Bureau of Indian Standards

Fastener Certification in India (Part II) : Certification Compliance Assessment Procedures

印度市场紧固件认证(第二部分)：认证符合性评鉴程序

According to the Indian Quality Control Order (QCO), mandatory fastener products listed in Tables 1 and 2 must undergo product conformity assessment through the Bureau of Indian Standards (BIS) via the ISI mark certification process. This process includes several evaluation procedures— products must be tested by a third-party laboratory or tested in conjunction with a third-party laboratory at the manufacturing premises; on-site visits to assess the manufacturer's production premises, production processes, quality control, and testing capabilities of a manufacturer.

Applicants for ISI mark certification must first confirm the applicable standards for their products. They should complete Form-V from the BIS (Conformity Assessment) Regulations 2018, as well as a self-evaluation verification report for each standard, and submit these as part of their application. Forms and self-evaluation report formats can be obtained from the BIS official website for subsequent application processing.

1. Two Options for Applying for ISI Mark License:

Option 1

Ⓐ Applicants must submit the aforementioned forms to BIS to apply for an ISI mark license certificate.

Ⓑ If an applicant previously held an ISI mark license certificate for the same product at the same location and it was canceled, made expired or returned due to non-compliance, such applications will only be processed under Option 1 during this period. Refer to Annex XI of the BIS guideline document "Guidelines for Grant of Licence (GoL)."

Ⓒ Applicants' factory visit fees must be paid to evaluate their production infrastructure, processes, quality control, and testing capabilities, along with sampling for third-party laboratory testing.

Ⓓ If only factory product testing is considered for granting the ISI mark license certificate, samples may not be taken. Factory testing is permitted for products listed in Annex II(A) of the BIS guideline document "Guidelines for Grant of Licence (GoL)" (e.g., products that are large or difficult to transport). For new products requiring certification without third-party laboratories, granting ISI mark licenses may be considered based on factory testing.

E However, if a third-party laboratory obtains any product certification at an appropriate time, each certification can be decided by the head of the BIS regional office/branch office (Head, BO as Enforcement Officer of BO), processing applications under either Option 1 or Option 2 until the product transitions to Option 2.

F Products granted an ISI mark license certificate under Option 1 are limited to specific items listed in Annex II(B) of the BIS guideline document "Guidelines for Grant of Licence (GoL)." Additionally, all cases involving foreign manufacturers obtaining an ISI mark license certificate will be processed under the principles of Option 1.

Option 2

A Products eligible for an ISI mark license certificate should follow the principles outlined in Option 1 as listed in relevant BIS guideline documents.

(i) If there are no effective third-party laboratories available due to cancellation/suspension of accreditation or unimplemented revised standards for products listed in BIS guidelines, or if the third-party laboratory does not have inspection facilities/approval for specific different types of products, then decisions can be made by BO (responsible officer). In such cases, licenses may be granted based on Option 1 principles but must be documented with reasons.

(ii) If applicants previously held licenses for the same products at the same manufacturing site that were canceled due to non-compliance or expiry or return, such applications cannot be processed under Option 2 but only under Option 1. Refer to Option 1(B) and Annex XI of BIS guideline document "Guidelines for Grant of Licence (GoL)."

B Applicants may apply to BIS for an ISI mark license certificate along with application forms and samples of products produced by them and compliance test reports issued by third-party laboratories (if applicable). The received application must comply with conditions specified in Option 2(C) through (M).

C The applicant's factory visit fees must be paid to assess manufacturing infrastructure, processes, quality control, and testing capabilities while sampling for tests at a third-party laboratory. Testing reports from samples taken during factory visits will be used for review purposes.

D When operating under Option 2, applicants must first register themselves on IT software and will receive a unique code. This code must be submitted to third-party laboratories when submitting samples for testing (see (E)), along with obtaining a corresponding receipt. After sending samples to laboratories, this receipt should be uploaded onto IT software. Sample testing should adhere to valid product group guidelines issued by BIS covering various types within the scope of license certificate grants.

E Laboratory: Testing reports from the following laboratories should be accepted:

(i) Laboratories established, maintained, or accredited by BIS (including those designated as Group II laboratories under BIS laboratory accreditation schemes);

(ii) Government laboratories appointed by BIS;

(iii) Any other laboratory deemed appropriate by the BIS enforcement committee; testing reports must be current.

