BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:2 (Part 2)

02 February 2023

Subject: Guidelines for dealing with unsatisfactory performance (other than matters related to non-conformity of the product) during operation of Licence including suspension and revocation of suspension under Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018 - reg.

This document stipulates the guidelines for dealing with unsatisfactory performance (other than matters related to non-conformity of the product) including imposition of Suspension (SUS), Revocation of Suspension (RoS) and cancellation or special situations. These are to be read in conjunction with the BIS Act 2016 and Rules, Regulations framed thereunder. In particular, the provisions for SUS and RoS of a licence are addressed in Regulation 10 and Paragraph 11 of Scheme - I, Regulation 11 and Paragraph 12 of Scheme - I BIS (Conformity Assessment) Regulations, 2018 respectively. Any situation, in general, not covered in these guidelines are to be dealt with as per provisions of the Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs).

Unsatisfactory Performance of licence

- 1. Performance of a licence shall be treated as unsatisfactory in case of discrepancies observed in the operation of the licence. Such situations are not limited to, but may include the following:
 - (i) Non-availability of testing personnel even as the Standard Mark is being used and product being dispatched/sold without testing
 - (ii) Use of Standard Mark on non-conforming products
 - (iii) Major deviations observed in the implementation of scheme of inspection and testing
 - (iv) Major modification(s) in the manufacturing process without prior evaluation of the Bureau
 - (v) Unsatisfactory hygienic conditions in case of food products
 - (vi) Non-availability of manufacturing machinery and test equipments declared by the manufacturer

Inspection report indicating unsatisfactory performance

2. In case of unsatisfactory performance, the inspection report along with the DVR shall be submitted by the certification officer within 5 working days from the date of inspection and necessary data entry shall be made by him/her in IT Software.

Review of performance (RoP)

3. (i) The DO shall prepare a Review of Performance (ROP) wherein he shall determine whether it is a case of first instance of unsatisfactory performance or consecutive instances of unsatisfactory performance. The RoP shall also

contain details about outcomes of corrective actions taken by licensee and special inspection visits carried out in last 2 years.

(ii) The decision on RoP shall normally be completed preferably within five working days from the date of recording of unsatisfactory performance. The reasons for non-completion of decision on RoP within ten working days from date of inspection shall be recorded by Head BO.

Suspension due to unsatisfactory Performance

- 4. In case of consecutive instances of unsatisfactory performance, suspension shall be imposed. However, suspension is not to be considered on the basis of combination of non-conformity of sample(s) in Third Party Laboratory (TPL)/ Factory Testing (FT) only and unsatisfactory performance.
- 5. In case of unsatisfactory performance due to the discrepancies mentioned at para 1 (iv), (v) and (vi) above, suspension may be imposed at the first instance itself.
- 6. In case of discrepancies mentioned at para 1, except 1 (iv), (v) and (vi), the reasons for unsatisfactory performance shall be communicated to the licensee through email/speed post/IT portal with a copy of the DV report. The licensee shall be advised to take corrective actions and submit its reply within 30 days (one month) from the date of communication. (template of the letter attached as *Annexure I*)
- 7. (i) When the corrective actions are received within 30 days (one month), the DO shall put up the case to the Head BO for nominating an officer for verification of the corrective actions preferably within 90 days through a surveillance inspection.
 - (ii) However, if complete and satisfactory reply is not received within 30 days (one month) from the date of communication of unsatisfactory performance, the case may be processed for suspension.

Notice for suspension

- **8.** (i) Before imposition of suspension for the reasons listed under para 4 or 5 above, a notice shall be issued by the Head BO seeking explanation from the licensee giving 10 days time from the date of issuance of the notice. (template attached as *Annexure II*)
 - (a) In case no reply is received within stipulated time, the suspension may be imposed.
 - **(b)** In case reply is received within stipulated time, it shall be examined and reviewed by the Head BO.

- For cases where the requisite corrective actions along with inspection charges have been received, the case may not be processed for suspension. The case shall be further taken up for verification of corrective actions within the next 10 days. In case, this special inspection visit is unsatisfactory, the case may be processed for suspension without any further notice.
- For cases where the Head BO is satisfied that it is necessary to impose suspension, she/he shall record the reasons while taking decision for imposition of suspension.

