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

हमारा सन्दर्भ: सीएमडी-1/2:12:2

विषयः अनुरूपता निर्धारण स्कीम-। () के अंतर्गत लाइसेंस के संचालन के दौरान देखे गए उत्पाद(दों) की गैर-अनुरूपता और असंतोषजनक प्रदर्शन के निपटारण दिशानिर्देश - हेतु।

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

> (मोहित जनोहिया) वैज्ञ-'सी'/सीएमडी-I

03 **फरवरी** 2023

<u>प्रमुख, सीएमडी-।</u>

उपमहानिदेशक (प्रमाणन एवं सीएसएम)

Bureau of Indian Standards

(Central Marks Department - I)

Our Ref: CMD-I/2:12:2

Subject: Guidelines for dealing with non-conformity of product(s) and unsatisfactory performance observed during operation of Licence under conformity assessment Scheme - I (()) - reg.

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

(Mohit Janoiya) Sc.C/CMD-I

Head, CMD-I

DDG (Certification & CSM)

परिचालित/circulated to:

सभी क्षेत्रीय कार्यालयों/ शाखा कार्यालयों All ROs/BOs

सभी उपमहानिदेशक (क्षेत्रीय) एवं उपमहानिदेशक (एमएससी, सीआरएस और एफएमसी) All DDGRs and DDG (MSC, CRS & FMC)

प्रमुख, सी॰एस॰एम॰ विभाग Head, CSMD

अन्य सभी संबंधित पक्ष All other concerned

प्रमुख, आई॰टी॰एस॰ विभाग - बी आई एस इंट्रानेट पर डालने हेतु। Head, ITSD - with request to host on BIS Intranet

(Central Marks)

03 February 2023

Bureau of Indian Standards (Central Marks Department - I)

Our Ref: CMD-I/2:12:2

03 February 2023

Subject: Revision of guidelines for dealing with product non-conformity and unsatisfactory performance under product certification (57) scheme - reg.

This has reference to the subject mentioned above.

- 2) The guidelines have been reviewed (including feedback received from ROs/BOs) and changes have been made which are as briefed below:
 - i) Guidelines for dealing with non-conformity of product(s) observed during operation of licence (detailed document enclosed as *Annexure I*)
 - a) Introducing 'Suspension Notice' provision before decision at BO level.
 - b) Licence cancellation grounds elaborated and to be recorded with adequate justification by DDGR.
 - c) Performance assessment of licensee inline with risk based approach.
 - d) Updation of product recall template to mention type of risk, non-conforming requirement with illustrative examples.
 - ii) Guidelines for dealing with unsatisfactory performance (other than matters related to non-conformity of the product) (detailed document enclosed as *Annexure II*)
 - a) Introducing 'Suspension notice' provision before decision at BO level.
 - b) Licence cancellation grounds elaborated and to be recorded with adequate justification by DDGR. Issuance of cancellation notice without suspension with mention of instances of misuse.
 - c) Only one action either cancellation or prosecution to be taken. Cases without commercial activity to be processed with proper checks.
 - d) Performance assessment of licensee inline with risk based approach.
- 3) The enclosed revised guidelines supersedes the earlier guidelines on the subject and comes into force with immediate effect.
- 4) This issues with the approval of the competent authority.

Encl. As above

(Mohit Janoiya) Sc.C/CMD-I

Head, CMD-I

DDG (Certification & CSM)

circulated to:

i) <u>All ROs/BOs</u>

- ii) <u>All DDGRs</u> and <u>DDG (MSC, HM, CRS & FMC)</u> iii) <u>Head, CSMD</u>
- iv) Head, ITSD
- iv) <u>All other concerned</u> through BIS intranet

Annexure - I

BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:2 (Part 1)

02 February 2023

Subject: Guidelines for dealing with non-conformity of product(s) observed during operation of Licence including product recall, 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 non-conformity of product(s) observed during operation of Licence including submission and verification of corrective action, product recall, imposition of Suspension (SUS), Revocation of Suspension (RoS) and cancellation on account of non-conformity of the product to the relevant Standard(s). These are to be read in conjunction with the BIS Act 2016 and the Rules and the Regulations framed thereunder. In particular, the provisions for product recall, SUS & RoS and cancellation are addressed in Section 18(6) of the BIS Act 2016 and Regulation 6(5), Regulation 10 and Paragraph 11 of Scheme - I, Regulation 11 and Paragraph 12 of Scheme - I of the 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).

Receipt of test reports	1.	The test reports are received at BOs dashboard through Laboratory Information Management System (LIMS). The test reports are received on the dashboard of the Head (BO) and concerned Dealing Officer (DO).
Examination of test reports	2.	(i) The DO shall examine the test reports and record 'Conforming/ Non-conforming' in the system normally within 5 working days from date of receipt of test report. In case of non-conforming test report, the DO shall also record the requirements (parameters as well as clause number) in which the sample is non-conforming and make requisite entry(ies) in portal.
		(ii) The Head (BO) shall monitor the adherence of time norms for examination of test reports.
1st non-conformity	3.	(i) The non-conformity of product in Third Party Laboratory (TPL) or Factory Testing (FT) shall be treated as first non-conformity, if the previous test report (based on date of manufacturing or in its absence date of drawl) is found conforming.
Consecutive non-conformity		(ii) Any non-conformity of product in TPL or FT shall be treated as a consecutive non-conformity if its date of manufacturing (in case date of manufacturing is not available, then date of drawl) is after the date of completion of corrective actions on first non-conformity and there is no 'conforming' test report in between.