F **Testing reports must not exceed 90 days. The calculation period starts from the date of issue until received by BO. If multiple testing reports exist for a product, the latest report must not exceed 90 days while earlier reports must not exceed 180 days.**

G If BO determines that acceptance of designated period test reports is necessary based on valid reasons, such cases may require approval from DDGR (Deputy Director General of Region), with appropriate justification. DDGR may permit acceptance of test reports not submitted within deadlines if justified.

H Conformity of Raw Material

(i) If Indian raw material standards mentioned in Indian standards are merely references, evidence of raw material compliance should not be strictly required. The applicant is responsible for ensuring consistency in raw materials/components.

(ii) If ensuring raw material conformity is a mandatory requirement for certifying product standards, conformity can be confirmed as follows:

- The raw materials are ISI marked products;
- Any laboratory-issued test report complies with item (E);
- If A and B cannot be performed, then test certificates or reports from NABL accredited laboratories;
- If A and B cannot be conducted, then in-house factory test reports.

(iii) When submission of inspection reports is required to determine raw material consistency, applicants should submit these reports with their applications applicable under both options.

(iv) If any raw material test report is found missing during application processing, applicants will be advised to submit such reports. In cases under Option 1, these raw material samples can be collected during on-site inspections for testing at third-party laboratories.

I Submission of Partial Test Reports

(i) Applicants are responsible for ensuring completeness and compliance with relevant Indian standards regarding submitted test reports. If submitting partial test reports, applicants must provide reasons and justifications acceptable to BO. Based on the received justifications/reasons, remaining tests may proceed at the applicants' laboratory in accordance with procedures specified below under item (ii).

(ii) Remaining tests will take place during factory visits conducted by certifying officials but must comply with the following:

- The applicant's laboratory has full testing facilities capable of conducting remaining tests.
- Paying factory test fees.
- Sufficient materials from the same control unit submitted with test reports must remain available for further tests. If materials from that control unit are unavailable, sufficient materials from two new control units should be provided.

J For products requiring testing that takes 30 days (one month) or longer to obtain proof of compliance, evidence may be provided in the form of test reports from any laboratory, by the companies themselves (as mentioned in item (E)), or any testing agency. Annex X of the BIS guideline document "Guidelines for Grant of Licence (GoL)" should be applicable to such tests. **Applicants must also provide evidence that any laboratory specified in item (E) is conducting long-term tests and that the laboratory can issue a test report (TR) within the designated timeframe (as specified). This report must be submitted by the applicant to BIS.**

(i) These provisions also apply to factory tests. Certifying officials will witness completion during factory visits and review cases afterward.

(ii) If applicants are located in India, regulations regarding long-term internal/external laboratory test report submissions can have relaxed terms if:

- They are newly established and such tests last over six months; or
- They recently began producing that product and such tests last over 6 months. Appropriate evidence regarding establishment or commencement should be provided.

K The applicant must provide a written guarantee (refer to the on-site factory visit) that if samples taken by the certifying officer during the factory visit are found to be non-compliant after long-term testing or if the test report cannot be submitted immediately, but no later than 30 days from the date of confirmation of the test report by the laboratory, then the license certificate (if granted) shall be revoked.

L The applicant must guarantee in writing (refer to on-site factory visit) that if the samples obtained during the factory visit by the certifying officer do not meet the standard requirements, the license certificate (if approved) will be suspended.

M Consideration of pre-cancellations, expirations, or relinquishments of certificates should take into account the requirements outlined in Annex XI of the BIS announcement document "Guidelines for Grant of Licence (GoL)."

2. Foreign Manufacturers Certification

Foreign manufacturers with factories located outside India can apply under the Foreign Manufacturers Certification Scheme (FMCS). The FMCS differs from Indian manufacturers in the following ways:

(1) The applicant is required to submit two copies of the application form as per Option 1 and other necessary documents (currently, a paper copy is required).

(2) All foreign manufacturers are considered "large" enterprises under FMCS regulations.

(3) For foreign manufacturers (applicants and licensees), a nominated Authorized Indian Representative (AIR) must be designated. When nominating an AIR, it should be ensured that:

A The AIR must be a resident of India.

B The AIR represents only one manufacturing company and is not an AIR for other foreign manufacturers certified by BIS. However, this restriction does not apply if the foreign manufacturer belongs to the same corporate group and the importer (related to the foreign manufacturer) is designated as AIR.

C The AIR(s) must not have any conflicts of interest. Their actions should be akin to those in third-party laboratory sample testing, and their conduct and roles should not present any conflicts of interest.

D It is preferable that AIR(s) have at least qualification certification and understand the provisions of the BIS Act and its associated rules, regulations, and implications.

