



## Tax alert: BIS issues guidelines for certification under Scheme-X for OTR Regulation

**18 July 2025**

The Machinery and Electrical Equipment Safety (Omnibus Technical Regulation) Order, 2024 (OTR) is a regulatory framework introduced to mandate Bureau of Indian Standards (BIS) certification for a wide range of industrial machinery and electrical equipment. It was released on 28 August 2024 and is scheduled to come into effect from 1 September 2026.

In view of the same, the BIS has released detailed guidelines for the grant of such certification under Scheme-X for products covered under the OTR. These guidelines are applicable to both domestic and foreign manufacturers and are aimed at ensuring conformity to safety and technical standards.

### In a nutshell



Scheme-X certification is applicable to products under the OTR notified by the Central Government.



Two types of certifications are available:

- License to use Standard Mark (valid on a continuous basis)
- Certificate of Conformity (valid for specific prototype, lot, or batch)



Certification is granted based on a technical file and Product Compliance Report submitted by the manufacturer.



The process includes desk audits and site audits, with specific timelines and documentation requirements.



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On 14 July 2025, BIS released a comprehensive set of guidelines for the grant of certification under Scheme-X for both domestic and foreign manufacturers, applicable to products regulated under the OTR notified by the Central Government. These guidelines have been framed under the BIS Act, 2016 and the Conformity Assessment Regulations, 2018. The guidelines aim to streamline the certification process while ensuring product safety and compliance.

The guidelines emphasize risk assessment, hazard identification, and safety validation. They mandate compliance with relevant Indian Standards (IS), including IS 16819 and type A, B, and C standards, ensuring that certified products are safe for use.

## Certification Pathway

The guidelines outline two distinct certification options based on the nature and frequency of product manufacturing or import.

### Grant of Certification (GOC) to use Standard Mark

The Grant of Certification (GOC) for use of the Standard Mark (SM) is issued for **continuous manufacturing or frequent import clearance needs**. The license is valid for a duration of **three to six years** and **may be renewed** for the same period.

### Certificate of conformity (CoC)

The CoC is issued for **one-time** or limited production or import cases, including custom-built machinery or batch-specific products. The CoC is **valid only for the specific lot, batch, or prototype** mentioned in the application and is **not renewable**.

## Certification Process



- **Technical File Compilation:** Before directly making an application for the certification, the manufacturer must compile a comprehensive technical file. The said file shall include details such as:
  - Product description along with applicable specified standards
  - Design drawings and manufacturing process description
  - Identification details (brand name, trademark, batch/lot/serial number)
  - Product Compliance Report (PCR), which must include the following:
    - Risk assessment and reduction measures
    - Safety function diagrams
    - Safety validation reports

- Supporting documents for components (e.g., BIS certificate of component, original manufacturer's test certificate, lab reports)
- **Application Submission:** Application is required to be submitted in FORM I, as specified in Scheme X. Applicant, while filing this form, must indicate the type of certification sought (Standard Mark or Certificate of Conformity) and submit the technical file and supporting documents along with such application form.
- **Desk Audit:** Desk Audit is conducted by the Head of Branch Office (BO).
  - The purpose of the desk audit is to review completeness and appropriateness of submitted documentation.
  - Any shortfall or query at this stage is communicated to the applicant. Applicant must respond with compliance and confirm readiness for site audit.
  - Any shortfall or query identified during the desk audit evaluation will be communicated to the applicant, along with proposed site audit date(s) within 15 days, during which the applicant must respond with compliance and confirm readiness, upon which the assigned audit team will proceed with the site visit.
- **Site Audit:** Site audits are mandatory in all cases to support the evaluation of the PCR.
  - The purpose of site audit is as follows:
    - Verify details of the technical file;
    - Demonstration of the product functionality, including testing of trigger points for safeguarding mechanisms;
    - Assess manufacturing process; and
    - Include additional sites in site audits if final assembly or subcontracted operations occur outside the main factory.
  - Typically, site audits are conducted for four man days.
- **Evaluation and Decision:**
  - The evaluation and decision stage involve a comprehensive review of all audit findings and technical assessments.
  - Any inadequacies or non-conformities identified during the desk or site audit are formally communicated to the applicant in writing. The applicant's response is then examined for completeness and adequacy and assessed in consultation with the audit team.
  - Based on this review, the Head of the Branch Office decides whether further desk or site audits are required.
  - If the applicant's explanation is found to be unsatisfactory, the application is initiated for rejection.
  - If the product is found to be compliant, the certification is granted, and the applicant receives a formal communication detailing the certification number, validity period, and scope of certification.

## Process Fees

Type of Fees/ Charges	Statutory Fee (In INR)
Application Fee for Grant of License	₹2,000
Application Fee for Certificate of Conformity	₹2,000
Certification Fee for License Grant or Renewal	₹25,000 per year
Certification Fee for Certificate of Conformity	₹10,000 (Per certificate)
Technical File Review Fee (for license, certificate, or scope changes)	₹20,000 per technical file
Inspection Fees (Including Surveillance)	₹20,000 per man-day
Performance Bank Guarantee (In case of Foreign Manufacturers)	\$10,000/- (in USD)*
Sample Procurement Charges	Based on actual costs
Testing Charges	Based on actual costs
Factory Audit (Visa, Travel, Accommodation Support)	Based on actual costs

## Concluding Remarks:

- The OTR Order 2024 encompasses a wide range of products and is expected to significantly impact across industry. Originally scheduled for implementation on 25 August 2025, the effective date has now been deferred to 1 September 2026 due to operational challenges and initial ambiguities in the compliance framework.
- The recent guidance issued by the Central Marks Department (CMD) of the BIS has brought much-needed clarity regarding the application process, certification pathways, timelines and procedural aspect. It is evident that the certification process is comprehensive and time intensive.
- Given this, companies falling within the scope of the OTR are strongly advised to initiate the one-time registration process without delay, begin compiling their technical documentation, arrange for requisite test reports, and prepare for site audits. Early action will be critical for ensuring timely compliance and avoiding potential disruptions.



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