BUREAU OF INDIAN STANDARDS
(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:2 (Part 1) **25 February 2026**

Subject: Guidelines for dealing with non-conformity of product(s) observed during operation of licence under Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018 - reg.

Section-I : Introduction

Available provisions

1. 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, risk assessment, 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 said Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs).

Section-II : Handling test reports

Receipt of test reports

2. The test reports of samples drawn during factory visits and market surveillance are received at BOs dashboard through Laboratory Information Management System (LIMS).

Examination of test reports

3. **(i)** The test reports shall be examined and recorded as 'Conforming or Non-conforming' in the IT portal normally within 5 working days from date of receipt of test report. In case of non-conforming test report, the requirements (parameters as well as clause number) in which the sample is non-conforming shall also be recorded with requisite entry(ies) in the IT portal.

Note: In case, the grade/type/class/variety etc. is not marked on the sample (where it is a requirement of labelling and marking as per Indian Standard/Scheme of Inspection and Testing SIT), such samples may be got tested/evaluated against the most stringent grade/type/class/variety etc. covered in the Standard, unless the applicable grade/type/class/variety etc. is apparently distinguishable and technically appropriate.

(ii) The Head (BO) shall monitor the adherence of time norms for examination of test reports.

1st / non-consecutive non-conformity

4. **(i)** The non-conformity of product in Third Party Laboratory (TPL) or Factory Testing (FT) shall be treated as first/non-consecutive non-conformity, if the previous test report of surveillance sample (based on date of drawl) is found conforming.

Consecutive non-conformity

5. **(i)** Any non-conformity of product in TPL or FT shall be treated as a consecutive non-conformity if its date of drawl is after the date of intimation of corrective actions on first non-conformity and there is no 'conforming' test report of surveillance sample in between.

Section-III : Review of Performance

Review of performance (RoP)

6. **(i)** When any non-conformity of sample is observed, either in TPL or FT, a comprehensive RoP shall be prepared wherein following actions shall be undertaken (RoP shall be self-contained detailing the grounds for proposing suspension or cancellation, and the relevant provisions of the Regulations):

(a) Determining whether it is a consecutive or 1st / non-consecutive non-conformity of product

(b) Risk assessment analysis of non-conformity(ies) observed

(c) All non-conformity to be recorded as critical unless otherwise specified as non-critical.

(d) All test reports received in past 2 years from the date of receipt of latest test report (i.e. from date of uploading on the portal) indicating non-conformity and samples drawn shall be listed in the RoP.

(e) %age of samples tested found non-conforming in critical requirements shall be determined taking into account test reports of all surveillance samples received in past 2 years as per (d) above

(f) Record and assess licensee's performance based on outcomes of surveillances in past 2 years with details of corrective actions taken by licensee and special inspection visits carried out

(g) If deviation is observed in labelling and marking requirements, the same shall be reviewed as per para 7

(h) Other actions like corrective actions to be taken, product recall instructions (as necessary) with recommendations for operation of licence

The decision on RoP shall normally be completed within five working days from the date of recording of non-conformity. For cases where the period since grant of licence is less than 2 years, then also provisions of this guidelines document shall be applicable.

Labelling and marking requirements

7. **(i)** Any deviation observed in requisite labelling and marking requirements (specified in Indian Standard or SIT or both) shall not be treated as sample non-conformity unless otherwise specified. However, the RoP for the same shall be put up keeping in account observations from factory & market surveillance reports and depending upon seriousness of deviation, necessary action shall be taken as per provisions of the BIS (Conformity Assessment) Regulations, 2018.

(a) For minor deviations like in requirements for marking of batch no./C.U./lot no./D.O.M. (non-food products)/grade/type/variety/ product booklet/ operating instructions etc. - In the 1st instance and 2nd instance, corrective actions shall be sought. In the 3rd instance, notice for suspension shall be issued.

