<u>भारतीय मानक ब्यूरो</u> (केन्द्रीय मुहर विभाग - 1)

हमारा सन्दर्भः सीएमडी-1/2:17:4

विषय: भारतीय मानक ब्यूरो (अनुरूपता निर्धारण) विनियम, 2018 की अनुसूची-11 की अनुरूपता निर्धारण स्कीम-X के अंतर्गत लाइसेंस के विस्तार क्षेत्र में परिवर्तन एवं विशेष स्थितियों के दिशानिर्देश -हेतु।

उपर्युक्त विषय पर सक्षम प्राधिकारी द्वारा अनुमोदित दस्तावेज़ सभी संबंधित पक्षों के कार्यान्वयन के लिए सलंग्न है।

> (मोहित जनोहिया) वैज्ञ-'डी'/सीएमडी-I

<u>प्रमुख, सीएमडी-।</u>

उपमहानिदेशक (प्रमाणन एवं सीएसएम)

Bureau of Indian Standards

(Central Marks Department - I)

Our Ref: CMD-I/2:17:4

Subject: Guidelines for Change in Scope of Licence (CSoL) and special situations as per the conformity assessment Scheme-X of Schedule-II of the BIS (Conformity Assessment) Regulations, 2018 - reg.

The document on the above subject as approved by the Competent Authority is attached herewith for implementation by all concerned.

(Mohit Janoiya) Sc.D/CMD-I

<u>Head, CMD-I</u>

DDG (Certification & CSM)

परिचालित/circulated to:

सभी क्षेत्रीय कार्यालयों/ शाखा कार्यालयों All ROs/BOs

सभी उपमहानिदेशक (क्षेत्रीय) All DDGRs

अन्य सभी संबंधित पक्ष All other concerned

01 November 2024

01 नवम्बर 2024

BUREAU OF INDIAN STANDARDS (CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:17:4

01 November 2024

Subject: Guidelines for Change in Scope of Licence (CSoL) and special situations as per the conformity assessment Scheme – X of Schedule – II of the BIS (Conformity Assessment) Regulations, 2018

This document stipulates the guidelines for change in scope of licence (CSoL), its procedures and any special situations encountered during the operation of licence. These are to be read in conjunction with the BIS Act 2016 and Rules, Regulations framed thereunder. In particular, the provisions for CSoL are addressed in Regulation 9 and Paragraph 10 of Scheme - X of Schedule - II of the BIS (Conformity Assessment) Regulations, 2018, as amended from time to time. Any situation, in general, not covered in these guidelines are to be dealt as per the provisions of the Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs).

- Application
for CSoL1. An application for change in scope of licence shall be made as per Annexure-I
along with requisite fee and relevant documents.
- General Principles for
 2. The scope given in the schedule of licence covers types, sizes, grades, varieties for cSoL
 2. The scope given in the schedule of licence covers types, sizes, grades, varieties, etc. for which licence is granted by the Bureau to licensee to use standard mark for the product manufactured in accordance with relevant specified requirement(s) mentioned in the schedule of licence. The change in scope of licence shall be endorsed as per Annexure-II.
 - **3.** The provisions provided under grant of licence guidelines and all remaining relevant procedures regarding technical file(s)/ product compliance report(s)/ undertakings/ inspection visit / raw material etc. are to be followed (unless otherwise specified to deviate here in this document).
- Change of scope (with or without inspection visit)
 4. (i) If the application for change in scope of licence is accompanied with the technical file covering all aspects, including compliance report of product having complete test report issued by third party laboratory(ies), then based on desk assessment of the technical file the case may be processed for change in scope of licence.

(ii) In-principally, as far as feasible, the manufacturer shall submit product compliance report in the form of test report(s) issued by third party laboratory(ies), especially for the products where third party laboratory(ies) are available.

(iii) In the event of submission of partial technical file (including compliance report of product), the BO may seek clarification from the manufacturer and take decision for further processing based on reply from the manufacturer. The manufacturer shall furnish remaining details of the technical file (including compliance report of product).

(iv) In the event of submission of product compliance report having test report(s) issued by laboratory(ies) other than third party laboratory(ies), the applicable parameters can be witnessed through an inspection visit. The applicant may request for witnessing of these applicable tests by the certification officer during inspection visit, subject to:

(a) Facilitating witnessing of applicable tests in the factory premises or any other site including sub-contracted test facilities

- (b) Payment of inspection fee for the visit
- (c) Availability of sufficient material for carrying out the applicable tests
- Inspection
 5. Depending upon the product category and/or feasibility about the number of mandays required for witnessing the applicable test(s), the Head (BO) may decide to depute the certification officer(s) for inspection visit. The Head (BO) shall also decide the number of mandays required for inspection visit taking into account nature, complexity of product and time required to witness the test(s).
- Deficiencies
 6. (i) In case of any deficiencies observed in the application for change in scope of licence, the same shall be communicated to the manufacturer for providing information within 21 days. This communication shall include that in case reply is not received within 21 days or reply received is incomplete, the same shall be treated as rejection notice (Template enclosed as *Annexure-III*).

(ii) The decision on rejection shall be taken based on the merit of the case.

