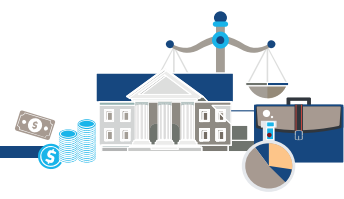


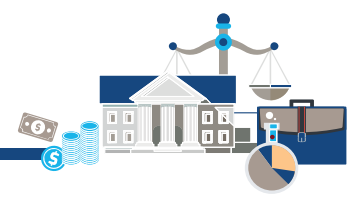
# OTR Implementation: Detailed Certification Guidelines

This is to apprise you regarding the key developments under the Machinery and Electrical Equipment Safety (Omnibus Technical Regulation) Order, 2024 ('OTR'), and Machinery and Electrical Equipment Safety (Omnibus Technical Regulation) Order, 2024, dated June 12, 2025 ('OTR Amendment Order'). The Bureau of Indian Standards (BIS) has issued operational guidelines on 14 July 2025 for grant of certification under the OTR. This alert provides a summary of the key processes and documentation framework outlined in the guidelines.

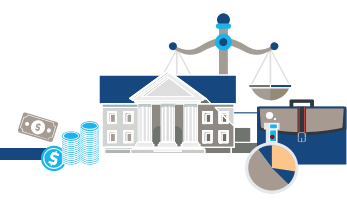
Subject	Particulars
Background	<ul style="list-style-type: none"> <li>The OTR aims to regulate a broad class of machinery and electrical equipment from a safety and conformity standpoint. While the OTR has been deferred till 1 September 2026, the lack of procedural clarity left industry stakeholders unsure about how to operationalize compliance.</li> <li>Key aspects such as the required contents of the technical file, the manner of scrutiny (e.g., desk audit vs. site audit), the specific formats and supporting documentation were not prescribed. As a result, companies were unable to effectively initiate internal readiness or begin the application process in a structured manner.</li> <li>The BIS has now issued detailed <b>"Guidelines for grant of certification under Scheme-X for OTR regulation"</b> on <b>14 July 2025</b>. These guidelines bring much-needed clarity to the procedural framework under the OTR and lay down the steps for certification under the <b>Scheme-X</b>.</li> </ul>
Key highlights of the guidelines	<p><b>Types of certifications:</b></p> <ul style="list-style-type: none"> <li>The guidelines provide for two types of certifications under Scheme-X: <ul style="list-style-type: none"> <li>Licence to use the Standard Mark having a validity duration</li> <li>Certificate of Conformity (CoC) for a specific lots, batches, or prototypes</li> </ul> </li> </ul>



Subject	Particulars
	<p><b>Application and certification grant process</b></p> <ul style="list-style-type: none"> <li>• The application is to be submitted in Form-I, along with the Technical File and other supporting documents</li> <li>• Certification is granted upon successful assessment, subject to the applicant demonstrating that: <ul style="list-style-type: none"> <li>– The product meets all applicable requirements of the relevant Indian Standard, and</li> <li>– All procedural and documentation requirements under Scheme-X are fulfilled</li> </ul> </li> <li>• BIS will form its decision on a review of the Technical File, desk audit findings, and site audit observations</li> </ul> <p><b>Assessment Mechanism</b></p> <p>The assessment process comprises two stages:</p> <p><u>Desk Audit</u></p> <ul style="list-style-type: none"> <li>• BIS will conduct a desk-based review of the application for completeness, including the Product Compliance Report</li> <li>• Any deficiencies or queries identified during this stage will be communicated to the applicant</li> <li>• The applicant must respond with clarifications or additional documents within 15 days of receipt of the query</li> </ul> <p><u>Site Audit</u></p> <ul style="list-style-type: none"> <li>• A physical audit will be conducted at the manufacturing site to verify infrastructure, quality systems, traceability mechanisms, and alignment with submitted documentation</li> <li>• The audit would be conducted over 4 man-days by a team of 2 auditors (a departure from other schemes, which generally involve a single auditor)</li> <li>• The Technical File will be critically evaluated for conformity with applicable safety and performance requirements</li> <li>• BIS will issue formal observations post-audit, which must be addressed by the applicant</li> <li>• Certification will be granted only if BIS is satisfied that the product conforms to the applicable Indian Standard and the manufacturing setup is capable of ensuring consistent conformity</li> </ul> <p><b>Technical File</b></p> <p>The Technical File forms the foundation of the certification process. It must include, at a minimum, the following:</p> <ul style="list-style-type: none"> <li>• Product specifications, engineering drawings, and photographs</li> </ul>



Subject	Particulars
	<ul style="list-style-type: none"> <li>• Risk assessment and validation of safety-critical features</li> <li>• Traceability mechanisms (batch/serial number systems)</li> <li>• Test reports (in-house or BIS-recognized/accredited labs)</li> <li>• Product Compliance Report, mapping each clause of the Indian Standard</li> <li>• Process flowchart, process map, and factory layout</li> <li>• Packaging details and marking/labelling information etc.</li> </ul> <p><b>Additional requirements for Foreign Manufacturers</b></p> <ul style="list-style-type: none"> <li>• Applications must be submitted in physical form (manual submission); online filing is not currently available</li> <li>• Appointment of an Authorized Indian Representative (AIR) is mandatory <ul style="list-style-type: none"> <li>– The guidelines specify eligibility criteria and responsibilities for AIRs</li> </ul> </li> <li>• The AIR is responsible for compliance liaison and post-certification obligations</li> <li>• All associated costs (e.g., inspection, travel, testing, audit logistics) must be borne by the applicant</li> </ul> <p><b>Fees and charges</b></p> <ul style="list-style-type: none"> <li>• Applicable fees and charges for application processing, audits, and related services have been specified in the guidelines</li> </ul>
<p><b>DHRUVA COMMENTS</b></p>	<p>The issuance of the guidelines marks a significant milestone in operationalizing the OTR regime. The guidelines provide a direction on the expected contents of the technical file, the structure and depth of factory assessments, submission protocols for foreign manufacturers, and the scope and conduct of on-site inspections.</p> <p>Product-specific guidelines and the final grouping logic are being progressively released, with guidelines for metal cutting machines issued on 17 July 2025. Once all product specific guidelines are issued, the companies will be in position to submit a fully complete application. That said, the guidelines still provide sufficient clarity for stakeholders to meaningfully initiate their preparatory efforts. Businesses should assess the applicability of the OTR to their product portfolio and begin compiling the necessary technical documentation to ensure they are well-positioned to submit applications as soon as the remaining details are published.</p>



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