E AIR(s) must declare their agreement to comply with the terms and conditions stipulated in the BIS Act, rules, regulations, as well as BIS licenses, agreements, commitments, etc., signed by the foreign manufacturer or a representative authorized by them concerning license certificate applications.

F The name of the AIR must be noted in the license certificate.

(i) The applicant must confirm acceptance of inspection completeness and take necessary actions for officials, such as arranging tickets, issuing visas and insurance, and arranging transportation abroad for an early factory visit by certifying officials.

(ii) The manufacturing company is responsible for safely

delivering samples to laboratories and covering testing costs (if samples are sent to an external laboratory OSL, payment should be made directly to OSL; if sent to BIS Labs, payment should go to BIS accounts).

(iii) According to BIS (Conformity Assessment) Regulations 2018: After obtaining a license certificate, foreign manufacturers must immediately submit detailed information regarding goods marked with ISI labels (including details about Indian importers, distributors, resellers, retailers, final destinations, and expected dates of entry into Indian ports) online or via email to BIS.

(iv) Fees and charges

- **For countries outside the South Asian Association for Regional Cooperation (SAARC), all payments are made in equivalent US dollars. For SAARC countries, payments can be made in Indian Rupees or equivalent US dollars.**
- Per-diem charges for travel.
- Costs for factory visits: daily charges plus three days' expenses.
- Contingency funds: applicants pay for each license certificate (calculated based on the number of certificates).
- After granting a license certificate, signing agreements mentioned in the application forms regarding compensation guarantees and performance bank guarantees (PBG) is necessary. These guarantees must come from banks with RBI-approved branches in India, with a validity period extending six months beyond that of the certificate.

3. Initial Application for Certificate

If applying for a product certificate that has not been previously obtained, it will be processed according to option 1. If there is no third-party laboratory available, the case will be determined via approval from BO or factory testing as per Annex X of BIS announcement document "Guidelines for Grant of Licence (GoL)." In such cases, if a third-party laboratory is accredited at an appropriate time, BO may decide to further process applications under option 2 or option 1 procedures until products transition into option 2 procedures. Resources for third-party laboratory testing can be searched on the BIS website.

https://lims.bis.gov.in/home/search_is_number/

4. Factory Visit

Ⓐ For each certificate application, the factory visit duration is: one day for manufacturers within India; one day for foreign manufacturers. If additional days are needed, BO may decide.

Ⓑ If considering complete product testing at the factory to grant a license certificate, required working days can be assessed and approved by BO.

Ⓒ During a factory visit, activities should adhere to BIS (Conformity Assessment) Regulations 2018 provisions. Factory visits must have details recorded as referenced in Annex Form – VII of BIS Conformity Assessment Regulations 2018; under BIS authority, the following activities should be performed:

(i) Verification of documents submitted by the manufacturer;

(ii) Discuss whether control levels submitted by the manufacturer are appropriate, if applicable;

(iii) Verification of factory layout and operational control levels at various stages;

(iv) Verification of available infrastructure including manufacturing machinery, testing equipment, personnel capabilities (quality control, storage conditions, sanitation), if applicable;

(v) Verification of calibration status of testing equipment;

(vi) Factory testing and sampling sent to third-party laboratories, if applicable.

5. Factory Testing

Factory tests should be conducted where possible. All subjective requirements such as product processing status, visual characteristics, surface defects, product descriptions, smell and taste should be checked at the factory.

If applicants submit partial test reports, remaining requirements will undergo factory testing. Additional working days required for such tests will incur inspection fees if applicable.

For large products that cannot be fully submitted for third-party laboratory testing: size measurements and other tests (for steel plates, boards and pipes, etc.) should take place during factory testing.

If any non-compliance issues are observed during factory testing, samples will not be sent to third-party laboratories. Applicants may be advised on improvements which will require another factory check and testing to verify results at their expense. (The applicant is responsible for paying the additional costs for the factory visit.) Verification regarding raw materials' compliance with product standards will refer to raw material conformity requirements.

6. Labelling and Marking

After the review and confirmation of compliance with certification, the applicant being granted a certificate should:

Ⓐ Adhere to BIS Conformity Assessment Regulations 2018 and product standard requirements and use the label.

Ⓑ If specific product guidelines published by BIS permit it, labels beyond standard marks and certificate numbers can be shown on products or packaging in digital formats such as barcodes and QR codes. ■

Reference

1. "Guidelines for Grant of Licence (GoL)" released by BIS

2. BIS (Conformity Assessment) Regulations, 2018