

India's ambitious quality regulation: Why it's the time to act for India Inc



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The landscape of industrial manufacturing and import in India is quietly being transformed. At the centre of this shift is the Bureau of Indian Standards (BIS), which is India's national standards body tasked with formulating Indian Standards and overseeing quality compliance across sectors. BIS certification is typically voluntary; although the Government of India is increasingly adopting a more interventionist approach to legally mandate compliance and thereby sub-serve the consumers.

With objective of securing public health, safety, environmental protection, and more recently in Trump's world-as a strategic non-tariff barrier, a growing number of Indian Standards are being made mandatory through issuance of Quality Control Orders (QCOs) by different line ministries in Government of India.

Once a product is brought under the purview of a QCO, it cannot be manufactured, imported, stored, or consumed in India, unless it bears the BIS Standard Mark and the manufacturer holds a valid licence. The consequences of non-compliance with BIS are far from trivial. Goods manufactured or imported in violation of QCOs may be seized, and businesses could face penalties up to ten times the value of the goods, or even imprisonment for up to two years.

As can be imagined, this fundamentally reshapes how businesses approach product development, sourcing, supply chain and compliance. Manufacturers and foreign suppliers may in certain situations be forced to alter product design, composition, or even quality attributes to align the products with applicable Indian Standards. For importers and OEMs,

sourcing decisions may need to factor in BIS compliance, potentially requiring a shift to certified suppliers or requalification of existing ones. As a result, QCOs impact several functions across the value chain of an organization, ranging from R&D to procurement.

In the last two years, the number of QCOs has expanded significantly from around 115 in 2023 to over 185 by 2025. However, none of these QCOs have as far-reaching an impact as the Machinery and Electrical Equipment Safety (Omnibus Technical Regulation) Order, 2024 (OTR), a sweeping and omnibus regulation introduced by the Ministry of Heavy Industries.

Issued in January 2024, the OTR covers over 400 products across 20 categories of machinery and electrical equipment, including cranes, pumps, compressors, transformers, machine tools, textile machinery, packaging equipment, etc. More importantly, unlike many earlier QCOs, the OTR goes beyond finished goods and also covers assemblies, sub-assemblies, and components, thereby drawing entire supply chains into its compliance net. The OTR is expected to significantly impact industries such as industrial machinery, electrical equipment, packaging, textiles and other industries involved in manufacturing, importing, or assembling regulated products and components.

The regulation references nearly 90 Indian Standards, divided in three levels (Types A, B, and C), addressing product-specific benchmarks, safety principles, and general design rules. The expansive coverage of OTR makes it one of the most significant quality mandates ever issued in India.

Originally scheduled to take effect from August 2025, the OTR's implementation timeline was recently extended to 1 September 2026. However, businesses would be ill-advised to treat this extension as downtime. The compliance process is elaborate and time consuming, not to mention the various complexities surrounding applicability and procedural requirements. Companies will need to evaluate applicability across their product portfolios, prepare technical documentation, initiate conformity assessments where needed, and coordinate with suppliers, particularly in cases involving imports. Given the OTR's scale and intended footprint, early preparation is not just prudent; it is an imperative.

Until recently, there was uncertainty around several procedural aspects of the OTR. This prevented industry players in taking effective steps for OTR preparedness. Key questions loomed around documentation formats, factory inspection requirements, application protocols, and the compliance pathway for foreign manufacturers. Most of these issues now stand clarified with the release of the Guidelines for grant of certification under Scheme-X for OTR on 14 July 2025.

These Guidelines provide much needed clarity on several operational aspects. As per the Guidelines applications are to be filed in Form I, accompanied by a technical file that must contain comprehensive documentation, including product specifications, risk analyses, compliance declarations, test reports, process flowcharts, traceability systems, and more. The assessment of application will begin with a desk audit to review the completeness of the application including the Product Compliance Report. The assessment mechanism includes a physical audit at the manufacturing site to verify infrastructure, quality systems,

traceability mechanisms, and alignment with submitted documentation. Process for foreign manufacturers has been spelt out, which requires them to appoint Indian Authorized Representative (IAR) and submit additional documents, including financial guarantees, as is the case in respect of other QCOs.

The Guidelines are a milestone in operationalising the OTR. Many of the initial procedural ambiguities have now been addressed. Product-specific guidelines and grouping logic are awaited for several categories, though BIS has initiated this process by issuing guidelines for metal cutting machines, indicating that similar guidelines for other product categories will follow. All guidelines, once issued, will enable companies to submit fully complete applications. Nevertheless, the current OTR Guidelines provide sufficient clarity for businesses to begin their preparatory work in a meaningful way.

It cannot be emphasized enough that businesses will have to treat OTR compliance with priority and importance. Accordingly, businesses must begin mapping their SKUs against OTR's scope, studying applicable Indian Standards, and initiating collation of technical documentation. Relevantly, the BIS portal has opened pre-registration for manufacturers and foreign suppliers, which is an important first step toward obtaining licences.

Specifically, the companies importing goods need to make sure that their overseas suppliers, including group entities are aware about the OTR, its implication, and are taking necessary steps wherever compliance with BIS is warranted, as certification of foreign suppliers involve many nuances and longer lead time.

In conclusion, the OTR is not just another regulation, it is a pivotal shift in India's quality compliance regime that will reshape the operational landscape for manufacturers and importers. The time extension by reason of deferment of its implementation should be wisely used to prepare. As has been said, it is better to sweat in peace than bleed in war!

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