		 (iii) In other cases of non-conforming test report(s), like (a) period prior to receipt of a conforming test report or (b) period prior to RoS (either on account of non-conformity of product or other reasons of unsatisfactory performance).
		the RoP may not include actions for undertaking suspension. However, for these cases, RoP shall include risk assessment of non-conformity and other actions to be taken by licensee like corrective actions, product recall (where applicable) etc. Non-conformity, if any, including applicable actions for corrective actions, product recall notice etc. shall be communicated to the licensee.
Payment of testing charges	4.	Each BO shall maintain records for test reports received in BOs in line with Standard Operating Procedure for Processing and Payment of Testing Charges issued by Accounts Department.
Review of performance (RoP)	5.	 (i) When non-conformity of sample is observed, either in TPL or FT, the dealing officer shall prepare RoP wherein following actions shall be undertaken: (a) Determining whether it is a first or consecutive non-conformity of product (b) Risk assessment analysis of non-conformity(ies) observed (c) Risk assessment of licensee keeping in view performance of last 2 years (d) Detailing outcomes of corrective actions taken by licensee and special inspection visits carried out in last 2 years
Labelling and marking requirements		(ii) Any deviation observed in requisite labelling and marking requirements (for example, absence of Batch/ Control Unit (C.U.)/ Lot No., date of manufacturing/expiry (say for food products) which may result in traceability issues, grade/type etc.) is also to be treated as non-conformity of the product. However, if the non-conformity is only in requirements like referencing the BIS website, whereas the sample is conforming to all other parameters, it may not be considered as a non-conformity for the purpose of treating as consecutive failure. However, the same shall be communicated to the manufacturer for necessary corrective actions.
Risk assessment		(iii) Upon receipt of information about every non-conformity of product(s) as per test report from TPL or FT, risk assessment analysis of the failure w.r.t. impact of non-conformity of the product on public health/safety shall be done. For this purpose, Head (BO) should constitute a committee of officer(s) at BO level.

(iv) In case, the requisite expertise is not available within the BO for a particular product, the Head (BO), after consultation with DDGR, may involve any other officer(s) within the Region.

(v) For specific products, if it may require involvement of CMDs/ Technical Departments, the case may be referred to concerned CMD with the approval of DDGR. The concerned CMD will then propose a committee for the approval of DDG (Certification).

(vi) The committee shall carry out the risk assessment analysis and provide its recommendations for issuance/non-issuance of "product recall notice", taking into account the justifiability and feasibility of product recall. A guidance template to undertake risk assessment analysis of non-conformity of product is enclosed as *Annexure - I*. Further, a guidance document on risk assessment technique is enclosed as *Annexure - II*.

(vii) In case of unavailability of details like Batch/C.U./Lot No. /Date of manufacturing of the non-conforming sample, then the production of immediately preceding thirty days from the date of drawl of sample shall be considered for the purpose of product recall, if applicable.

(viii) After risk assessment analysis, the DO shall put up RoP alongwith recommendations of the committee to Head (BO) for consideration.

Product recall notice

(ix) Head (BO) shall take into account the justifiability and feasibility of issuance of product recall notice and pass speaking orders and record on the RoP regarding the decision for issuance/ non-issuance of product recall notice to the manufacturer with reasons. The decision on RoP shall normally be completed within five working days from the date of recording of non-conformity.

Communication The non-conformity shall be communicated to the licensee through 6. for seeking email/speed post/IT portal with a copy of the test report normally within 15 corrective actions days of receipt of test report. The communication shall also include probable and notice for causes for non-conformity for guidance to the manufacturer. After the risk product recall assessment analysis, if it is decided to issue product recall notice, then the notice for product recall shall also be included in the non-conformity intimation letter. A template letter for seeking corrective actions and notice on product recall is attached as Annexure – III (TPL) and Annexure – IV (FT). The licensee shall be advised to take corrective actions and submit its reply along with applicable supporting evidence (including root-cause analysis) within 15/30⁺ days from the date of communication.

[†]Note: In case product recall notice has been issued, only 15 days to be given. Otherwise, 30 days.

Receipt of reply 7. (i) When the corrective actions and reply to product recall notice (if applicable) are received within 15/30 days (as applicable), the DO shall evaluate the response received from licensee w.r.t corrective actions and put up the case to the Head (BO) for verification of the corrective actions.

Review of reply to product recall notice (ii) The Head (BO) shall examine and review the explanation received from licensee towards product recall notice and take decision. In case of non-acceptance of explanation, the directions for product recall shall be issued to the licensee (template of the letter attached as *Annexure - V*).

Special inspection visit to establish relevance of response (iii) For the purpose of verification of corrective actions and its relevance, a special inspection visit (chargeable) shall be carried out by certification officer normally within next 15/30⁺ days.

[†]Note: In case product recall notice was issued, visit within 15 days. Otherwise, 30 days.

During such a special inspection visit, the facts stated in the report of corrective actions vis-à-vis the non-conformity(ies) observed in the product shall be verified. For example, it may involve witnessing the interlinkages of the production process or other technical reasons with root-cause analysis.

(iv) During this visit, FT shall be carried out for as many requirements as possible and sample for TPL testing is not to be drawn.