(iii) In case, the application for change in scope of licence is rejected, the same shall be communicated to the manufacturer. (Template enclosed as *Annexure-IV*)

Reduction in scope of licence	 7. (i) If at any time, there is reason to reduce the scope of licence, a notice month shall be issued to the manufacturer. (Template enclosed as <i>Annexi</i> (ii) The change in scope of licence shall be informed (Template enclosed as <i>Annexi</i> (iii) The change in scope of licence shall be informed (Template enclosed as <i>Annexi</i> (iii) The change in scope of licence shall be informed (Template enclosed as <i>Annex</i>). 		
		<i>Annexure-VI</i>) and endorsed as per <i>Annexure-II</i>.(iii) The competent authority shall pass speaking orders for the decision taken.	
Special situations	8.	For any special situation arising during the operation of licence with regard to change of name, management, ownership etc., appropriate details with requisite documents as required at the time of grant of licence shall be collected. Such changes shall be duly endorsed in the licence. For guidance, following templates are enclosed (i) Change in name of licensee; <i>Annexure-VII</i> (ii) Change in specified requirement(s); <i>Annexure-VIII</i>	
Fees	9.	The fees for review of technical file for change in scope of licence is rupees twenty thousand per technical file. The fees for inspection, for any site as applicable, is rupees twenty thousand per manday. For latest fees structure, amount and applicable concession, see the notifications available on BIS website under following path: https://www.bis.gov.in/ >> Conformity Assessment >> Scheme-X Certification	
Product specific guidelines	10.	In addition to this document, any product specific guidelines issued by CMDs shall be followed.	

Annexure-I

Application for change in scope of licence

Head Branch Office Bureau of Indian Standards

Changes in seems desired.

Dear Sir/Madam,

n

2. Change in scope	desired:		
Product	Specified requirements	Whether, extension or reduction	Technical file enclosed (Yes or No)

3. I/We have made the payment of ₹ vide receipt No. dated towards the above application.

Signature Date Name Designation For and on behalf of

Seal of Firm

Note : Attach separate sheet, if required

Annexure-II

Attachment to licence no.

Name of the licensee with the factory address	Name of the product	Specified requirements

Endorsement no. Dated

The following change in scope of licence has (have) been approved by the Bureau with effect from

Consequent upon the above changes, the revised scope of licence in Column (2) of the table in Schedule of the licence for the product set out in Column (1) of the Schedule is amended as follows:

Other conditions of the licence remain the same.

Annexure-III

Our Ref: BO/CML-

Dated:

Subject: Providing information towards deficiencies in application - cum - Rejection notice of application for change in scope of licence - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

2. We regret to inform you that it has not been found possible to further process your change in scope of licence application because of the following:

(BO to give the reasons in this space, including deficiencies observed in the application)

3. In view of the above, you are requested to submit the requisite information with necessary documents within 21 days. Further, if no reply is received within 21 days or the information received is incomplete, please treat this as a rejection notice towards your application for change in scope.

4. In case you have anything to say in the matter or you would like to be heard either in person or through a representative authorised by you in this behalf, kindly do so within 21 days of issue of this letter-cum-notice. In case, no reply is received from your end within the stipulated period, your application for change in scope shall be rejected without any further notice to you.

Annexure-IV

Our Ref: BO/CML-

Date:

Subject : Rejection letter of application for change in scope of licence - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. granted to you for use of Standard Mark on your product under Scheme-X of Schedule-II of the BIS (Conformity Assessment) Regulations, 2018 valid upto

2. Kindly refer to our rejection notice Ref: dated In this notice you had been informed of our intention to reject your application for change in scope of licence.

3. Your reply to our rejection notice was due by, but we have not received any reply from you till date.

(or)

The reply received with your letter Ref: dated has not been found satisfactory due to following reasons:

(Reference to reply from manufacturer, its examination and consideration. Also, if any personal hearing is held, reference to the same needs to be indicated)

4. It has, therefore, been decided that the case relating to your above mentioned application for change in scope of licence be rejected. You may apply afresh with requisite fee as per our procedure.

5. If you are aggrieved by the above order, you may prefer an appeal to the Director General, Bureau of Indian Standards within ninety days from the date of the order with a fee of two thousand rupees as per provisions of section 34 of the BIS Act 2016 read along with Rule 37 of the BIS Rules 2018.

Annexure - V

Our Ref: BO/CML-

Date:

Subject : Notice for reduction in scope of licence - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. granted to you for use of Standard Mark on your product under Scheme-X of Schedule-II of the BIS (Conformity Assessment) Regulations, 2018 valid upto

2. It is proposed to reduce the scope of your licence from present scope of due to the following :

(BO to mention reasons)

3. In case you have anything to say in the matter or you would like to be heard either in person or through a representative authorised by you in this behalf, kindly do so within 30 days of issue of this notice.

Annexure-VI

Our Ref: BO/CML-

Date:

Subject : Reduction in scope of licence - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. granted to you for use of Standard Mark on your product under Scheme-X of Schedule-II of the BIS (Conformity Assessment) Regulations, 2018 valid upto

2. Kindly refer to our reduction in scope of licence notice Ref: dated dated been informed of our intention to reduce the scope of licence for the following reasons.

(Reference to reply from manufacturer, its examination and consideration. Also, if any personal hearing is held, reference to the same needs to be indicated)

3. The revised endorsement for the reduction in scope of licence is enclosed herewith this letter.

4. If you are aggrieved by the above order, you may prefer an appeal to the Director General, Bureau of Indian Standards within ninety days from the date of the order with a fee of two thousand rupees as per provisions of section 34 of the BIS Act 2016 read along with Rule 37 of the BIS Rules 2018.

Annexure - VII

Attachment to Licence No. CM/L-

CM/L-	Name of the Licensee with the Factory Address	Name of the Product	Specified requirements

Endorsement No. Dated

Other terms and conditions of the licence remain the same.

Annexure - VIII

Attachment to Licence No. CM/L-

CM/L-	Name of the Licensee with the Factory Address	Name of the Product	Specified requirements

Endorsement No. Dated

Consequent upon the revision/amendment of specified requirements, the scope of licence specified in the schedule of the licence stands revised as under with effect from

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Other terms and conditions of the licence remain the same.