulting or equipping Sector Skill Councils to develop relevant training programs or professional certification modules. As a result, industries are expected to meet complex technical standards and conformity assessment procedures without access to trained and/ or certified personnel, or even standardised compliance curricula and certified training providers.

This disconnect reveals a broader issue of limited inter-ministerial coordination between key institutions such as the Department for Promotion of Industry and Internal Trade (DPIIT), the Bureau of Indian Standards (BIS), the Ministry of Skill Development and Entrepreneurship (MSDE), the Ministry of MSMEs, and relevant line ministries. Each operates in functional silos, often leading to the issuance of regulations without adequate readiness on the ground-especially in MSME-dominated sectors.

b) Need for financial assistance - Notably, the Ministry of MSMEs remains largely disengaged from the regulatory transition, focusing its financial assistance on schemes like ZED, which have limited utility in helping enterprises upgrade to mandatory or internationally recognised technical standards. standards rather than support compliance to globally acceptable regulations and standards. A good example is the approach adopted by the UP Govt in its policy based on advice from the Department of Commerce[16]

For India to implement effective and scalable regulatory frameworks, technical regulations must be designed in tandem with institutional capability-building. This includes:

- Mapping skill gaps at the time of regulation drafting,
- Integrating Sector Skill Councils into the consultation and rollout process,
- And ensuring that workforce skilling keeps pace with evolving compliance requirements.
- Identifying sectors where small and micro industry may need financial assistance and providing for it

Without this alignment, even well-intentioned regulations risk becoming counterproductive, overburdening industry without improving actual compliance or safety outcomes.

5.6 Lack of Global Acceptance and Accreditation of BIS Certification

A recurring issue undermining the credibility and international utility of India's QCO regime is the lack of global acceptance of BIS-issued certifications and test results. While BIS laboratories are accredited and it recognises only accredited labs for most certification activities, in the case of gold hallmarking-a key export-relevant sector-BIS has opted not to mandate accreditation for assaying centres. This deviation from international practice, which typically relies on ISO/IEC 17025-accredited labs, has contributed to the hallmarking system being unacceptable in foreign markets.

This absence of accreditation not only isolates Indian conformity assessment systems from the international ecosystem but also prevents the conclusion of Mutual Recognition Agreements (MRAs) with key trading partners such as the United States, United Kingdom, and the European Union. Many countries-especially in the Gulf, Africa, and Latin America-explicitly require that product certifications be issued by accredited bodies. In the absence of accreditation for BIS certification under international norms such as ISO/IEC 17065, MRAs remain out of reach. Consequently, Indian exporters are often subjected to duplicative testing and certification abroad, even for products that already meet

international standards adopted by BIS and mandated under QCOs, such as gold jewellery, toys, and electrical goods.

Ironically, national standards bodies of several neighbouring countries-including Nepal, Bhutan, Bangladesh, and Sri Lanka-have secured accreditation for their certification activities, in some cases from India's own accreditation body. BIS's lack of such accreditation places it in a weaker position by comparison, diminishing its credibility internationally and further reducing prospects for recognition. In the absence of accreditation, BIS lost acceptance by Singapore for electrical and electronics products under India -Singapore FTA.

Furthermore, while India has competent accreditation bodies such as the National Accreditation Board for Certification Bodies (NABCB), National Accreditation Board for Testing and Calibration Laboratories (NABL) under the Quality Council of India (QCI) and now some home grown private accreditation bodies, all of which have secured the necessary international equivalences by signing mutual recognition arrangements for their international bodies IAF and ILAC respectively, BIS has not subjected itself to their accreditation processes especially for products where international standards have been adopted by BIS and prescribed in QCOs.

To address this, India must urgently take steps to get BIS conformity assessment systems accredited under internationally accepted schemes initially for certification against those standards which are adoption of ISO/IEC standards or those which are accepted by another country, say Bhutan which has adopted BIS standards for cement and steel. Only then can QCOs help Indian industry integrate more effectively into global value chains and ensure mutual regulatory trust with trading partners. It is a disservice to the industry, and the country, that where industry meets international standards, it still has to undergo duplicate testing/ certification for exports because BIS certification is unaccredited and unacceptable.

