BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:2 (Part 1) **28 December 2021**

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 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,

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

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 for seeking corrective actions and notice for product recall

6. The non-conformity shall be communicated to the licensee through email/speed post/IT portal with a copy of the test report normally within 15 days of receipt of test report. The communication shall also include probable causes for non-conformity for guidance to the manufacturer. After the risk 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 and review of corrective actions

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 informing about non-conformity of certified products

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 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.

(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 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 of samples

10. 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.

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

11. **(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 – VII***.

(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.

Visit to check compliance of suspension orders

12. **(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.

(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.

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

13. **(i)** On receipt of complete reply, an inspection for considering RoS shall be 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 Revocation of Suspension (RoS)

(iv) If all the requirements in which non-conformity was reported can be tested in the factory in one or two day(s), then sample from the 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.

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

Processing RoS

14. **(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 product recall directions

15. If during the inspection visits (special inspection visit 7(v), RoS visit 13(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.

Intentionally using Standard Mark on non-conforming goods

16. **(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.

(ii) If explanation is found to be satisfactory, the RoS shall be done as per as per para 13, 14.

Suspension on establishment of complaint or on account on unsatisfactory feedback

17. **(i)** If a complaint regarding quality of any goods or article bearing the Standard 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 with cancellation notice

18. The licence may be put under suspension when the cancellation proceedings are initiated against a licensee.

Proceedings for cancellation

19. **(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 ***Annexure - VIII***).

(iii) The competent authority shall pass speaking orders for decision taken.

(iv) The decision to cancel the licence shall be communicated to the licensee (template of the letter attached as ***Annexure - IX***).

Suspension in vogue for more than a year

20. The licence may be cancelled without giving any further notice if licence has been under suspension for more than a year.

Product specific guidelines

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

Inspection fee

22. 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

23. 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

24. 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 ***Annexure - IX*** of grant of licence guidelines).

Discreet visit

25. 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

(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)	

Annexure - I

(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), *For example*: 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, *For example*, 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 is indicated below. 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 of occurrence of harm	**Severity (Consequence) 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- **Date:**

Subject: Non-conformity of sample pertaining to CM/L ..... for ……. (Product name) as per …….. (Indian 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 ( ) on ..... (Product name) according to IS ..... which is valid up to …….

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: 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 which sample is non-conforming

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.

4) You are required to investigate the reasons for non-conformity by reviewing your quality assurance system and to take appropriate corrective actions which are relevant to the observed non-conformities. Some probable causes that could have led to occurrence of this non-conformity may be attributed (but is not limited) to ..... You may test the improved product after the corrective actions have been taken to ensure that the actions taken are appropriate and relevant to prevent recurrence of non-conformities observed.

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 pertaining to CM/L …… for …….. (Product name) as per …….. (Indian 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 ( ) 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: Date of manufacturing:
Batch/Control Unit (C.U.)/Lot No.: 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.

4) You are required to investigate the reasons for non-conformity by reviewing your quality assurance system and to take appropriate corrective actions which are relevant to the observed non-conformities. Some probable causes that could have led to occurrence of this non-conformity may be attributed (but is not limited) to ..... You may test the improved product after the corrective actions have been taken to ensure that the actions taken are appropriate and relevant to prevent recurrence of non-conformities observed.

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 recall in respect of 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 the BIS Standard Mark ( ) on …… (Product name) according to IS ……. which is valid up to …….

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:
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 which sample is non-conforming

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)

Annexure - VI

<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	
Brand Name	
Batch/Control Unit (C.U.)/Lot No.	
Date of Manufacturing	

Head

(..... Branch Office)

Bureau of Indian Standards

Use "BIS CARE" App to check the authenticity of Standard Mark ( ) products.

Annexure - VII

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,

1) This has reference to the BIS Certification Marks Licence No. CM/L …… granted to you for use of the BIS Standard Mark ( ) on …… (Product name) according to IS ……. which is valid up to …….

2) Due to the ..... (BO to mention reasons and details of non-conformities) and in accordance with 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, it has been decided to put your licence under suspension with immediate effect.

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.

9) You are required to investigate the reasons for non-conformity by reviewing your quality assurance system and to take appropriate corrective actions which are relevant to the observed non-conformities. Some probable causes that could have led to occurrence of this nonconformity may be attributed (but is not limited) to .....
You may test the improved product after the corrective actions have been taken to ensure that the actions taken are appropriate and relevant to prevent recurrence of non-conformities observed.

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.

Annexure - VIII

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 the BIS Standard Mark ( ) on ……. (product name) according to IS……which is valid up to……..

2) The following serious discrepancies 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) 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

Annexure - IX

Our Ref: ..... BO/CML- **Date:**

Subject: Cancellation of BIS Certification Licence CM/L …..…… for……. (Product name) as per .....……. (Indian 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 ( ) on ……. (product name) according to IS ……..... which was valid up to……..

2) The Competent Authority has 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)

3) 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 BIS Standard Mark ( ) on your product after …….

4) 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.

5) 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

6) 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.

7) 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.

8) 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.

9) Please acknowledge the receipt and ensure compliance.

Signature of designated authority
(Name of designated authority)