(v) Inputs received on explanation to product recall notice or plan of action on product recall, as applicable, shall also be verified to the extent possible during this special inspection visit and reported. The report for such a special inspection visit shall highlight whether the corrective actions taken by licensee are relevant or not and verification on product recall as above. For non-compliance observed, if any, appropriate action shall be taken as given below:

(a) If the relevance of corrective actions is not acceptable and/or the sample is non-conforming in FT, then the case may be considered for imposition of suspension.

- (b) If the relevance of corrective actions is acceptable, then the case shall be referred by Head (BO) to CSMD for planning an early surveillance inspection.
- (c) The reporting of verification of inputs received on explanation to product recall notice or plan of action on product recall, as applicable, shall be examined and reviewed by Head (BO) for necessary action, if any.

(vi) If during the surveillance inspection, the sample is non-conforming in FT, it shall be treated as consecutive non-conformity and actions as per para 10 shall be taken.

(vii) The licensee shall maintain records for recalled products including the actions taken like Repair/Replacement/Reprocessing/Disposal etc.

8. (i) If corrective actions are not received within 15/30 days (as applicable), the case may be processed for imposition of suspension.

(ii) If explanation to product recall notice is not received, the directions for product recall shall be issued to the licensee (template of the letter attached as Annexure - V).

(iii) If both the corrective actions and explanation to product recall notice are not received, the case may be processed for imposition of suspension. In such cases, the directions for product recall shall also be included in the suspension intimation letter.

Public alert 9. (i) Wherever, directions are issued for product recall, public shall be alerted through BIS website and BOs webpage regarding such product recall directions including the failure aspects as well as its impact on public health/safety. A template for public alert notice including type of risk is enclosed as Annexure - VI. For each case of product recall, Head (BO) shall assess the need for wider publicity through print media (Press release, advertisement etc.) and take decision for such publicity in print media with approval of DDGR. For reporting type of risk, few illustrative examples have been indicated and enclosed as Annexure - VII.

> (ii) The information about product certification licences () that have been put under suspension/ cancelled or expired due to non-conformity of sample(s) or establishment of complaint will be made publicly available on the dashboard of e-BIS portal website and BIS Care app. Public alerts must

informing about non-conformity of certified products

have the information that consumers can check the validity of the licence for a product using BIS website or BIS Care app.

(iii) The ROs/BOs shall spread awareness about the public alerts information available on BIS website, online portals and BIS care app. This shall include information on directions issued for product recall, licences put under suspension/ cancelled or expired due to reasons of failure of sample(s) or establishment of complaint w.r.t. BOs under their respective jurisdiction.

(iv) While giving reference to the status of licences (including suspension/ cancellation or expiry) as reflected on the BIS website/portal/BIS care app, it shall be ensured that emphasis is made on the dynamic nature of information. The relevant details about how to access the real-time information from BIS website, portals and BIS care app shall also be shared and propagated during events organised by ROs/BOs like licensee meets, industry awareness programmes etc. The impact of non-conforming product on public health/safety etc. shall also be highlighted during such events.

(v) The BOs shall raise awareness among licensee manufacturers (especially MSMEs) about the assessment procedures and documentation involved in procedures of root-cause analysis, risk assessment and product recall during the training programmes.

(vi) The BOs shall regularly maintain information summary about non-conformity of product and decision(s) taken about product recall. This information shall be informed by BOs to respective RO on a quarterly basis. The Head of the Region shall review the findings of the BOs under their jurisdiction so as to ensure uniformity of practice within the Region to the extent possible.

- Suspension due to
non-conformity of10.Suspension may be imposed in the event of consecutive non-conformity of
samples. However, in case of food products non-conforming in the
requirement like toxicity or pesticide residues or radioactive residues etc. or
as per the product specific guidelines, suspension may be imposed on first
non-conformity itself.
- Notice for11.(i) Before imposition of suspension for the reasons listed under para 10, asuspensionnotice shall be issued by the Head BO seeking explanation from the licenseegiving 10 days time from the date of issuance of the notice. (template attachedas Annexure VIII)

(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.

(ii) For the cases mentioned in para 14 (v) and 14 (vi), the notice before imposition of suspension need not be issued.

Communication of 12.
 (i) The decision of suspension shall be communicated to the licensee through email/speed post/IT portal with a copy of test report normally within 15 days of receipt of test report. A template letter is attached as *Annexure – IX*.

(ii) If the risk assessment analysis has established that the non-conformity has an impact on public health/safety, then the notice for product recall shall also be included in the suspension intimation letter.

13. (i) 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.

Suspension, seeking corrective actions and issuance of product recall notice or directions, as applicable

Visit to check compliance of suspension orders (ii) 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.

(i) On receipt of complete reply, an inspection for considering RoS shall be 14. organised by the Head (BO) normally within 15 days. In case it is not possible to do so, the reasons for the same shall be recorded. During the inspection, the certification officer shall verify the actions taken by the licensee in line with para 7(iii) and 7(v) above.

(ii) If the relevance of corrective actions is acceptable, the RoS inspection visit shall proceed as given below, otherwise the licensee shall be advised to review and re-submit actions which are to be checked in a fresh RoS inspection visit.

(iii) For non-acceptance of explanation towards product recall notice, action as per para 7(ii) shall be taken.