(b) For major deviations like in requirements for marking of D.O.M./Expiry date (food products), Safety labelling, BIS licence number, IS number etc. - In the 1st instance, corrective actions shall be sought. In the 2nd instance, notice for suspension shall be issued.

(c) For multiple repeated (4 opportunities already given for improvements to the manufacturer) instances of deviation in any labelling and marking requirements which are related to safety and health of consumers (irrespective of major/intermediate/minor), the case may be put up to consider initiating proceedings for cancellation of licence.

Note: For determining 2nd or 3rd or 4th instance for deviation in labelling and marking requirements, all instances in previous 2 years duration from the date of reporting of current deviation shall be used.

Section-IV (A) : Corrective actions for product non-conformity

Communication to the manufacturer

8. **(i)** The cases involving

(a) first/non-consecutive non-conformity in any requirement or

(**b**) consecutive (2nd) non-conformity with one of them in non-critical requirement or

(c) consecutive (2nd) non-conformity with both of them in non-critical requirement,

corrective actions shall be sought from the manufacturer.

(ii) However, if the overall past 2 years performance indicates non-conformities in more than 1/3rd test reports of surveillance samples received, then the case shall be processed for initiating necessary action as per applicable provisions given in this document. The test reports of conforming revocation of suspension sample(s) shall not be counted for the purpose of assessing the percentage.

(iii) The non-conformity shall be communicated to the manufacturer through the IT portal and may be followed by speed post/email with a copy of the test report normally within 15 working days of receipt of the test report. A template letter for seeking corrective actions is attached as ***Annexure-I*** (TPL) and ***Annexure-II*** (FT). The manufacturer 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 is part of communication, only 15 days to be given. Otherwise, 30 days. Issuance of product recall notice and instructions are covered in section-IV(B).

(iv) Alongwith the corrective actions, the manufacturer shall submit an in-house (including cluster based or shared facilities) test report of the same variety as supporting evidence to demonstrate effectiveness of corrective actions. This test report shall include routine tests and requirements where non-conformity has been observed.

(v) The manufacturer also has the option to submit test reports from outside laboratories which are recognised/ empanelled by BIS or accredited as per ISO/IEC 17025 in place of in-house test report.

(vi) In case the manufacturer is not in a position to submit test report within prescribed time (15/30† days), then the evidence of sample under test shall be submitted. The likely timeframe for submission of test report to BIS shall also be informed.

(vii) Such test report shall include all the parameters excluding long duration tests where testing time exceeds 30 days (1 month). It shall be the responsibility of the manufacturer to submit this test report within 45 days from the date of communication of non-conformity.

Receipt of reply and review of corrective actions

9. **(i)** On communication of non-conformity of product by BIS, it shall be the responsibility of manufacturer to take corrective actions including withdrawing non-conforming products from the market.

(ii) When the corrective actions and reply to product recall notice (if applicable) are received within 15/30† days, the drawl of market samples shall be planned to monitor performance of licence. For the cases where the recall notice was also issued, the matter shall also be put up to the Head (BO).

Non-receipt of corrective actions

10. **(i)** The onus of taking corrective actions rests with the manufacturer. If corrective actions are not received within 30 days, then it shall be presumed that the manufacturer has taken the corrective actions and an immediate market surveillance shall be planned. If required, an early visit may be planned by the Head (BO).

Market surveillance for verification of implementation of corrective actions - Drawl of sample for TPL testing

(ii) For the purpose of drawl of market sample, surveillance shall be carried out normally within the next 60 days. Sample(s) of the variety(ies) found non-conforming shall be drawn for TPL testing. In case sample of such variety(ies) are not available, then other variety sample shall be drawn from the market. As a last resort, market sample may be drawn from any point in the supply-chain including the dispatch point.

(iii) For products covered under FT basis operation or not amenable for drawl of samples from open market, an early surveillance inspection visit shall be planned and carried out normally within next 60 days.

(a) For such cases, Head BO shall arrange for early surveillance preferably by BIS officer or through Technical Auditors of the empanelled agencies through CSMD.

