BUREAU OF INDIAN STANDARDS
(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:2 (Part 1) **13 May 2024**

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 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), 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:

- **(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 latest test report 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.

Labelling and marking requirements

7. **(i)** Any deviation observed in requisite labelling and marking requirements (specified in Indian Standard or Scheme of Inspection and Testing or both) shall not be treated as sample non-conformity unless otherwise specified. However, the RoP for the same shall be put up 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) 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 intermediate deviations like in requirements for marking of grade/ type/ variety etc. - In the 1st instance, corrective actions shall be sought. In the 2nd instance, the notice for suspension shall be issued.

(c) For major deviations like in requirements for marking of D.O.M./Expiry date (food products), Safety labelling, BIS licence number, IS number etc. - notice for suspension in the 1st instance shall be issued. For repeated instances, proceedings for cancellation of licence may be initiated for violation of conditions of licence.

(d) For 4th instance of deviation in any labelling and marking requirements (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 (or above) test reports of surveillance samples received, then the case shall be processed for initiating necessary action as per applicable provisions given in this document.

(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 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 III (B).

(iv) Alongwith the corrective actions, the manufacturer shall submit an in-house (including cluster based or shared common 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 by NABL 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)** When the corrective actions and reply to product recall notice (if applicable) are received within 15/30† days (as applicable), the case shall be put up with evaluation of the reply received from manufacturer w.r.t corrective actions, supporting test report and reply to product recall notice (as applicable) submitted by the manufacturer.

(ii) After evaluation of reply and test report (in-house or outside) received from the manufacturer, the case shall be put up to the Head BO for verification of the corrective actions. Head BO shall arrange for an early surveillance either by BIS officer or through Technical Auditors of the empanelled agencies through CSMD. This surveillance visit shall be carried out by the certification officer of the BO to the extent possible.

Surveillance visit for verification of implementation of corrective actions

(iii) For the purpose of verification of implementation of corrective actions, a surveillance visit shall be carried out normally within the next 15/30† days.

†*Note:* In case product recall notice was part of communication, visit within 15 days. Otherwise, 30 days.

During this surveillance visit, in addition to regular assessment, corrective actions reported by the licensee shall also be verified. For example, it may involve witnessing the interlinkages of the production process or other technical reasons with root-cause analysis.

Testing in factory

(iv) During this visit, factory testing shall be carried out for as many requirements as possible in a day on the following samples:.

(a) variety(ies) that was/were found non-conforming.
(b) Additional sample(s) from stock (if available) with production done before the date of corrective actions.
Note 1: Depending upon stock availability - Efforts shall be made to cover two varieties, i.e. one the same variety which was found non-conforming and another sample of different variety.
Note 2: If fresh lot has not been offered for variety(ies) at (a) above, then factory testing of another sample of different variety from available stock.

Drawl of sample for TPL testing

(v) Sample(s) of the variety(ies) found non-conforming shall be drawn for TPL testing. In case sample(s) of such variety(ies) are not available, then other variety sample shall be drawn from available stock.

(vi) In case during this surveillance, factory testing or sampling for TPL could not be done, the BO may plan another surveillance within a month.

(vii) The report for such a surveillance visit shall highlight whether the corrective actions taken by licensee are found to be implemented satisfactorily. 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.

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 surveillance shall be planned.

(ii) If corrective actions submitted by the manufacturer are not relevant/complete, the deficiencies in the reply shall be informed to the manufacturer.

(iii) In such cases, the Head BO shall plan an immediate surveillance visit either by BIS officer or through Technical Auditors of the empanelled agencies through CSMD. This surveillance visit shall be carried out by the certification officer of the BO to the extent possible. For verification of

corrective actions, factory testing and drawl of sample for TPL testing refer para 9(iii), (iv), (v), (vi) and (vii).

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

(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

on non-conforming goods

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.

Notice for suspension

13. **(i)** Before imposition of suspension for the reasons listed under para 10, 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.

(ii) 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 informed to DDGR.

(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 Scheme of Inspection and Testing 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 - manufacturer with in-house test facility

(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.

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. 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 Revocation of Suspension - manufacturer 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

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.

of normal operation

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

17. **(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(iii)(c) 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.

(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).

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

(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 a critical requirement in TPL or FT, then the suspension shall be imposed immediately or continued and proceedings for cancellation may be initiated as per para 20 after taking a review of overall performance of licensee in last 2 years.

Based on the merits of the case, DDGR may give another opportunity for improvement and corrective actions.

(vii) If the sample tested shows non-conformity in a non-critical requirement in TPL or FT, then the suspension shall be imposed immediately or continued and licensee shall be advised to take further corrective actions and re-offer improved lots for considering RoS.

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)** Consecutive non-conformity of three surveillance samples in critical requirements

(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) In case reply is received within stipulated time, it shall be examined and reviewed by the DDGR. Where the DDGR is satisfied that it is necessary to cancel the licence, she/he shall record the reasons for cancellation of licence.

(c) If the licence is not cancelled, the matter shall be taken up for corrective actions and its verification as per applicable 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 (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 through DDGR.

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) Factory surveillance once every three months

(b) Market surveillance twice every three months

This enhanced surveillance shall continue till 3 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) Factory surveillance once every three months

(b) Market surveillance twice every three months

This enhanced surveillance shall continue till 4 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 either factory surveillance or visit for procurement of market sample from dispatch point shall be planned every month till the time desired number of overall minimum surveillance samples are drawn.

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 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 ***Annexure - IX*** of 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) failing which 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 failing which your case may be processed for imposition of suspension. As supporting evidence of corrective actions taken, a test report establishing relevance of corrective actions is also required to be submitted.

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

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-conformities of samples observed and communicated earlier
# 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:
(BO to mention the reasons)

4) Your above mentioned licence, therefore, stands Cancelled w.e.f. ……..... You are therefore, not entitled to mark/ dispatch your product (product name) as per IS …… with BIS Standard Mark after …… or to claim in your advertisements or in any other publicity material that you are a licensee to use the 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) If you are aggrieved by the above order, you may prefer an appeal to the Director General, Bureau of Indian Standards within ninety days from the date of the order with a fee of two thousand rupees as per provisions of section 34 of the BIS Act 2016 read along with Rule 37 of the BIS Rules 2018.

10) Please acknowledge the receipt and ensure compliance.

Signature of designated authority
(Name of designated authority)

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)

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		Physical or Mechanical Safety requirements - like small parts test and expanding	Choking hazard

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

CORRIGENDUM

Our Ref: CMD-I/2:12:2 (Part 1) **27 June 2024**

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.

1) With regard to clause 6 (i) (d), all test reports received in past 2 years from the date of **receipt of** latest test report (i.e. date of uploading of test report in the portal) indicating non-conformity and samples drawn shall be listed in the RoP.

2) With regard to clause 13 (i), the word "para 10" mentioned in the first line to be read as "**para 12**".

3) With regard to clause 17 (ii) (b), the word "para 16 (iii) (c)" mentioned in the second line to be read as "**para 16 (ii) (d) (B)**".

4) With regard to clause 20 (iv), the words "expiry notice shall be processed through DDGR" mentioned in the last line to be read as "expiry notice shall be processed **by** DDGR".