Inspection for (iv) If all the requirements in which non-conformity was reported can be **Revocation** of tested in the factory in one or two day(s), then sample from the Suspension (RoS) Batch/C.U./Lot offered shall be tested in the factory for all possible tests including the requirements in which non-conformity was observed.

> (v) In case one or more requirements in which non-conformity was reported cannot be tested in the factory within two days, then sample shall be drawn for TPL testing and got tested for all requirements except the ones for which testing time is more than 30 days (one month). However, if the non-conformity is in such requirements for which testing time is more than 30 days (one month), then sample shall be drawn for TPL testing and got tested for all requirements including the ones for which testing time is more than 30 days (one month). In both the cases, RoS shall be permitted on the basis of possible test(s) and an undertaking shall be taken that in case the sample drawn for TPL testing during such RoS visit is found to be non-conforming, SUS shall be imposed.

> (vi) If the sample drawn on the first occasion for considering RoS shows non-conformity in testing (either FT or TPL, as the case may be), another chance may be given for improvement and reoffering of sample. In such cases, sample shall be drawn for TPL testing, except those products for which the licence is granted on FT basis, for all the requirements except for those relaxed as per product specific guidelines and RoS will be based on result of such TPL testing only.

Receipt and review of compliance to suspension, corrective actions and reply to product recall notice or directions, as applicable

(vii) However, if the sample is found to be non-conforming even on second occasion, the licence may be processed for cancellation.

Processing RoS 15. (i) The information about product recall, as applicable, sought from licensee shall be checked before taking any decision about reinstatement (revocation of suspension, cancellation proceedings etc.) of certification.

(ii) However, RoS may be processed if the corrective actions have been found to be satisfactory, sample shows conformity in FT or TPL, as the case may be, and the manufacturer has provided inputs on product recall plan (as applicable) and the plan is being implemented by the manufacturer. RoS shall normally be processed within 7 days.

Review of 16. If during the inspection visits (special inspection visit 7(v), RoS visit 14(i)
 product recall directions 16. If during the inspection visits (special inspection visit 7(v), RoS visit 14(i)
 etc.), it is observed that the product recall process has not been completed and is under implementation by the licensee, the manufacturer may be advised to submit their product recall plan implementation report on completion of all actions for review by the BO.

Intentionally17.(i) In case there is evidence that non-conforming goods with Standard Mark
are being produced intentionally, suspension shall be imposed immediately
and an explanation shall be sought from the licensee. If the explanation is not
found to be satisfactory, the licence may be processed for cancellation.

goods

account on unsatisfactory

feedback

(ii) If explanation is found to be satisfactory, the RoS shall be done as per as per para 14, 15.

Suspension on18.(i) If a complaint regarding quality of any goods or article bearing theestablishment of
complaint or onStandard Mark is established, the licence may be put under suspension and
licensee shall be required to take corrective actions.

(ii) The instances of receipt of unsatisfactory feedback shall be treated on par with that of receipt of complaint.

(iii) The requisite actions shall be taken in accordance with the complaint management manual/guidelines.

Suspension along 19. 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. The reasons for suspension shall be recorded by the competent authority and mentioned in the cancellation notice.

Proceedings for cancellation	20.	(i) The cancellation of a licence shall be done as per the Regulation 11 of 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 <i>Annexure</i> - X). 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. Where the DDGR is satisfied that it is necessary to cancel the licence, she/he shall record the reasons while taking decision for cancellation of licence.
		(c) 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 14 & 15) of this document.
		(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 <i>Annexure - XI</i>).
Suspension in vogue for more than a year	21.	(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 about to complete one year, a prior cancellation notice shall be issued by the competent authority (preferably 30 days before completion of one year) before considering cancellation of licence.
Product specific guidelines	22.	In addition to these guidelines, any product specific guidelines issued by CMDs shall be followed, as applicable.

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Inspection fee	23.	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	24.	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	25.	For cases where 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 <i>Annexure - IX</i> of grant of licence guidelines).
Discreet visit	26.	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.

<u>Annexure - I</u>

(Part A) General Information

Sr. No.	Aspect	Details
(i)	IS No.	
(ii)	Product	
(iii)	CM/L -	
(iv)	Manufacturer name	
(v)	Sample drawl date	
(vi)	Sample manufacturing date	
(vii)	Grade/Type/Size/Variety etc.	
(viii)	Test report issued by	
(ix)	Test report date	
(x)	Non-conforming parameter(s)	
(xi)	Product shelf life till/expiry date (if applicable)	

<u>Annexure - I</u>

(Part B)

Risk Assessment Analysis

(Risk Assessment to be carried out for each non-conformity. Use separate sheets, if required)

Sr. No.	Aspect	Observations/Remarks
(i)	Identification of product and its non-conformity(ies)	
(ii)	a) Extent of non-conformity(ies)b) Does the non-conformity(ies) indicate intentional use of sub-standard raw materials/inputs	
(iii)	Nature of non-conformity parameter: Safety or performance	
(iv)	 Identify hazard(s), <i>For example</i>: a) Thermal hazards like explosion, flame, radiation, hot surfaces etc. b) Electrical hazards like live parts, short-circuits, overload etc. c) Mechanical hazards like vibration, instability, break-down during operation, moving parts susceptible to causing physical harm to the operator, falling or ejected objects, edges or corners etc. d) Chemical/Biological hazard like presence of toxins, expiry of product etc. 	
(v)	Identify subject at risk, <i>For example</i> , Human, plant, animal, environment etc.	