(b) During this surveillance visit, in addition to regular assessment, corrective actions reported by the licensee shall also be verified. The report for such a surveillance visit shall highlight whether the corrective actions taken by licensee are found to be implemented satisfactorily.

(c) If the corrective actions communicated by licensee are not found to be implemented satisfactorily, then the case may be considered for initiating suspension through issuance of notice.

(d) In case during this surveillance, factory testing could not be done like non-availability of stock, the BO may plan another surveillance preferably at the earliest.

Section-IV (B) : Risk assessment - For products notified for compulsory BIS certification

Risk assessment

11. **(i)** Upon receipt of information about 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 take decision on issuance of product recall notice based on the recommendation of a committee of officer(s) constituted at BO level. For the same product with similar non-conformity, the earlier decision may be referred to by Head (BO) for taking the decision.

(ii) 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.

(iii) The committee shall carry out the risk assessment analysis and provide its recommendations for issuance/non-issuance of product recall notice. The RoP put up (inline with section-II) for consideration of Head BO shall inter-alia include findings of risk assessment analysis and recommendations of the committee towards issuance of product recall notice. For more details on product recall, refer section-IX of this document.

(iv) 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).

Section-V : Notice and imposition of suspension

Provisions for imposition of suspension

12. Whenever a non-conforming test report is received, a comprehensive RoP shall be put up which shall enlist all samples drawn and test report received in last 2 years from the date of uploading of latest non-conforming test report. Suspension may be imposed in the cases of

(i) 1st non-conformity of food products non-conforming in requirement(s) of toxicity or pesticide residues or radioactive residues etc. or as per product specific guidelines

(ii) consecutive 2nd critical non-conformity of samples

(iii) consecutive 3rd non-conformity of samples (either critical or non-critical)

Suspension due to intentional or repeated use of Standard Mark on non-conforming goods

(iv) Repeated non-conformities with more than 1/3rd of test reports (FT for products operated solely on FT basis, TPL for other products) of surveillance samples (with atleast 3 surveillance samples drawn and test reports received) are found non-conforming in critical requirement(s) during the last 2 years.

(v) Repeated non-conformities with more than 3/4th of test reports (FT for products operated solely on FT basis, TPL for other products) of surveillance samples (with atleast 4 surveillance samples drawn and test reports received) are found non-conforming in any (non-critical or critical) requirement(s) during the last 2 years.

(vi) Evidence that non-conforming goods with Standard Mark are being produced intentionally and repeatedly.

Note: While preparing RoP, actions as per para 19(iii)(a) may also be ensured. Also, for cases where the period since grant of licence is less than 2 years, the provisions of this guidelines document shall be applicable.

Notice for suspension

13. **(i)** Before imposition of suspension for the reasons listed under para 12, a notice shall be issued (along with a copy of test reports) 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-III***)

(ii) (a) In case no reply is received within stipulated time, the suspension shall be imposed.

(b) A. In case reply is received within stipulated time, it shall be examined and reviewed by the Head BO. While considering the reply towards notice for suspension, the Head BO should also consider the quality assurance system being followed and implemented by the manufacturer for its routine production to ensure consistent quality production as per relevant Indian Standard. The information available with BIS including from previous surveillance reports may be taken into account for the same.

B. For cases where the requisite corrective actions along with inspection charges have been received and improved material of latest variety reported non-conforming has been offered, the case may not be processed for suspension. For cases where it is decided not to impose suspension, the case shall be taken up for verification of corrective actions within the next 20 days and visit shall be planned by Head BO.

C. 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.

D. In case, the reply received is partial or incomplete and the manufacturer does not provide corrective actions, doesn't offer improved material of latest variety reported non-conforming, special inspection charges or facilitate special inspection within 20 days, the case may be processed for suspension without any further notice.

(iii) For details about visit to be carried out for verification of corrective actions after issuance of notice for suspension, refer para 16.

