

REGISTRATION DEPARTMENT

Our Ref: Registration/Guidelines RG: 02

Date 20 08 2019

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

These guidelines stipulate the procedure for change in scope of licence (CSoL) and any special situations encountered during the operation of licence. These are to be read in conjunction with BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018. In particular, the provision for CSoL are addressed in Regulation 9 and Paragraph 10 of Scheme - II of Schedule - II of BIS (Conformity Assessment) Regulations, 2018. Any situation, in general, not covered in these guidelines are to be dealt as per the provisions of Act, Rules and Regulations. All the forms mentioned herein correspond to those given in Scheme - II of Schedule - II of BIS (Conformity Assessment) Regulations, 2018. All the forms mentioned herein correspond to those given in Scheme - II of Schedule - II of BIS (Conformity Assessment) Regulations, 2018.

General Principles for CSoL	1.1	Licence is granted by the Bureau to the manufacturing unit for the name, address, brand(s) and model(s) as per the declarations made. Declarations also include management composition, contact details of manufacturer and name, address and contact details of Authorized Indian Representative etc. These declarations form the basis of scope of Registration. The Grant of Licence (GoL) letter mentions the name, address, product name, Indian Standard, brand(s) and model(s) as declared. Manufacturer may wish to change the scope of the licence with respect to the varieties covered (inclusion/withdrawal) or management composition or name/address/contact details of manufacturer/authorized Indian representative or change in Authorized representative or brand(s).
	1.2	Inclusion of model(s) is granted by the Bureau based on submission of relevant Test Report(s) conforming to the relevant Indian Standard(s) alongwith an Undertaking (as per Form-II) by the manufacturer/Authorized Indian Representative through the online application.
	1.2	Withdrawal of model(s) is done automatically by portal as per online withdrawal request from manufacturer.
	1.3	Reduction in scope of the licence with respect to the model(s)/series covered can be done by the Bureau in case non-conformity of the product is observed or if licence for particular model(s)/series is granted in error and the said licence contain other model(s)/series.
	1.4	Change the scope of the licence with respect to management composition or name/address/contact details of manufacturer/authorized Indian representative or change in

		Authorized representative is to be applied online by the manufacturer as and when such changes occur.
	1.5	The change in scope of licence is to be communicated by the Bureau through portal/email/letter as the case may be.
<i>Application for CSoL</i>	2.1	An application for change in scope of licence with respect to the varieties covered (inclusion/withdrawal) is to be made online along with relevant documents. CSoL shall be communicated online as per format given at Form-IX A and changes will be reflected on portal.
	2.2	An application for change in scope of licence with regard to change of name, address, management, ownership, AIR (Authorized Indian Representative) etc. shall be made online. Relevant documents as required at the time of grant of licence shall also be submitted. Such changes shall be communicated as per format given at Form-IX B.
<i>Laboratory</i>	3.	<p>a) Test reports of the following laboratories shall be accepted:-</p> <ul style="list-style-type: none"> i) Laboratories established, maintained or recognized by the Bureau for the product (including Group-2 labs as specified under the Laboratory Recognition Scheme of the Bureau); ii) Government laboratories empaneled by the Bureau; iii) Any other laboratories as decided by the Executive committee of the Bureau.
<i>Test reports shall be the latest</i>		b) The test reports of the product shall not be more than 90 days old. The period for counting 90 days shall be from the date of issue of the test reports to the date of receipt of the online application.
<i>Supplementary Test Report</i>		<p>c) In case of supplementary test report(s) issued for brand addition with reference to original test report which are already received and accepted by BIS, date of issue of supplementary test report shall be considered instead of date of issue of referred original test report. However, the supplementary test report shall be submitted within 90 days of issue.</p> <p>d) Similarly, in case of supplementary test report(s) issued for addition of series model(s) in the same series as per series guidelines issued from notifying ministry with reference to original test report which are already received and accepted by BIS, date of issue of supplementary test report shall be considered instead of date of issued referred original test report. However, the supplementary test report shall be submitted within 90 days of issue.</p> <p>It is the responsibility of the applicant to ensure that the test reports submitted are complete in all respects and conforming to the relevant Indian Standard.</p>
<i>Test Report beyond 90 days</i>		e) If the Department/BO is of the opinion that the test report(s) to be considered for Grant of Licence need to be accepted beyond specified time norms due to genuine reasons, concerned DDG is empowered to do so, provided Department/BO provides adequate justification. DDG after due consideration of the facts