One of the most tangible consequences of BIS's non-accreditation is India's inability to pursue Mutual Recognition Agreements (MRAs) with

major trading partners. This credibility gap weakens India's negotiating power in trade forums and forces exporters to undergo duplicative certification processes abroad.

The Indian National Strategy for Standardization (INSS),[15] released in 2018, had already flagged many of the structural issues discussed here. It recommended the separation of regulatory and certification functions, promotion of third-party accredited certifiers, alignment with ISO/IEC 17065, and the adoption of risk-based conformity assessment methods such as SDoC. However, implementation has been partial, and many QCOs notified since then continue to centralise authority with BIS, contrary to INSS's roadmap for institutional reform and international alignment.

While seeking accreditation under ISO 17065 would enhance BIS's global acceptance, it also underscores a structural dilemma: should BIS continue as a certifier, or should its conformity assessment role be gradually separated, as recommended by WTO's TBT guidelines and India's own National Strategy for Standardization? Until such institutional decoupling is implemented, accreditation may be a practical necessity-but not a long-term substitute for reforming BIS's overlapping mandates.

5.7. Trade-Driven vs. Safety-Driven Regulation

Technical regulations, particularly those issued through Quality Control Orders (QCOs), are fundamentally intended to protect public interest- ensuring that products in the market are safe, reliable, and environmentally sound. Globally, such regulations are led by consumer protection authorities, as they directly impact public health and safety. However, in India, the recent proliferation of QCOs has not been primarily driven by consumer welfare concerns. Instead, it has been strategically led by the Department of Commerce, motivated by trade and market access considerations.

The shift began around 2017, when it became apparent that India lacked robust technical regulation across sectors like telecom, chemicals,

textiles, medical devices, and machinery. Rather than emerging from a coordinated public safety agenda, the push for regulation was shaped by three trade-related objectives:

- Strengthening India's position in bilateral and multilateral trade negotiations, where lack of reciprocal regulation weakened its leverage.
- Containing the trade deficit by limiting low-quality imports.
- Offsetting asymmetries in Free Trade Agreements (FTAs), where India reduced tariffs but gained little due to regulatory barriers faced by Indian exports abroad.

While these motivations are strategically valid, they risk distorting the original purpose of QCOs, turning them from instruments of public protection into defensive trade tools. This inversion of purpose can have unintended consequences:

- Overregulation or poorly designed QCOs may hurt domestic producers more than importers.
- Regulatory burdens imposed without proper technical or skilling support can backfire on Indian MSMEs.
- The credibility of India's regulatory framework may suffer if partners perceive QCOs as non-tariff barriers rather than genuine consumer protection measures.

Moreover, the Department of Consumer Affairs, under whose administrative control BIS operates, has played a secondary role in this process- despite being institutionally and legislatively better positioned to lead the legitimate public interest dimension of technical regulation.

To ensure long-term credibility and effectiveness, India must rebalance its QCO regime to reflect its original purpose. Technical regulations should be based on risk assessments, consumer safety data, and transparent consultation, not trade strategy, alone. Only then can India align its domestic regulatory framework with global norms and secure both public trust and international recognition.

6. Global Practice and Lessons

As India expands its use of technical regulations through Quality Control Orders (QCOs), it is important to evaluate whether its institutional model aligns with global best practices. International experience shows that effective regulatory systems are typically designed around separation of roles, risk-based approaches, and evidence-based policy tools such as Regulatory Impact Assessments (RIA). In contrast, India's current model- centered around the Bureau of Indian Standards (BIS)- shares more features with regulatory frameworks in developing or capacity-constrained economies than with those of advanced industrial nations.

6.1. Institutional Design in Developed Economies

In most developed countries, there is a clear separation between regulatory functions and the work of national standards bodies (NSBs). NSBs are often independent, industry-led private organisations, and their primary role is to develop and maintain voluntary standards, often aligned with international norms such as those set by the International Organisation for Standardization (ISO) and the International Electrotechnical Commission (IEC). These bodies are not involved in enforcement or conformity assessment.