Communication of suspension, seeking corrective actions and issuance of product recall notice or directions

14. **(i)** The decision of suspension shall be communicated to the manufacturer through the IT portal and may be followed by speed post/email with a copy of the test report normally within 15 days of receipt of the test report. A template letter is attached as ***Annexure-IV***.

(ii) As applicable, the information regarding product recall notice or product recall order (refer section-IX) shall also be included in the suspension intimation letter.

Visit to check compliance of suspension orders

15. **(i)** The 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.

(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 be taken as per provisions.

Section-VI : Revocation of suspension (RoS) / Continuation of normal operation after notice for suspension

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

16. **(i)** On receipt of complete reply, an inspection for considering RoS or allowing continuation of normal operation after issuing notice for suspension shall be organised by the Head (BO) normally within 15 days. The visit shall be carried out by BIS officer. However, BO Head may get the visit done from Technical Auditors of empanelled agencies through CSMD with proper justification in case of any specific exigencies/ situations. Such cases shall also be brought to the notice of DDGR who may consider nominating any officer from other BOs under his jurisdiction.

(ii) During the inspection, following activities shall be carried out:

(a) Verification of corrective actions taken by the manufacturer. The verification of actions shall also include the implementation of corrective actions taken by the manufacturer to avoid non-conformity of product and plan of action on product recall, as applicable.

(b) Compliance to the Quality Assurance Plan declared by the manufacturer or SIT accepted by the manufacturer since last surveillance inspection visit shall be checked and reported.

(c) If suspension was imposed, then compliance to suspension order shall also be checked during the visit and reported.

Inspection for verification of corrective actions (after suspension notice) or visit for Revocation of Suspension -

(d) If all the requirements in which non-conformity was reported can be tested in the factory in two days, 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. If it is felt that only one day factory visit is sufficient, then the same may be duly justified and recorded by Head BO.

Manufacturers with in-house test facility

A. The manufacturers having in-house test facility for requirement(s) in which non-conformity was/were reported may even opt to request BIS for factory visit for a higher number of days (either continuous or intermittently depending upon the requirement) to witness the conduct of concerned tests. BO Head may consider such requests for a decision provided testing time is only upto 30 days (one month).

B. The manufacturers who have made arrangements in vicinity of their premises, where it is possible to make visits in same day as that of manufacturing premises, BO Head may consider such cases at par with those having in-house test facility.

C. In case the manufacturer doesn't opt to request BIS for factory visit for higher number of days (for products with testing time more than 2 days) or BO Head has not agreed for factory visit for higher number of days, then a sample shall be drawn for TPL testing and an undertaking shall be taken that in case any of the sample drawn for TPL testing during this visit is found to be non-conforming, licence shall be liable for cancellation.

Inspection for verification of corrective actions (after suspension notice) or RoS - Manufacturers without in-house test facility

(e) For manufacturers who do not have in-house test facility, a 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).

Processing RoS or continuation of normal operation

17. **(i)** The inspection report and test reports (FT or TPL, as applicable) shall be reviewed for processing RoS or continuing the normal operation of licence.

Processing RoS or continuation of normal operation of licence - Manufacturers without in-house test facility

(ii) RoS or continuation of normal operation of licence may be processed if

(a) the corrective actions have been found to be implemented satisfactorily, and

(b) sample shows conformity in FT or undertaking submitted as per para 16(ii)(d)B for samples under test at TPL (as the case may be) and

(c) the manufacturer has provided inputs on product recall plan (if applicable) and its implementation as per plan verified during the visit.

Processing RoS or continuation of normal operation of licence - Manufacturers with in-house test facility

(iii) RoS or continuation of normal operation of licence shall normally be processed within 7 days and the manufacturer shall be advised to submit a detailed report on product recalled (if applicable).