		may take a decision whether to allow acceptance of the test report(s) which are not within the time limits specified above.
Conformity of Raw Material/ Critical Components		<p>g) Where ensuring conformity of raw materials/critical components is a mandatory requirement of the product standard being considered for certification or if required by regulator, such conformity shall be established through following:-</p> <p>(I) In case Raw material/critical component is notified under QCO/CRO, raw material/critical components shall have BIS standard mark.</p> <p>(II) In case Raw material/critical component is not notified under QCO/ CRO,</p> <p>i) Test report from any laboratory as specified at 3 c) above;</p> <p>ii) In case i) above is not possible due to non-availability of Indian Standard or test facility, then test certificate as per IECEE CB/UL/VDE etc. or raw material manufacturers' test certificate.</p> <p>iii) In case i) and ii) above is not possible due to no national /international standards, conformity as reported by lab ('tested within appliance/equipment') can be accepted.</p> <p>Ensuring conformity of raw material/components shall rest with the applicant.</p>
Processing for Grant of inclusion of model(s)	4.	<p>a) Process of grant of Inclusion is expected to be completed within 10 working days provided all the documentation and conformity of the product is established satisfactory at first instance.</p> <p>b) In case of any deficiencies observed in the application for Grant of inclusion, the same shall be communicated to the applicant with a rejection notice of not less than 30 days to resolve that query.</p> <p>c) If the queries are resolved by the applicant within stipulated time, application to be processed for grant of inclusion.</p>
Processing for Reduction of scope	5.	<p>If licence for particular model(s)/series is granted in error or in case where non-conformity of the product is observed, the non-conforming model (or series, if it is part of a series) of the product will be cancelled through reduction of scope.</p> <p>If no other model(s)/series exists in the licence, then the licence is processed for cancellation in accordance to cancellation guidelines.</p> <p>Before cancelling through reduction of scope of licence, a notice of not less than thirty days shall be given to the licensee (template attached Indicative Annexure - I), providing opportunity for submitting their reply in writing.</p> <p>The decision of CA shall be communicated to the licensee (template of the letter attached as Indicative Annexure - II).</p> <p>MEITY will be informed about change in Scope of Licence with a request to draw early sample for surveillance.</p>

<i>Processing for CSol other than model inclusion</i>		Change the scope of the licence with respect to name/ management composition/ address/ contact details of manufacturer or change in Authorised representative would be processed based on the submission of relevant documents.
<i>Rejection of CSoL application</i>	6.	<p>a) The application may be processed for rejection as per the sub-regulation (6) of regulation 4 of BIS (Conformity Assessment) Regulations, 2018. It may include one or more of the situations mentioned below:-</p> <ul style="list-style-type: none"> i) The applicant has not been clearing the financial dues to the Bureau; ii) The applicant has tampered with documents or have submitted tampered documents in connection with the grant of the licence; iii) The applicant has indulged in unethical practices in the context of grant or operation of the licence; iv) Major deviation is observed in the declarations, or declarations are found to be false; v) Test report submitted is found to be non-conforming; vi) The applicant has failed to submit satisfactory reply/documents with respect to queries raised in rejection notice within stipulated time.
		<p>b) Before rejection of an application, applicant shall be given a reasonable opportunity of being heard either in person or through its representative if requested. In case the facts or the explanation furnished by the applicant or its representative is not satisfactory, the application shall be rejected. The closing of application shall be communicated to the applicant through portal/email/post.</p> <p>c) The competent authority shall pass speaking orders for decision taken.</p>
<i>Product specific guidelines</i>	7.	In addition to these guidelines, any product specific guidelines/instructions issued by BIS/notifying authority shall be followed, as applicable.
<i>Fee</i>	8.	Fee as notified in BIS (Conformity Assessment) Regulations, 2018 will be charged.
<i>Provision for appeal</i>	9.	<p>If manufacturer wishes to appeal to the Director General, Bureau of Indian Standards, he must do so 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.</p> <p>For the cases, in which manufacturer submits appeal to DG, the brief history of the case shall be prepared by the BO.</p>

Annexure I

Our Ref: Registration/R-

Dated:

Subject: Notice for model/series cancellation through reduction of scope due to non-conformity of licence No. R- as per Scheme-II of Schedule-II of BIS (CA) Regulations, 2018 (Registration based on Self Declaration of Conformity) for.....(Product Name) as per(IS No.)

M/s

(Name and address of licensee)

Kind Attn: (Name of the CEO/MD)

Dear Sir/Madam,

This has reference to the licence No. R- as per Scheme-II of Schedule-II of BIS (CA) Regulations, 2018 (Licence based on Self Declaration of Conformity) for(Product Name) as per(IS No.) held by you to use the Standard Mark on your product..... of brand.....which is valid up to.....