(vi)	Description of potential harm scenario(s) For example, absence of proper labelling and marking resulting in consumption of expired food product	
(vii)	Describing the potential harm(s) For example, potential electrical shock/burn/loss of life due to leakage of current from electrical wire	
(viii)	Risk assessment about impact of non-conformity on public health/safety Assessing severity of harm(s) and probability of its occurrence	
(ix)	Whether the product recall is feasible (Yes or No)	
(x)	Need for issuance of product recall notice (Yes or No) with reasons thereof and if Yes, List all the non-conformity(ies) which led to decision for recommending issuance of product recall notice	

Signature (Committee members) (Name and Designation)

Head (BO) – (For speaking orders on issuance/ non-issuance of product recall taking into account justifiability and feasibility of product recall)

Annexure - II

The risk assessment techniques are utilised to provide structured information to support decisions and actions where there is uncertainty so as to assist in making realistic strategic and operational objectives. The way in which risk should be assessed depends on the context, its complexity and level of available expertise. Depending on these factors, suitable risk assessment techniques given in National or International Standard may be utilised. As an example, bow-tie analysis risk assessment technique may be used. For assessing the risk and taking decision on product recall, factors like escalation barrier, preventive controls (like electric fuse, circuit breaker) and feasibility (product shelf life) should be taken into account. As a guidance, risk matrix tool may be utilised by defining ranges of severity (consequence of harm) and probability of occurrence of harm. An illustrative example is as given below:

Probability	Severity (Consequence) of harm					
of occurrence of harm	Catastrophic	Serious	Moderate	Minor		
Very likely	High	High	High	Medium		
Likely	High	High	Medium	Low		
Unlikely	Medium	Medium	Low	Negligible		
Remote	Low	Low	Negligible	Negligible		

Severity Levels:

- **Catastrophic** death/disabling injury/illness (unable to return to work)
- Serious severe debilitating injury/illness (able to return to work at some point)
- **Moderate** significant injury/illness requiring more than first aid (able to return to same job)
- **Minor** no injury or slight injury requiring no more than first aid (little or no lost work time)

Probability Scales:

- Very likely near certain to occur
- Likely can occur
- Unlikely not likely to occur
- **Remote** so unlikely as to be near zero

Annexure - III

Our Ref:	. BO/CML-
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Date:

Subject: Non-conformity of sample pertaining to CM/L for (Product name) as per (Indian Standard)

M/s

Madam/Sir,

- 2) In accordance with the provisions of clause (a)/(d)* of sub-paragraph (6) of Paragraph 3 of Scheme-I of Schedule-II under the BIS (Conformity Assessment) Regulations, 2018, a factory/market* sample mentioned below was drawn and found not conforming to the requirements of the standard during third party testing (copy of test report is enclosed).

Particulars of sample: Name of the product: Batch/Control Unit (C.U.)/Lot No.: Size/Variety/Type/Grade: Source: Factory/Market Sample (purchase details)

Date of manufacturing: Date of sampling:

Name of Laboratory	Test Report No	Requirements non-conforming	in	which	sample	is

- 5) You are, further, required to inform BIS within 15/30[†] days of the issuance of this letter, the details of corrective actions taken along with applicable supporting evidence failing which your case may be processed for imposition of suspension. You are also required to inform the production schedule of the product as per the improved process for verification of corrective actions by BIS.
- 6) A sum of ₹ (plus applicable taxes) shall be payable to BIS, in advance, towards the special inspection charges.
- 7) You are also required to retest the other available stock and ensure conformity to the relevant standard(s) before dispatch. Record of such retesting shall be maintained.
- 8) It may also be noted that the Bureau may suspend the BIS certification licence according to the provisions of the clause (a) of sub-paragraph (5) of Paragraph 11 of Scheme-I of Schedule-II under the BIS (Conformity Assessment) Regulations, 2018 if any other sample (after completion of corrective action) is found not conforming to the relevant standard(s).
- 9) Kindly acknowledge the receipt and ensure compliance.

Signature of designated authority (Name of designated authority)

Encl: As stated.

- * Strike off (factory or market) whichever is not applicable.
- [@] Strike off where not applicable
- *†* In case of product recall notice, only 15 days to be given. Otherwise, 30 days.

Annexure - IV

Our Ref: BO/CML-	Date:
Subject: Non-conformity of sample pertain	ing to CM/L for
(Product name) as per (In	dian Standard)

M/s

Madam/Sir,

- 1) This has reference to the BIS Certification Marks Licence No. CM/L granted to you for use of the BIS Standard Mark (2) on (Product name) according to IS which is valid up to.....
- 2) A surveillance inspection was carried out at your factory premises on...... During the visit, a sample as per details mentioned below was tested in the laboratory of your factory and found not conforming to the requirements of the standard. (copy of test report is enclosed)

Particulars of sample: Name of the product: Batch/Control Unit (C.U.)/Lot No.:

Date of manufacturing: Size/Variety/Type/Grade:

Sl. No.	Requirement	Clause	IS Reference	Specified requirement	Observed value(s)

3) [@]Further, a risk assessment analysis about the impact of non-conformity of product on public health/safety was undertaken at BIS. Considering the impact of failure in parameters on public health/safety, you are hereby directed to furnish an explanation as to why orders should not be issued to recall the non-conforming material pertaining to the Batch/C.U./Lot No. (refer paragraph 2 above) from market/dealer/distributor/purchaser in accordance with the sub-section 6 of section 18 of the BIS Act, 2016 and sub-regulation 5 of regulation 6 of the BIS (Conformity Assessment) Regulations, 2018. Also, you are advised NOT to dispatch the material and inform the quantity available in your stock pertaining to this non-conforming Batch/C.U./Lot No.