(iv) RoS or continuation of normal operation of licence may be processed if

(a) the corrective actions have been found to be implemented satisfactorily, and

(b) sample shows conformity in TPL and

(c) the manufacturer has provided inputs on product recall plan (if applicable) and its implementation as per plan verified during the visit.

(v) RoS or continuation of normal operation of licence shall normally be processed within 7 days of receipt of test report (including long duration test, if applicable) and the manufacturer shall be advised to submit a detailed report on product recalled (if applicable).

Non-conforming sample for verification of corrective actions (after suspension notice) or RoS sample

(vi) If the sample tested shows non-conformity in any requirement in TPL or FT, then the suspension shall be imposed immediately or continued and another opportunity may be given to manufacturer for corrective actions by the Head BO. However, if the sample shows non-conformity again, proceedings for cancellation may be initiated as per para 20 after taking a review of overall performance of licensee in last 2 years.

Review of product recall directions

18. If during the inspection visits (surveillance visit, RoS visit 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 implementation report on completion of all actions for review by the BO.

Section-VII : Cancellation of licence

Provisions for cancellation

19. **(i)** The cancellation of a licence shall be done as per the Regulation 11 of BIS (Conformity Assessment) Regulations, 2018.

Suspension in vogue 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.

Cancellation due to intentional or repeated use of Standard Mark on non-conforming goods

(iii) In case there is evidence that non-conforming goods with Standard Mark are being produced repeatedly, the proceedings for cancellation of licence may be initiated with suspension of licence in following cases:

(a) More than half of test reports of surveillance samples (with atleast 4 surveillance samples drawn and test reports received) found non-conforming in critical requirement(s) in independent testing during the last 2 years

(b) Continuous three or more surveillance samples found non-conforming in critical requirements, provided atleast one opportunity for corrective actions before the date of drawl of latest sample found non-conforming in succession is given during the period under review

Note: For cases where the period since grant of licence is less than 2 years, then also provisions of this guidelines document shall be applicable.

(iv) In case there is evidence that non-conforming goods with Standard Mark are being produced intentionally and repeatedly.

Proceedings for cancellation

20. **(i)** 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 in the cancellation notice.

(a) In case no reply is received within stipulated time, the licence may be cancelled.

(b) DDGR may consider giving an opportunity to the manufacturer for making improvements through corrective actions at the first instance within last three years of cancellation proceedings, which may be considered based on the following:

(A) nature of product and impact of the non-conformity

(B) extent of repeated non-conformities vis-a-vis overall number of samples drawn

(C) adherence to declared QAP or accepted SIT

(D) prompt responsiveness and explanation provided by the manufacturer

(E) any other test report received from third party laboratory after putting up of RoP under consideration

(c) In case reply is received within stipulated time, it shall be examined and reviewed by the Head BO and submitted with his/her comments to DDGR. BO shall follow-up for acknowledgement towards receipt of cancellation notice and reply submission by manufacturer within stipulated timeframe. Where the DDGR is satisfied that it is necessary to cancel the licence, she/he shall record the reasons for cancellation of licence.

(d) If it is decided not to cancel the licence, the manufacturer shall be required to submit an undertaking on its official letterhead to strictly comply with conditions for use of BIS Standard Mark on their product. The matter shall be taken up for corrective actions and its verification as per applicable provisions of this document.

(ii) 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.

(iii) The decision to cancel the licence shall be communicated to the licensee by the Head BO (template of the letter attached as ***Annexure-VI***).

(iv) For cases with reasons for cancellation as above, where the validity date of licence has crossed, then proceedings for expiry of licence / issuance of expiry notice shall be processed by DDGR. Templates for issuance of notice for expiry / expiry letter attached as ***Annexure-XII*** and ***Annexure-XIII***.

Section-VIII : Enhanced surveillance on non-compliant manufacturers

Classifying manufacturers for enhanced surveillance

21. **(i)** In case of 1st or non-consecutive non-conformity of sample in TPL or FT, the manufacturer shall be kept under enhanced surveillance as given below:

(a) Market surveillance once every three months

This enhanced surveillance shall continue till 2 consecutive surveillance samples shows conformity in independent testing.