2. The following non-conformity(s) were observed with regard to the operation of the above licence which is violation of the Regulation..... of BIS (Conformity Assessment) Regulations, 2018:

(Reason(s) for proposed reduction of scope)

3. In view of the above, it is proposed to reduce the scope of licence R by deleting a series(detail of series) held by you in accordance with the provisions under Section 13 of the BIS Act, 2016 read in conjunction with the provisions of Regulation 11 of BIS (Conformity Assessment) Regulations, 2018.

(relevant provisions)

4. In view of the above you are advised to stop the supply and sale of the non-conforming goods or articles under the said licence and withdraw it from the warehouse/ market/ distributor/ in-transit etc. or any such place from where they are likely to be offered for sale.

5. You are also advised to submit us the following details for articles covered under this licence, as on the date of receipt of this communication through speed post/email/portal:

- (a) Quantity of goods or articles with Standard Mark held in stock;
- (b) Batch No(s) and date(s) of manufacture (model-wise);
- (c) Packaging material details affixed with BIS Standard Mark
- (d) Pending Orders for material with Standard Mark, if any with purchasers' name and address
- (e) Quantity of goods or articles with Standard Mark available with warehouse/ market/ dealer/ distributor/in-transit

5. In case you have anything to say in this matter, you may submit your explanation to the Bureau within 30 days from the date of issue of this notice, failing which, it will be presumed that you are no longer interested in continuing the said licence and as such the licence will be processed for cancellation without any further reference to you.

This notice is being issued without any prejudice to the right of this Bureau to take any legal action under section 29 of the BIS Act, 2016.

6. If you desire to be heard in person or through a representative authorized by you on your behalf, you may seek an appointment for such a hearing with the undersigned, after submitting your written explanation within the stipulated period either by post or by email to

7. Kindly note that the authorized signatory of the manufacturing unit with proper authorization letter, should positively be present for the hearing, if sought. In case, if it is not possible for the foreign manufacturer to present for the hearing, they may depute their Indian representative with prior intimation in this regard. The person attending the hearing should establish his identity through Company ID card along with Aadhaar Card/ Passport or any other valid identification. The hearing can also be held through Video Conferencing if such a request is made.

8. Kindly acknowledge the receipt of this letter and ensure compliance.

Thanking You,

(Name & designation of officer)

Copy to:

Authorized Indian Representative (In case of Foreign Manufacturer)

Annexure - II

Our Ref: Registration/R-

Dated:

Subject: Model/series cancellation through reduction of scope of licence No. R- as per Scheme-II of Schedule-II of BIS (CA) Regulations, 2018 (Registration based on Self Declaration of Conformity) for.....(Product Name) as per(IS No.)

M/s

(Name and address of licensee)

Kind Attn: (Name of the CEO/MD)

Dear Sir/Madam,

This has reference to the licence No. R- as per Scheme-II of Schedule-II of BIS (CA) Regulations, 2018 (Registration based on Self Declaration of Conformity) for.....(Product Name) as per(IS No.) held by you to use the Standard Mark on your product..... of brand which is valid upto....

2. The Competent Authority, vide order dated has decided to cancel model/series of your Licence with effect from as per the provision of Regulation of BIS (Conformity Assessment) Regulations, 2018 due to the following reasons:

(Reasons)

3. As your above mentioned model/series of licence stands cancelled w.e.f.....you are therefore, NOT entitled to mark/ dispatch your product (product name) of brandas per IS with BIS Standard Mark after or to claim in your advertisements or in any other publicity material that you are a licensee to use the Standard Mark on your product after

4. Any publicity material such as handbills, pamphlets, letterheads, etc. claiming that you hold BIS licence for your above mentioned series of models of product should be destroyed or such markings obliterated/defaced immediately. This should be confirmed by you at the earliest, positively within 15 days.

5. Please note that any material found marked with BIS Standard Mark after, will be deemed to be the violation of the provisions of the BIS Act 2016, and Rules and Regulations framed thereunder and action will be taken as per the BIS Act 2016, and Rules and Regulations framed thereunder.

6. You are advised to submit an undertaking to the effect that you shall use your licence document with reduced scope in future.

7. In case you apply within three months of decision of Competent Authority with applicable fee, the models under the scope of cancelled series can be considered for new inclusion based on proof of corrective actions, to avoid failure in future, supported by complete testing of the model failed in surveillance. In case the failure model is end of life/ discontinued, then fresh test report of any lead model from the same series which is cancelled can be submitted instead.

8. If you are aggrieved by the above order, you may 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.

9. Please acknowledge receipt of this letter and confirm compliance within the stipulated period.

Yours sincerely,

(Name & designation of officer)

Copy to:

Authorized Indian Representative (In case of Foreign Manufacturer)