- 5) You are, further, required to inform BIS within 15/30[†] days of the issuance of this letter, the details of corrective actions taken along with applicable supporting evidence failing which your case may be processed for imposition of suspension. You are also required to inform the production schedule of the product as per the improved process for verification of corrective actions by BIS.
- 6) A sum of ₹ (plus applicable taxes) shall be payable to BIS in advance towards the special inspection charges.
- 7) You are also required to retest the other available stock and ensure conformity to the relevant standard(s) before dispatch. Record of such retesting shall be maintained.
- 8) It may also be noted that the Bureau may suspend the BIS certification licence according to the provisions of the clause (a) of sub-paragraph (5) of Paragraph 11 of Scheme-I of Schedule-II under the BIS (Conformity Assessment) Regulations, 2018 if any other sample (after completion of corrective action) is found not conforming to the relevant standard(s).
- 9) Kindly acknowledge the receipt and ensure compliance.

Signature of designated authority (Name of designated authority)

Encl: as stated.

[@] Strike off where not applicable

† In case of product recall notice, only 15 days to be given. Otherwise, 30 days.

Annexure - V

Our Ref: BO/CML-			Date:	
Subject: Directions for (Product name	•	-		for

M/s

Kind Attn: (Name of the CEO/MD)

Madam/Sir,

- 2) As informed earlier vide our letter dated the sample with below mentioned particulars was found non-conforming (copy of test report is enclosed):

Particulars of sample:Date of manufacturing:Name of the product:Date of manufacturing:Batch/Control Unit (C.U.)/Lot No.:Date of sampling:Size/Variety/Type/Grade:Source: Factory/Market Sample (purchase details)

 Name of Laboratory
 Test Report No
 Requirements in on-conforming
 which sample is

 Image: A state of the s

- 3) Further, you were also advised to furnish an explanation as to why orders should not be issued to recall the non-conforming material pertaining to Batch/C.U./Lot No. (refer paragraph 2 above) from market/dealer/distributor/purchaser. The explanation submitted by your firm vide letter dated has not been found satisfactory due to following: (BO to mention reasons)
- 4) Accordingly, you are hereby directed to take appropriate action to recall the non-conforming material pertaining to the Batch/C.U./Lot No. (refer paragraph 2 above) from market/dealer/ distributor/purchaser in accordance with the sub-section 6 of section 18 of the BIS Act, 2016 and sub-regulation 5 of regulation 6 of the BIS (Conformity Assessment) Regulations, 2018.

- 5) You are further required to inform BIS within 15 days of the issuance of this letter, plan of action for product recall of the non-conforming Batch/C.U./Lot No. including likely date by which non-conforming Batch/C.U./Lot No. of product would be recalled, failing which your case may be processed for imposition of suspension.
- 6) After completion of actions as per plan of product recall, you shall be required to submit a report about compliance to the plan including efforts made and actual quantity recalled with evidence. You shall also maintain appropriate records with supporting evidence for recalled products including the actions taken like Repair/Replacement/Reprocessing/ Disposal etc. for verification by BIS.
- 7) 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)

<u>Annexure - VI</u>

<BO letterhead content with contact details>

PUBLIC ALERT FOR PRODUCT RECALL

This is to bring to the notice of the general public that the manufacturer with details as given below has been advised for product recall in view of the non-conformities observed in the product w.r.t. the requirements stipulated in relevant Indian Standard and the non-conformities have an impact on public health/safety:

Manufacturer Name and Address	
BIS Product Certification Licence No.	
Name of the Product	
Indian Standard No.	
Grade/Type/Variety/Class/Size/Rating	
Non-conforming parameter	
Clause No. of the Indian Standard	
Type of risk	
Brand Name	
Batch/Control Unit (C.U.)/Lot No.	
Date of Manufacturing	
	Head (Branch Office) Bureau of Indian Standards Date of order:
Use "BIS CARE" App to check the authority	enticity of Standard Mark () products.

<u>Annexure - VII</u>

(Examples of non-conformity and type of risk - for illustration purposes only)

Sr. No.	IS No.	Product	Non-conforming parameter	Type of risk
i	694 : 2010	PVC insulated unsheathed and sheathed cables/cords with rigid and flexible conductor for rated voltages ≤ 1100 V	High voltage test Tensile strength of insulation Insulation resistance Insulation thickness Conductor resistance	Electric hazard Electric hazard Electric hazard Electric hazard Electric hazard & Fire hazard
ii	269 : 2015	OPC cement	Insoluble Residue Chloride Magnesia Soundness Setting time Compressive Strength Drying Shrinkage	Structural hazard
iii	1489 (Part 1) : 2015 1489 (Part 2) : 2015	PPC cement - fly ash based PPC cement- calcined clay based	Insoluble Residue Chloride Magnesia Soundness Setting time Compressive Strength Drying Shrinkage	Structural hazard
iv	9873 (Part 1) : 2019		Physical or Mechanical Safety requirements	Choking hazard