(ii) In case of where suspension notice is issued or suspension is done, the manufacturer shall be kept under enhanced surveillance as given below:

(a) Market surveillance once every three months

This enhanced surveillance shall continue till 3 consecutive surveillance samples shows conformity in independent testing.

Frequency for enhanced surveillance

22. **(i)** In case the desired number of surveillance samples couldn't be collected, then market surveillance may be done from any point in supply-chain till the time desired number of overall minimum surveillance samples are drawn. As a last resort visit for procurement of market sample from dispatch point may be planned.

Section-IX : Product recall provisions

Risk assessment for product recall

23. **(i)** For product recall purposes, a guidance template to undertake risk assessment analysis of non-conformity of product is enclosed as ***Annexure-VII***. Further, a guidance document on risk assessment technique is enclosed as ***Annexure-VIII***.

(ii) 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.

Product recall notice

24. **(i)** Head (BO) shall take into account the justifiability and feasibility of issuance of product recall notice and pass speaking orders regarding the decision for issuance/ non-issuance of product recall notice to the manufacturer with reasons. If it is decided to issue a product recall notice, then the notice for product recall shall also be included in the non-conformity intimation letter.

Review of reply to product recall notice

(ii) Reply and explanation received in response to the product recall notice shall be examined by the Head (BO) for taking final 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-IX***).

(iii) Explanation received against product recall notice or plan of action on product recall, as applicable, shall also be verified to the extent possible during immediate next surveillance visit. The report for such a surveillance visit shall also highlight actions taken on product recall. 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.

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

(v) If explanation to product recall notice is not received or the explanation received is not acceptable, then the directions for product recall shall be issued to the manufacturer.

(vi) If both the corrective actions towards non-conformity of sample and explanation to product recall notice are not received, in such cases, the directions for product recall shall also be included in the suspension intimation letter/notice.

Public alert informing about non-conformity of certified products

25. **(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-X***. 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-XI***.

(ii) The information about product certification licences that have been put under suspension/ cancelled or expired are made publicly available on the dashboard of e-BIS portal website. 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 BOs shall raise 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.

(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, consumer 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.

Section-X : Complaint matters

Handling complaint and feedback

26. **(i)** If a complaint regarding the quality of any goods or article bearing the Standard Mark is received and found to be established, the requisite actions shall be taken in accordance with the complaint management manual/guidelines.

(ii) The instances of receipt of adverse feedback about quality of product shall be treated on par with that of receipt of complaint.

(iii) The outcomes from complaint samples shall also be considered for putting up a comprehensive RoP. For preparation of RoP, the complaint sample(s) shall be treated as surveillance sample(s).

Section-XI : Miscellaneous General provisions

Product specific guidelines

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

Payment of testing charges

28. 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.

Inspection fee

29. 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

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

Fresh application of cancelled licences

31. The manufacturers whose licence for a product has got cancelled/expired/ surrendered due to reasons owing to non-conformity of products shall not be eligible to re-apply for BIS product certification licence under option-2 (simplified) procedure.

Provision for appeal

32. 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 grant of licence guidelines).

Discreet visit

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

Annexure-I

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

Subject: 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. (Test report can be viewed by logging into ManakOnline portal)

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. You are also required to test the product after corrective actions to ensure that the actions taken are appropriate and relevant to prevent recurrence of non-conformities observed. As a supporting evidence of corrective actions taken, test report from either your in-house laboratory or outside laboratories either recognised/empanelled by BIS or accredited by NABL is also required to be submitted.

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 (including test report or evidence of sample under test). In case it is observed that corrective actions have not been undertaken satisfactorily, then your case may be processed for imposition of suspension.

6) You are also required to inform the production schedule of the product as per the improved process for verification of corrective actions by BIS. The improved material after corrective actions is required to be made available for surveillance sample testing purposes.