Communication of suspension

9. **(i)** The decision of suspension shall be promptly communicated to the licensee through email/speed post/IT Software seeking its response (template of the letter attached as *Annexure - III*). If response is received, then further action shall be taken as per para 10 and 11.

Visit to check compliance of suspension orders

- (ii) The ROs/BOs may arrange visit(s) as given below to check compliance with suspension orders and any possible violation of the BIS Act, 2016 and Rules, Regulations framed thereunder:
 - (a) Products notified by the Central Government for compulsory BIS certification: No response received from the manufacturer within 15 days Visit within next 15 days.
 - **(b)** Products under voluntary certification: No response received from the manufacturer within 30 days Visit within next 15 days.

If there is still no response received from the manufacturer, licence may be processed for cancellation.

(iii) In case of detection of misuse or any violation of the provisions of the BIS Act, 2016 and Rules, Regulations framed thereunder, further necessary action shall also be taken.

Inspection for Revocation of Suspension (RoS)

- 10. (i) On receipt of corrective actions, an inspection for considering RoS shall be organised by the Head BO preferably within 15 days. In case it is not possible to do so, the reasons for the same shall be recorded. Wherever it is necessary for verification of corrective actions, sample from one lot shall be tested in the factory for all possible tests in a day.
 - (ii) In case of suspension due to major modification(s) in the manufacturing process without prior evaluation of the Bureau [Para 1(iv)], sample shall be drawn for complete testing.

Processing RoS

- 11. (i) The processing for RoS shall be completed preferably within 7 days after the inspection for RoS. However, if the corrective actions are found to be insufficient, or if the sample shows non-conformity in factory-testing (where applicable), the licensee shall be advised to take corrective actions.
 - (ii) In case of para 10 (ii), the action for RoS shall be completed within 7 days from the date of receipt of test report indicating conformity of the sample. However, if the sample shows non-conformity in TPL or FT for products certification operated on FT basis, the licensee shall be advised to take corrective actions.

Shifting of premises

- 12. When a licensee informs about shifting of the manufacturing facilities to a new premises, suspension shall be imposed. The decision on suspension shall be communicated to the licensee (template attached as *Annexure II*) with an advise to also inform-
 - (i) The proposed new address to which the manufacturing facilities are being shifted,
 - (ii) Document for authentication of the new premises of manufacture,
 - (iii) Location map for the new premises,
 - (iv) The probable date for completion of the shifting process.
 - (v) All other relevant documents as taken during Grant of Licence.

Inspection for considering RoS

- 13. On receipt of information from the licensee about completion of shifting process, inspection shall be carried out at the old as well as the new premises to verify the same. During the inspection at the new premises, among other things, the certification officer shall
 - (i) verify the manufacturing machinery, test equipment, plant layout and, if applicable hygienic conditions. If the Quality Control In-charge (QCI) has changed, the competence of QCI shall also be checked.
 - (ii) verify the working condition of the manufacturing machinery and test equipment, a sample may be subjected to testing to ascertain the workability of manufacturing and testing equipment.
 - (iii) in case of Packaged Drinking Water (PDW), draw a product sample for complete TPL testing including radioactive residues, as change of source of water is involved. For other similar products product specific guidelines shall be followed, if any.

Processing RoS

- 14. (i) The process for RoS shall be completed preferably within 3 weeks from the date of receipt of information from the licensee about completeness of the shifting process. However, shifting of premises in case of PDW, the process for RoS shall be completed preferably within 7 days from the date of receipt of satisfactory test report. The new address shall be endorsed in the licence as per the template attached as *Annexure IV*.
 - (ii) In case the licensee does not confirm completion of shifting process for more than 90 days, a visit may be organised to both the new and existing premises to check any violation of the provisions of the BIS Act 2016 and Rules, Regulations framed thereunder.