			- like small parts test and expanding materials test	
		Toys	Physical or Mechanical Safety requirements - other tests	Physical hazard
v	9873 (Part 3) : 2017 9873 (Part 9) : 2017		Chemical Safety requirements	Toxicity hazard
vi	15644 : 2006		Electrical Safety requirements	Electric hazard
vii	15298 (Part 2) : 2016	PPE - safety footwear	Basic design and performance requirements of whole footwear or parts like upper, insole, outsole, lining such as height of upper, toe protection, Tear strength, Flexing resistance, Abrasion resistance, slip resistance bond strength etc.	Physical hazard
			Chemical safety requirements like pH value, Chromium VI content, Innocuousness	Toxicity hazard

<u>Annexure - VIII</u>

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,

- 2) The following product non-conformities have been observed with regard to the operation of the above licence which is a violation of the condition of licence given under provision of Regulation 6 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 product non-conformities 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 charges.
- 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.

7) Kindly acknowledge the receipt and ensure compliance.

Thanking You,

Signature of designated authority (Name of designated authority)

Encl.: As above

<u>Annexure - IX</u>

Our Ref: BO/CML-

Date:

Subject: Suspension of CM/L for (Product name) as per (Indian Standard)

M/s

Kind Attn: (Name of the CEO/MD)

Madam/Sir,

- This has reference to the BIS Certification Marks Licence No. CM/L granted to you for use of the BIS Standard Mark (19) on (Product name) according to IS which is valid up to
- 2) Further, reference is invited to suspension notice dated giving you 10 days time to submit an explanation response.
- 3) 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 by suitable means like speed post/e-mail/online portal. You are also advised to submit us the following details as on the date of receipt of communication:
 - i) Quantity of material with Standard Mark held in stock:
 - ii) (a) Batch/Control Unit (C.U.)/Lot 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

4) [@]Further, a risk assessment analysis about impact of non-conformity of product on public health/safety was undertaken at BIS. Considering the impact of failure in parameters on public health/safety, you are hereby directed to furnish an explanation as to why orders should not be issued to recall the non-conforming material pertaining to the Batch/C.U./ Lot No. (......)* from market/dealer/distributor/purchaser in accordance with the sub-section 6 of section 18 of the BIS Act, 2016 and sub-regulation 5 of regulation 6 of the BIS (Conformity Assessment) Regulations, 2018. Also, you are advised NOT to dispatch the material and inform the quantity available in your stock pertaining to this non-conforming Batch/C.U./Lot No.

5) #Further, you were also advised to furnish an explanation as to why orders should not be issued to recall the non-conforming material pertaining to Batch/C.U./Lot No. (refer paragraph 2 above) from market/dealer/distributor/purchaser. The explanation submitted by your firm vide letter dated has not been found satisfactory due to following:

(BO to mention reasons)

- 6) #Accordingly, you are hereby directed in accordance with the sub-section 6 of section 18 of the BIS Act, 2016 and sub-regulation 5 of regulation 6 of the BIS (Conformity Assessment) Regulations, 2018 to take appropriate action to recall the non-conforming material pertaining to the Batch/C.U./Lot No. (refer paragraph 2 above) from market/dealer/ distributor/purchaser under intimation to this Branch Office of BIS in accordance with the sub-section 6 of section 18 of the BIS Act, 2016 and sub-regulation 5 of regulation 6 of the BIS (Conformity Assessment) Regulations, 2018.
- 7) #You are further required to inform BIS within 15 days of the issuance of this letter, plan of action for product recall of the non-conforming Batch/C.U./Lot No. including likely date by which non-conforming Batch/C.U./Lot No. of product would be recalled, failing which your case may be processed for imposition of suspension.
- 8) #After completion of actions as per plan of product recall, you shall be required to submit a report about compliance to the plan including efforts made and actual quantity recalled with evidence. You shall also maintain appropriate records with supporting evidence for recalled products including the actions taken like Repair/Replacement/Reprocessing/ Disposal etc. for verification by BIS.
- 10) You are further required to inform BIS within 15/30⁺ days of the issuance of this letter

i) the details of corrective actions taken along with applicable supporting evidence

ii) the quantity available in your stock pertaining to non-conforming Batch/C.U./Lot No.

, failing which it will be presumed that you do not have such material in stock. In case it is subsequently found that you have dispatched or sold the material with Standard Mark after receipt of BIS instructions of suspension, it will be construed that the material so sold has been manufactured and marked subsequently contravening the provisions of 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.

- 11) 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.
- 12) You are advised to produce a fresh Batch/C.U./Lot No. after taking necessary actions and confirm your readiness for the visit by BIS to consider revocation of suspension.
- 13) A sum of ₹..... (plus applicable taxes) shall be payable to BIS in advance towards the special inspection charges.
- 14) 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 Regulation 11 of the BIS (Conformity Assessment) Regulations, 2018.
- 15) 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.

[#] Strike off where not applicable.

* The concerned Batch/C.U./Lot No./Date of manufacturing of sample pertaining to the latest of consecutive non-conformity sample to be filled.

† 15 days for compulsory BIS certification products. Other cases, 30 days.