7) You shall also retest the available stock produced before taking corrective actions and ensure conformity to the relevant standard(s) before dispatch. Record of such retesting shall be maintained. Efforts shall also be made to recall your product from the market which is potentially non-conforming to the requirements of relevant standard(s).

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 further any sample 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-II

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. (Test report can be viewed by logging into ManakOnline portal)

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. You are also required to 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 (in-house test report or test report from sub-contracted test facilities or evidence of sample under test). In case it is observed that corrective actions have not been undertaken satisfactorily, then your case may be processed for imposition of suspension.

6) You are also required to inform the production schedule of the product as per the improved process for verification of corrective actions by BIS. The improved material after corrective actions is required to be made available for surveillance sample testing purposes.

7) You shall also retest the available stock produced before taking corrective actions and ensure conformity to the relevant standard(s) before dispatch. Record of such retesting shall be maintained. Efforts shall also be made to recall your product from the market which is potentially non-conforming to the requirements of relevant standard(s).

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 further any sample 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-III

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

Subject: Notice for suspension of licence CM/L …… for……. (Product Name) as per ……(Indian Standard)

M/s

Kind Attn: (Name of the CEO/MD)

Madam/Sir,

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

2) i) Further, reference is invited to our earlier letter of even number dated ..... informing about product non-conformities for which corrective actions were required to be taken by your firm as informed vide letter dated .....

@ii) Reference is also invited to our earlier letter of even number dated ..... informing about product non-conformities for which corrective actions were required to be taken by your firm as informed vide letter dated .....

#iii) Reference is also invited to our earlier letter of even number dated ..... informing about product non-compliances (unsatisfactory performance inspection visit) for which corrective actions were required to be taken by your firm as informed vide letter dated .....

3) Now, again 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, another factory/market* sample mentioned below was drawn and which was also found not conforming to the requirements of the standard during third party testing. (Test report can be viewed by logging into ManakOnline portal)

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

4) The consecutive/repeated* failure of samples, as mentioned above, point towards your inability to produce conforming products consistently resulting in violation of the condition of licence given under provision of Regulation 6 of the BIS (Conformity Assessment) Regulations, 2018, your licence is liable for suspension.

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. In case no reply is received or the reply received is incomplete, your licence will be put under suspension without any further reference to you.

7) You may also submit the corrective actions taken along with following:

   i) Supporting evidence of corrective actions taken, a test report establishing relevance of corrective actions is also required to be submitted.

   ii) Production schedule of the product as per the improved process for verification of corrective actions by BIS. The improved material after corrective actions (for variety as mentioned at Sr. No. 3 above) is required to be made available for inspection and testing by BIS.

   iii) You shall retest the available stock produced and ensure conformity to the relevant standard(s) before dispatch. Record of such retesting shall be maintained. Efforts shall also be made to recall your product from the market which is potentially non-conforming to the requirements of relevant standard(s).

   iv) You are required to be ready for inspection for verification of corrective actions towards which a sum of ₹……. (plus applicable taxes) is payable to BIS in advance towards special inspection charges. You are therefore advised to deposit the same.

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

9) Kindly acknowledge the receipt and ensure compliance.

Thanking You,

Signature of designated authority
(Name of designated authority)

Encl.: As above

@ Mention all non-conformities of samples observed and communicated earlier
# Mention all non-compliances (unsatisfactory performance) observed and communicated earlier
* Select - as applicable

Annexure-IV

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

3) 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/IT portal/e-mail. 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. 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/IT portal/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-V

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

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

M/s

Kind Attn: (Name of the CEO/MD)

Madam/Sir,

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

2) i) Further, reference is invited to our earlier letter(s) of even number dated ....., ..., ... informing about product non-conformities for which corrective actions were required to be taken by your firm.

@ii) Reference is also invited to our earlier letter(s) of even number dated ....., ..., ... informing about non-compliances (unsatisfactory performance inspection visit) for which corrective actions were required to be taken by your firm.