Non-payment of fee

15. In case of non-payment of fee as specified in the BIS (Conformity Assessment) Regulations 2018, suspension shall be imposed after giving 21 days' notice to the licensee. Revocation of suspension shall be considered as soon as the necessary fee is paid by the licensee.

Non-implementation 16. of revised Indian Standard

- (i) In case of non-implementation of revised Indian Standard, amendment to Indian Standard, suspension shall be imposed, if-
 - (a) Additional testing facilities are required and the licensee fails to develop the facility within the stipulated time;
 - **(b)** Non-submission of evidence of conformity to the revised provisions where it is a requirement as per the relevant BIS guidelines.
- (ii) Before imposition of suspension for the reasons listed under this para 16, a notice shall be issued by the Head BO seeking explanation from the licensee giving 10 days time from the date of issuance of notice. (template attached as *Annexure II*)
 - (a) In case no reply is received within stipulated time, the suspension may be imposed.
 - **(b)** In case reply is received within stipulated time, it shall be examined and reviewed by the Head BO. Where the Head BO is satisfied that it is necessary to impose suspension, she/he shall record the reasons while taking decision for imposition of suspension.
 - **(c)** If suspension is not imposed, the matter shall be taken up for early implementation of revised Indian Standard or amendment to Indian Standard.

- 17. In case of SUS as at para 16,
 - (i) Where the licensee has to develop the additional testing facilities, RoS shall be permitted on confirmation of additional testing facility.
 - (ii) Where evidence of conformity to the revised Indian Standard is not available, RoS shall be permitted on receipt of evidence of conformity of the product as per the new provisions.

Cancellation notice

18. When the cancellation proceedings are considered against a licensee, the licence may also be put under suspension by DDGR provided justified reasons are available for imposing suspension and the reasons for suspension shall be recorded by the competent authority. The matter regarding imposition of suspension along with the reasons shall be mentioned in the cancellation notice.

Proceedings for cancellation

- 19. (i) The cancellation of a licence shall be done as per Regulation 11 of the BIS (Conformity Assessment) Regulations, 2018.
 - (ii) Before cancelling a licence, a cancellation notice of not less than twenty one days shall be given to the licensee (template attached Annexure V). Before issuing cancellation notice, the DDGR shall satisfy herself/himself about completeness of information and facts of the case. Where DDGR is satisfied that it is necessary to issue cancellation notice, she/he shall record the reasons while taking decision for issuance of cancellation notice.
 - (a) In case no reply is received within stipulated time, the licence may be cancelled.
 - **(b)** In case reply is received within stipulated time, it shall be examined and reviewed by the DDGR.
 - (iii) The competent authority shall take into account merits of the case and facts presented by licensee during personal hearing and shall pass speaking orders for the final decision taken.
 - (iv) The decision to cancel the licence shall be communicated to the licensee (template of the letter attached as *Annexure VI*).

Cancellation notice without suspension (specific cases)

20. (i) For the following cases, the licence may not be put under suspension during the issuance of cancellation notice:

(a) Cases where the Standard Mark has been used/applied in relation to variety outside the scope of licence

OR

Cases where the Standard Mark has been used/applied during the period of deferment or dormancy or suspension which comes to notice at a later date after renewal or revocation of suspension.

(b) Cases where non-cooperation with BIS certification officer(s) or agent(s) is reported.

Proceedings for cancellation (specific cases)

- 21. (i) For cases as stated 20 (i) (a) above, the matter shall be first investigated for collection of appropriate evidence and the investigation findings shall be presented by the BO to DDGR for taking decision before issuing the cancellation notice.
 - (a) If there is no evidence of commercial activity with the usage of Standard Mark, the licence may not be cancelled. In such cases,
 - where it is successfully processed for inclusion of varieties in the scope of licence, the licensee shall be directed to undertake tests and ensure checks as per SIT before dispatch of concerned lot/batch of available products.
 - where licence have become operative (i.e. currently not under deferment or dormant or suspension), the licensee shall be directed to undertake tests and ensure checks as per SIT before dispatch of concerned lot/batch of available products.
 - **(b)** If there is evidence of commercial activity with the usage of Standard Mark, the following may be considered:
 - O BIS normally processes the misuse cases for cancellation of licence of certified manufacturer. However, for similar violations by a non-licensee manufacturer, BIS takes up action as per provision of the BIS Act, 2016 through launch of prosecution in the Court of Law. Further, as per section 33 of the BIS Act, 2016, the provision for compounding will also apply.
 - Accordingly, as the BIS certified manufacturer who doesn't hold a valid licence for variety outside the scope of licence or during period of suspension or deferment, the option of taking action for violation of the BIS Act, 2016 through launch of prosecution in the