For example, NSBs in the United States, United Kingdom, and European Union function as voluntary standards organisations, supporting regulators but not acting as de facto regulators themselves as BIS has become. Technical regulations in these jurisdictions are typically notified through laws or sector-specific regulatory agencies, and rely on a mix of public and private conformity assessment bodies, many of which are internationally accredited.

6.2 Developing Country Models: Similarities to India

In contrast, many developing and less developed countries continue to rely on their NSBs to also function as regulatory bodies- a model that India has even inspired and currently follows. This is commonly seen in SAARC nations, the Middle East, and parts of Africa, where regulatory

capacity is limited outside the NSB system. In such settings, the NSB is tasked with not only standard development but also certification, enforcement, and sometimes even market surveillance.

While this integrated model may be administratively convenient in the short term, it poses risks related to conflicts of interest, over-centralisation of authority, and lack of flexibility in regulatory design. Moreover, it is often unsuitable for fast-evolving, innovation-driven sectors or for economies aiming to participate in global value chains.

6.3 The South African Example: A Dedicated Regulator

A noteworthy alternative is the model adopted by South Africa, which in 2008 established a dedicated National Regulator for Compulsory Specifications (NRCS) separating this activity from its national standards body which was earlier vested with this function. This regulator is legally empowered to notify technical regulations and oversee their enforcement. The NRCS model illustrates how emerging economies can evolve toward institutional separation while ensuring regulatory coherence and public interest protections.

6.4 Gaps in International Recognition and MRAs

In addition to institutional separation and regulatory coherence, international credibility of conformity assessment systems is a key benchmark for successful regulatory regimes. Most developed countries not only maintain clear boundaries between standard-setting, certification, and enforcement, but also ensure that their conformity assessment bodies are internationally accredited, enabling seamless participation in Mutual Recognition Agreements (MRAs). These MRAs allow certified products to enter foreign markets without duplicative testing or inspection, thereby lowering costs and improving time-to-market.

In contrast, India's conformity assessment system- anchored by BIS- remains outside major international accreditation frameworks, such as those recognised by the International Accreditation Forum (IAF). As a result, Indian certificates often fail to gain acceptance abroad, even

when products meet the same technical requirements as per international standards.

The experience of South Africa's National Regulator for Compulsory Specifications (NRCS) remains particularly instructive. South Africa not only separated its national regulator from its standards body, but also embedded it within internationally recognised accreditation and conformity assessment networks. The NRCS's alignment with ISO/IEC and IAF frameworks has significantly enhanced the global acceptability of South African regulatory certifications. While comprehensive public assessments of its performance are limited, the NRCS model offers useful insights for India's institutional reform, particularly in demonstrating how role separation and accreditation can work in practice without overburdening a single agency.

6.5 Implications and Lessons for India

India's reliance on BIS as the central agency for standardisation, certification, and regulation does not reflect the country's growing technical capabilities or economic ambition. As India positions itself for developed economy status under the "*Viksit Bharat*" vision, it must move toward a modern regulatory architecture based on:

- Legal separation of roles (standard-setting vs. regulation vs. conformity assessment)
- Accreditation-based recognition of third-party certifiers and labs.
- Proportionality and risk-based regulation
- A national legal instrument enabling line ministries to notify regulations within a common framework

Two possible options include:

- **Amending existing Acts** (such as the Industrial Development and Regulation Act or the Consumer Protection Act) to empower line ministries to notify technical regulations under a harmonised system, or

- **Enacting a new law** to establish a national technical regulator with authority to notify and enforce mandatory requirements across sectors, without encroaching on domain-specific regulators.

Such reforms would bring India's regulatory ecosystem closer in line with international best practices, improve trade compatibility, and reduce compliance burdens without compromising safety or public interest objectives.

7. Recommendations

India's growing reliance on Quality Control Orders (QCOs) for regulating products is a necessary step toward consumer safety, quality assurance, and global competitiveness. However, the current approach suffers from several operational rigidities and structural limitations that hinder effective implementation and disproportionately burden domestic industry, particularly micro, small, and medium enterprises (MSMEs). To improve the credibility, efficiency, and fairness of India's regulatory regime, a set of procedural and institutional reforms is urgently required.