3) The following product non-conformities and operational non-compliances were observed with regard to the operation of the above licence which are in violation of the provision of Regulation ..... of the BIS (Conformity Assessment) Regulations, 2018:

<Elaborate grounds with linkages to specific provisions of the BIS Act, 2016 and the BIS (Conformity Assessment) Regulations, 2018>

4) 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.

5) **(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/IT portal/

e-mail. 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/IT portal/e-mail. 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

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

@ Mention all non-compliances (unsatisfactory performance) observed and communicated earlier
* Select - as applicable

Annexure-VI

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) 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:

(Mention the reasons with linkages to specific provisions of the BIS Act, 2016 and the BIS (Conformity Assessment) Regulations, 2018)

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 BIS Standard 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) *For a fresh application to be submitted by your firm within two years from the date of cancellation mentioned above, the option to submit the application under option-2 (simplified procedure) is not available to your firm.

10) 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.

11) Please acknowledge the receipt and ensure compliance.

Signature of designated authority
(Name of designated authority)

*Select - only for domestic manufacturers.

Annexure-VII

(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-VII

(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)	b) Extent of non-conformity(ies) c) 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-VIII

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 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-IX

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 (Test report can be viewed by logging into ManakOnline portal):

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 with linkages to specific provisions of the BIS Act, 2016 and the BIS (Conformity Assessment) Regulations, 2018)

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-X

<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 authenticity of Standard Mark ( ) products.

Annexure-XI

(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	Toys	Physical or Mechanical Safety requirements - like small parts test and expanding materials test Physical or Mechanical Safety requirements - other tests	Choking hazard 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. Chemical safety requirements like pH value, Chromium VI content, Innocuousness	Physical hazard Toxicity hazard

Annexure-XII

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

Subject: Notice for Expiry 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 was valid up to……..

2) Renewal of the licence after the last validity was deferred due to non-submission of renewal application with requisite fee.

OR / AND

The renewal of licence was deferred after its last date of validity due to continuation of suspension of licence w.e.f. .....*<date of suspension>*..... on account of repeated non-conformity of surveillance samples.

3) Please refer to our earlier communications dated ..... intimating suspension of licence.

4) The following product non-conformities and/or discrepancies were observed with regard to the operation of the above licence which are in violation of the provision of Regulation ..... of the BIS (Conformity Assessment) Regulations, 2018 :

(Elaborate the grounds leading to expiry notice with linkages to specific provisions of the BIS Act, 2016 and the BIS (Conformity Assessment) Regulations, 2018)

5) In view of the above, it is proposed not to renew 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 8 of the BIS (Conformity Assessment) Regulations, 2018.

6) 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/IT portal/ e-mail. 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

7) 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 expiry 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.

8) 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.

9) Kindly acknowledge the receipt and ensure compliance.

Thanking You,

Signature of designated authority
(Name of designated authority)

Annexure-XIII

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

Subject: Expiry 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) Further, reference is invited to notice for expiry dated ....., your reply dated ..... and personal hearing held on .....

3) It has been decided not to renew your Licence after …… as per the provision of Regulation ..... of the BIS (Conformity Assessment) Regulations, 2018 due to the following reasons:

(Mention the reasons with linkages to specific provisions of the BIS Act, 2016 and the BIS (Conformity Assessment) Regulations, 2018)

4) Your above mentioned licence, therefore, allowed to expire w.e.f. ……..... You are therefore, not entitled to mark/ dispatch your product (product name) as per IS …… with BIS Standard Mark after ……<*date of suspension*>… 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.

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 …<*date of suspension*>….., 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) *For a fresh application to be submitted by your firm within two years from the date of expiry mentioned above, the option to submit the application under option-2 (simplified procedure) is not available to your firm.

10) 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.

11) Please acknowledge the receipt and ensure compliance.

Signature of designated authority
(Name of designated authority)

**Select - only for domestic manufacturers.*