Court of Law should also be made available to the certified manufacturers. An opportunity to the manufacturer for exercising the option of taking action by way of prosecution in the Court of Law or cancellation of licence shall be taken into account.

- Accordingly, during the cancellation proceedings, the provision for launching prosecution in the Court of Law for violation of the provisions of the BIS Act, 2016 shall also be informed to the licensee. If the licensee is eligible for compounding, the provision under section 33 of the BIS Act, 2016 and applicable Rules shall also be explained.
- o If a manufacturer during the cancellation proceedings (like personal hearing) opts for action as per the BIS Act, 2016, the licence shall not be cancelled. As a result of this option for launching prosecution in the Court of Law, provision for compounding of first offence may also apply. If the compounding gets materialised, then also the licence shall not be processed for cancellation.
- For cases where it is necessary to cancel the licence, DDGR shall record the reasons while taking decision for cancellation of licence including the option of cancellation indicated by the manufacturer. In such cases, the matter shall not be taken up for launching prosecution in the Court of Law.
- If the licence is not cancelled, the matter shall be taken up for corrective actions and its verification as per applicable paras (6 & 7 or 13 & 14) of this document.
- (ii) For cases as stated at 20 (i) (b) above, generally, a chance may be given to the manufacturer subject to submission of an undertaking for cooperation with BIS certification officer(s) or agent(s) in future. However, in exceptional cases of serious non-cooperation, DDGR may take a decision for cancellation of licence.

Suspension in vogue for more than a year

- 22. (i) The licence may be cancelled if the licence has been under suspension for more than a year.
 - (ii) In cases where suspension of licence is due to complete one year, a prior cancellation notice shall be served by the competent authority (preferably 30 days before completion of one year) before considering cancellation of licence.

Product specific guidelines

23. In addition to these guidelines, any product specific guidelines issued by CMDs shall be followed, as applicable.

Inspection fee

24. All inspections other than surveillance inspections or inspections carried out for complaint investigation shall be chargeable, in advance, as per provisions of BIS (Conformity Assessment) Regulations, 2018.

Testing fee

25. The testing fee of samples other than those, which may be drawn during surveillance or complaint investigation, shall be borne by the licensee.

Provision for appeal

26. For cases in which the manufacturer submits an appeal to the Director General, the brief history of the case shall be communicated by RO/BO to concerned CMD (template as per *Annexure - IX* of grant of licence guidelines).

Discreet visit

27. To check for compliance towards any instructions issued to the licensee (For example, cancelled/expired/dormant licences), the ROs/BOs may arrange discreet visit(s) to check any possible violation of the BIS Act, 2016 and Rules, Regulations.

Annexure - I

(Our Ref: BO/CML- Date:
	Subject: Unsatisfactory performance pertaining to Licence CM/L for
ľ	m M/s
1	Madam/Sir,
1)	This has reference to the BIS Certification Marks Licence No. CM/L granted to you for use of BIS Standard Mark () on
2)	A surveillance inspection was carried out at your factory premises on
3)	You are advised to take appropriate corrective actions to avoid such discrepancies in future and intimate BIS the details of actions taken along with applicable supporting evidence within one month from the issuance of this letter.
4)	Kindly note that in case, complete/satisfactory reply is not received within the stipulated period or performance during next surveillance visit is also found unsatisfactory, suspension may be imposed in accordance with clause (a) of sub-paragraph (5) of Paragraph 11 of Scheme - I of Schedule - II under the BIS (Certification) Regulations, 2018.
5)	Kindly acknowledge the receipt and ensure compliance.
-	Γhanking you
	Signature of designated authority (Name of designated authority)
1	Enal: As above