<u>Annexure - X</u>

Our Ref: BO/CML-

Date:

Subject: Notice for Cancellation of Licence CM/Lfor......(Product Name) as per(Indian Standard)

M/s

Kind Attn: (Name of the CEO/MD)

Madam/Sir,

- 2) The following product non-conformities were observed with regard to the operation of the above licence which is in 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)

- 3) In view of the above, it is proposed to cancel 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 11 of the BIS (Conformity Assessment) Regulations, 2018.
- 4) (A)* Your licence is already under suspension w.e.f. as communicated vide our letter dated It is to reiterate that during the suspension, you are not permitted to use and apply the Standard Mark and dispatch (including stock in hand) the above mentioned product with Standard Mark. You are advised to re-confirm that you have stopped using and applying Standard Mark by suitable means like speed post/e-mail/online portal. You are also advised to submit us the following details as on the date of receipt of communication:

(B)*In view of the above you are, henceforth, not permitted to use and apply the Standard Mark and dispatch (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 by

suitable means like speed post/e-mail/online portal. You are also advised to submit us the following details as on the date of receipt of communication:

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

- 5) 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.
- 6) 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.
- 7) 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

Annexure - XI

Our Ref: BO/CML-

Date:

Subject: Cancellation of BIS Certification Licence CM/L for...... (Product name) as per (Indian Standard)

M/s

Madam/Sir,

- 2) Further, reference is invited to cancellation notice dated, your reply dated and personal hearing held on
- It has been decided to cancel your Licence after as per the provision of Regulation of the BIS (Conformity Assessment) Regulations, 2018 due to the following reasons: (BO to mention the reasons)
- 5) Any publicity material such as handbills, pamphlets, letterheads, etc. claiming that you hold BIS Product Certification Licence for your above mentioned product should be destroyed or such markings obliterated/defaced immediately. This should be confirmed by you at the earliest, positively within 15 days.
- 6) Further, you are advised to furnish a statement of (Product name) with Standard Mark as follows:
 - i) Quality held in stock:
 - a) Type or Grade
 - b) Variety
 - 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)

<u>Annexure - II</u>

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

- 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
 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 9 of suspension]	(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 <i>Annexure - III</i>). If response is received, then further action shall be taken as per para 10 and 11.
Visit to check compliance of suspension		(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:
orders		(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)	(1 1	(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.
	1	(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 <i>Annexure - II</i>) 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 <i>Annexure - IV</i> .
		(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 of revised Indian	16.	(i) In case of non-implementation of revised Indian Standard, amendment to Indian Standard, suspension shall be imposed, if-

Standard

(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 1	6,
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(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.

Cancellation18.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 for19.(i) The cancellation of a licence shall be done as per Regulation 11 of the BIScancellation(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*).

Cancellation20. (i) For the following cases, the licence may not be put under suspension
during the issuance of cancellation notice:

notice without suspension (specific cases) (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
cancellation21. (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:

- 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.
- 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.

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.

Suspension in vogue for more than a year

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 <i>Annexure - IX</i> 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.

<u>Annexure - I</u>

Our Ref: BO/CML-

Date:

Subject: Unsatisfactory performance pertaining to Licence CM/L for (Product name) as per (Indian Standard)

M/s

Madam/Sir,

- A surveillance inspection was carried out at your factory premises on...... During the visit, following discrepancies in the operation of the licence were observed and communicated to you (Ref. Discrepancy-cum-Advisory Report issued during the visit, copy enclosed):
- 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.

Thanking you

Signature of designated authority (Name of designated authority)

Encl: As above

<u>Annexure - II</u>

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,

- 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.

7) Kindly acknowledge the receipt and ensure compliance.

Thanking You,

Signature of designated authority (Name of designated authority)

Encl.: As above

<u>Annexure - III</u>

Our Ref:	BO/CML-
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Date:

Subject: Suspension of Licence CM/L for (Product name) as per (Indian Standard)

M/s

Kind Attn: (Name of the CEO/MD)

Madam/Sir,

- 2) Further, reference is invited to suspension notice dated giving you 10 days time to submit an explanation response.
- 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

5) 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

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 mentioned in the Licence has been changed to with effect from

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,

- 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/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 11 of the BIS (Conformity Assessment) Regulations, 2018.

(B)*Further, you are henceforth, not permitted to use and apply Standard Mark and dispatch (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

<u>Annexure - VI</u>

Date:

Subject: Cancellation of BIS Certification Marks Licence No. CM/L for
(Product name) as per (Indian Standard)

M/s

Madam/Sir,

Our Ref: BO/CML-

- This has reference to the BIS Certification Marks Licence No. CM/L granted to you for use of BIS Standard Mark (2) on...... (Product name) according to IS...... which was valid up to
- 2) Further, reference is invited to cancellation notice dated, your reply dated and personal hearing held on
- 3) It has been decided to cancel your Licence after as per the provision of Regulation of the BIS (Conformity Assessment) Regulations, 2018 due to the following reasons:

(BO to mention the reasons)

- 4) Your above mentioned licence, therefore, stands cancelled w.e.f......You are therefore not entitled to mark/ dispatch your product (Product name) as 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 II Mark on your product after
- 5) Any publicity material such as handbills, pamphlets, letterheads, etc. claiming that you hold BIS Product Certification Licence for your above mentioned product should be destroyed or such markings obliterated/defaced immediately. This should be confirmed by you at the earliest, positively within 15 days.
- 6) Further, you are advised to furnish a statement of (Product Name) with Standard Mark as follows:

i) Quality held in stock:

- a) Type or Grade
- b) Variety
- 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 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)