7.1. Create a dedicated legal framework for technical regulations

Amend the IDR Act or Consumer Protection Act, or enact a new law to empower ministries to notify and enforce regulations. South Africa's NRCS model offers an example, but its long-term effectiveness should be evaluated before adoption.

7.2. Ensure institutional separation between regulator and certifier

BIS currently acts as the standard-setter, certifier, and enforcer. This conflicts with WTO TBT principles. India should move towards separating regulatory, standardisation, and conformity roles, enhancing transparency and trust.

7.3. Integrate Sector Skill Councils into regulatory planning

Technical regulations have been rolled out without equipping SSCs to prepare the required workforce. The government must map skill gaps during regulation drafting and partner with SSCs to build training modules and certify compliance professionals**.**

7.4. Adopt a risk-based, flexible conformity assessment model

The current reliance on Scheme I (Type-4 certification) imposes significant compliance costs on all manufacturers, regardless of product risk. A differentiated approach should be adopted, with simpler procedures such as third-party testing, registration schemes, or self-declaration of conformity.

7.5. Relax mandatory in-house laboratory requirements

BIS's insistence on in-house lab facilities as part of certification is burdensome for MSMEs. Allowing the use of external accredited labs and creating common testing infrastructure in clusters would reduce cost and widen access.

7.6. Reassess the BIS royalty model

BIS currently charges royalties based on production volumes. This model is regressive under mandatory regimes. A transparent fixed-fee structure, similar to FSSAI or CDSCO, would ease industry burden and align with international norms.

7.7. Avoid regulating raw materials and intermediates unnecessarily

QCOs on inputs like compressors have disrupted production. Unless essential, inputs should be exempted, or brought under simplified procedures like supplier declarations. RIAs must be conducted to assess downstream implications.

7.8. Limit the scope of mandatory BIS standards

Not all clauses in a BIS standard need regulatory backing. Only those dealing with safety, environment, or health risks should be notified.

Other parameters should remain voluntary. The MoEFCC's approach to lead content in paints offers a good precedent.

7.9. Promote voluntary certification as a preparatory step

In sectors not yet ready for QCOs, voluntary schemes like AYUSH Premium, IndG.A.P., and BEE's phased labelling can build capacity. This staged approach prevents disruption while improving quality.

7.10. Use public procurement to drive quality standards

Government platforms like GeM and CGHS can mandate compliance with Indian or international standards, encouraging industry to improve quality through market incentives.

7.11. Allocate a dedicated budget for regulatory preparedness

There is no line-item funding for standardisation or industry upgradation. The government should create budget heads for:

- Supporting industry to meet international requirements
- MSME compliance assistance
- India's participation in global standard-setting bodies like ISO, IEC, and CODEX.

8. Conclusions

This discussion paper has attempted a comprehensive examination of India's evolving technical regulation framework, with particular focus on the Quality Control Orders (QCOs). These regulatory instruments, while rooted in legitimate public interest objectives, have drawn increasing scrutiny- both from domestic stakeholders and international observers- due to their design, implementation, and trade implications.

It must be acknowledged that technical regulations are not only legitimate but essential tools of governance. Ensuring the health, safety, and welfare of citizens is a sovereign responsibility, and product regulation is central to fulfilling that mandate. However, India's historical underperformance in this domain has resulted in regulatory gaps that are now being addressed in a rapid and often uncoordinated manner.

The concern is not with the intent to regulate, but with how the regulatory regime is being constructed- often without sufficient risk assessment, institutional separation, or alignment with global norms. QCOs, in their current form, risk being perceived as trade tools rather than public welfare instruments. Without reform, they may impose undue burdens on industry, particularly MSMEs, and limit India's global competitiveness, even as they strive to elevate domestic standards.

Going forward, India must rethink its approach: not by weakening its regulatory commitments, but by making them more proportionate, transparent, internationally credible, and industry-inclusive. The challenge lies in balancing consumer protection with industrial growth and global trade engagement. This is especially critical as India aspires to become a developed economy under the vision of *Viksit Bharat*- a goal that requires a regulatory ecosystem rooted not just in authority, but also in accountability, capacity, and strategic foresight.

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