Annexure - II

	Our Ref: BO/CML- Date:
	Subject: Notice for suspension of licence CM/L for (Product Name) as per(Indian Standard)
	M/s
	Kind Attn: (Name of the CEO/MD)
	Madam/Sir,
1)	This has reference to the BIS Certification Marks Licence No. CM/L granted to you for use of BIS Standard Mark () on (Product name) according to IS which is valid up to
2)	The following discrepancies have been observed with regard to the operation of the above licence which is a violation of the provision of Regulation 10 of the BIS (Conformity Assessment) Regulations, 2018.
	(BO to give the reasons for proposed suspension in this space)
3)	Further, reference is invited to our earlier letter of even number dated informing about discrepancies for which corrective actions were taken by your firm as informed vide letter dated
4)	A sum of ₹ (plus applicable taxes) shall be payable to BIS in advance towards a special inspection visit.
5)	In view of the above, it is proposed to suspend the licence CM/L held by you in accordance with the provisions under Section 13 of the BIS Act, 2016 read in conjunction with the provisions of Regulation 10 of the BIS (Conformity Assessment) Regulations, 2018.
6)	In case you have anything to say in this matter, you may submit your explanation to the Bureau within 10 days from the date of issue of this notice, failing which your licence will be put under suspension 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.

Thanking You,

Signature of designated authority (Name of designated authority)

Encl.: As above

Annexure - III

(Our Ref: BO/CML- Date:	
	Subject: Suspension of Licence CM/L for (Product name) as per (Indian Standard)	
1	M/s	
	Kind Attn: (Name of the CEO/MD)	
	Madam/Sir,	
1)	This has reference to the BIS Certification Marks Licence No. CM/L granted to you for use of BIS Standard Mark () on	
2)	Further, reference is invited to suspension notice dated giving you 10 days time to submit an explanation response.	
3)	Due to the	
4)	You are not permitted to mark and dispatch (including stock in hand) the above mentioned product with Standard Mark. You are, therefore, advised to ensure stoppage of marking on the product with immediate effect & confirm the same immediately preferably by return speed post/e-mail. You are also advised to submit us the following details as on the date of receipt of fax/email:	
	 i) Quantity of material with Standard Mark held in stock: ii) a) Batch No(s). and date(s) of manufacture; b) Brand; c) size/type/grade/variety; iii) Packing details; and iv) Pending Orders for material with Standard Mark, if any with purchasers' names and addresses 	

Your reply with above stated details must reach us within 15/30† days of the issuance of this letter failing which it will be presumed that you do not have such material in stock. In

5)

case it is subsequently found that you have sold the material with Standard Mark after receipt of BIS instructions to suspension, it will be construed that the material so sold has been marked subsequently contravening provisions of the BIS Act, 2016. In such an eventuality, the Bureau will reserve the right to take such action against you as envisaged in the BIS Act, 2016, Rules & Regulations framed there under.

- 6) Kindly note that, according to Paragraph 5 of Scheme-I of Schedule-II under the BIS (Conformity Assessment) Regulations, 2018, the minimum marking fee of above mentioned licence is payable by you even during the period the licence is not in operation due to suspension.
- 7) You are required to take necessary corrective action in the context of the reasons for suspension as stated in paragraph 2 above and submit complete details of compliance with all supporting evidence, as applicable, for examination and verification. *You are advised to produce a fresh batch/lot/control-unit after taking corrective actions and confirm your readiness for the visit by BIS to consider revocation of suspension.
- 8) A sum of ₹...... (plus applicable taxes) shall be payable to BIS in advance towards this special inspection visit.
- 9) The reply with information sought should be sent immediately by return speed post/e-mail but not later than 15/30† days from the issuance of this letter failing which your licence will be considered for cancellation as per the Regulation 11 of BIS (Conformity Assessment) Regulations, 2018.
- 10) Kindly acknowledge the receipt and ensure compliance.

Encl. As stated

Signature of designated authority (Name of designated authority)

Copy to: Quality Control In-charge (Licensee Name & Address)

^{*} Strike off where not applicable

^{† 15} days for products notified for compulsory BIS certification. Other cases, 30 days.

Annexure - IV

Attachment to Licence No. CM/L-....

CM/L-	Name of the Licensee with the Factory Address	Name of the Product	Indian Standard No.

Endorsement No Dated	
Consequent to the shifting of the factory, the address of the licensee mer has been changed to	

Other terms and conditions of the Licence remain the same.

Signature of designated authority (Name of designated authority)

Annexure - V

	Our Ref: BO/CML- Date:	
	Subject: Notice for Cancellation of Licence CM/L for (Product Name) as per(Indian Standard)	
	M/s	
	Kind Attn: (Name of the CEO/MD)	
	Madam/Sir,	
1)	This has reference to the BIS Certification Marks Licence No. CM/L granted to you for use of BIS Standard Mark () on	
2)	The following discrepancies were observed with regard to the operation of the above licence which is a violation of the provision of Regulation of the BIS (Conformity Assessment) Regulations, 2018.	
	(RO/BO to give the reasons for proposed cancellation in this space and earlier notices served to the licensee)	
3)	In view of the above, it is proposed to cancel the licence CM/Lheld by you is accordance with the provisions under Section 13 of the BIS Act, 2016 read in conjunction with the provisions of Regulation 11 of the BIS (Conformity Assessment) Regulations 2018.	
4)	(A)* Your licence is already under suspension w.e.f	
	(including stock in hand) the above mentioned product with Standard Mark. Your licence is, therefore, put under suspension with immediate effect & you are advised to confirm that you	

have stopped using and applying Standard Mark immediately preferably by returned speed

post/e-mail.

5) *You are also advised to submit us the following details as on the date of receipt of speed

post/email:

i) Quantity of material with Standard Mark held in stock

ii) a) Batch No(s) and date(s) of manufacture;

b) Brand;

c) size/type/grade/variety

iii) Packing details; and

iv) Pending Orders for material with Standard Mark, if any with purchasers' name

and address

6) In case you have anything to say in this matter, you may submit your explanation to the

Bureau within 21 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.

7) If you desire to be heard in person or through a representative authorised by you on your

behalf, you may seek an appointment for such a hearing with the undersigned, after

submitting your written explanation.

8) Kindly acknowledge the receipt and ensure compliance.

Thanking You,

Signature of designated authority

(Name of designated authority)

Encl.: As above

* Strike off where not applicable

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Annexure - VI

(Our Ref: BO/CML-	Date:
	Subject: Cancellation of BIS Certificat (Product name) as per	ion Marks Licence No. CM/L for (Indian Standard)
]	M/s	
]	Madam/Sir,	
1)		mark (on (Product name) according to
2)	Further, reference is invited to cancella and personal hearing held on	tion notice dated, your reply dated
3)	•	nce after as per the provision of Regulation nt) Regulations, 2018 due to the following reasons:
	(BO to r	mention the reasons)
4)	entitled to mark/ dispatch your product	e, stands cancelled w.e.fYou are therefore not (Product name) as per IS with BIS Standard advertisements or in any other publicity material ark on your product after
5)	hold BIS Product Certification Licen	ills, pamphlets, letterheads, etc. claiming that you ce for your above mentioned product should be defaced immediately. This should be confirmed by days.
6)	Further, you are advised to furnish a st follows: i) Quality held in stock: a) Type or Grade b) Variety	atement of (Product Name) with Standard Mark as
	c) Brand, if any	

- ii) Batch/Control Unit (C.U.)/Lot No.
- iii) Packing
- iv) Pending order for ISI certified material, if any and purchaser's name and address
- 7) 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.
- 8) You are advised to surrender the original licence along with all the attachments/endorsements sheets, etc. and also submit an undertaking to the fact that you have not retained photocopy of the said licence document and shall not produce it anywhere under any circumstances subject to prior permission from BIS in this regard.
- 9) 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.
- 10) Please acknowledge the receipt and ensure compliance.

Signature of designated authority (Name of designated authority)