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

हमारा सन्दर्भ: सीएमडी-I/2:12 **09 अगस्त 2018**
विषय: भारतीय मानक ब्यूरो (अनुरूपता निर्धारण) विनियम, 2018 की अनुसूची - II की अनुरूपता निर्धारण स्कीम - I के दिशानिर्देश हेतु ।

सक्षम प्राधिकारी द्वारा अनुमोदित उपर्युक्त विषय पर दिशानिर्देश और परिपत्र सभी क्षेत्रीय कार्यालयों/ शाखा कार्यालयों के कार्यान्वयन के लिए सलंग्न है।

(मोहित जनोहिया)
वैज्ञ-'बी'/सीएमडी-I

<u>प्रमुख, (सीएमडी - I)</u>

सभी क्षेत्रीय कार्यालयों/ शाखा कार्यालयों को परिचालित

प्रतिलिपि: आई टी एस विभाग - बी आई एस इंट्रानेट पर डालने हेतु।

<u>Bureau of Indian Standards</u>
(Central Marks Department - I)

Our Ref: CMD-I/2:12 **09 August 2018**
Subject: Guidelines for the conformity assessment Scheme - I of Schedule - II BIS (Conformity Assessment) Regulations, 2018 - reg.

The circular and the guidelines on the above subject as approved by the Competent Authority are attached herewith for implementation of all ROs/BOs.

(Mohit Janoiya)
Sc.B/CMD-I

<u>Head, CMD-I</u>

Circulated to all ROs/BOs

Copy to: ITSD for hosting on the Intranet

Bureau of Indian Standards
(Central Marks Department-I)

Our Ref: CMD-I/2:12 **08 August 2018**

Subject: Guidelines for Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018 - reg.

1. BIS is operating conformity assessment scheme for grant of licence to use or apply Standard mark ISI on goods and articles as per Indian standard as per Scheme I of schedule II of BIS (Conformity Assessment) Regulations, 2018.

2. To ensure uniformity in the operation of scheme I as per BIS (Conformity Assessment) Regulations, 2018, the following guidelines have been approved by the Competent Authority:

   (a) Grant of Licence (GoL) - **CMD-I/2:12:1 dated 08 August 2018**
   (b) Suspension (SUS) & Revocation of Suspension (RoS) - **CMD-I/2:12:2 dated 08 August 2018**
   (c) Renewal of Licence (RoL) - **CMD-I/2:12:3 dated 08 August 2018**
   (d) Change in Scope of Licence (CSoL) - **CMD-I/2:12:4 dated 08 August 2018**
   (e) Coding and retesting of sample - **CMD-I/2:12:5 dated 08 August 2018**
   (f) Surveillance during operation of licence - **CMD-I/2:12:6 dated 08 August 2018**

3. The above mentioned guidelines supersede the existing provisions in Operating Manual for Product Certification (OMPC), its amendments and any guidelines issued for Grant of Licence, Suspension (earlier known as Stoppage of Marking/SOM), Revocation of Suspension (earlier known as Resumption of Marking/ROM), Change in Scope of Licence (earlier known as Inclusion), coding and retesting of sample and surveillance.

4. Clause 4 (d) of the guidelines for Grant of licence Ref:CMD-I/2:12:1 is kept under abeyance till a provision in IT software has been made.

5. The procedure of complaint handling shall be continued as per existing provisions in Operating Manual for Product Certification (OMPC) and guidelines till revised procedure and formats are issued by Consumer Affairs department, BIS Hqs.

6. Every attempt has been made to provide guidelines to the various situations, but many new situations may arise, which are not covered by the guidelines outlined here. In such cases the general principles of product certification shall be applied by Head BO with proper recording of justification and decision shall be taken with concurrence of DDGR. Such decisions with full background shall be informed to DDG (Certification) for determining whether it requires any policy guideline for uniform application on all India basis.

7. DDGRs and Head BOs are requested to bring these guidelines to the notice of all concerned for implementation with immediate effect.

(H.J.S. Pasricha)
Scientist F & Head, CMD-I)

08/08/18.

Sc. G & DDG (Certification)

To: All ROs/BOs
& DDGRs/Head (BO)

BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:1 **08 August 2018**

Sub: Guidelines for Grant of Licence (GoL) as per the conformity assessment Scheme – I of Schedule II of BIS (Conformity Assessment) Regulations, 2018

These guidelines stipulate the procedure for Grant of Licence (GoL). These are to be read in conjunction with BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018. In particular, the provision for Grant of Licence (GoL) are addressed in Regulation 4 & 5 and Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018. Any situation, in general, not covered in these guidelines is to be dealt as per the provisions of Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs).

General Principles for GoL

1. **a)** The Bureau grants a licence based on successful assessment of the manufacturing infrastructure, production process, quality control and testing capabilities of a manufacturer through a visit to its manufacturing premises. Conformity of the product to the relevant standard(s) is also established through third party laboratory testing or testing in the manufacturing premises or a combination of both.

   b) The applicant may choose one of the two options available for grant of licence (as given at Sl. No. 3 & 4 below).

Application

2. The application shall be made in the Form-V as specified in BIS conformity assessment regulations 2018 - Scheme I (process of submitting application online to the Bureau is available on its website). The applicant shall be required to submit the relevant documents as per the Form-V.

Option 1 for GoL

3. **a)** The applicant may apply for grant of licence to the Bureau along with the documents mentioned at Sl No. 2 above.

   b) A visit will be paid to the factory of the applicant for assessment of the manufacturing infrastructure, production process, quality control and testing capabilities, and the sample(s) will be drawn for testing in third party testing laboratory.

   c) The sample(s) may not be drawn in case the grant of licence is to be considered on the basis of factory testing only. Factory testing is permitted for products as listed at **Annexure-I.**

Option 2 for GoL (not available to foreign manufacturers)

4. **a)** The applicant may apply for grant of licence to the Bureau along with the documents mentioned at Sl. No. 2 above and conforming Test Report(s) of the product samples manufactured by the applicant and of raw material(s) (if applicable) issued by a third party testing laboratory. The application under option 2 shall be subject to conditions specified at c) to l).

b) A visit will be paid to the factory of the applicant for assessment of the manufacturing infrastructure, production process, quality control and testing capabilities, and drawl of samples for testing in the third party testing laboratory. The test report of the sample(s) drawn during the factory visit will be used for review purposes.

c) For the following products option 2 is not available:

i) Products such as cylinders, valves, regulators etc., where a joint inspection along with another statutory authority is required or products such as cement where approval is required form another statutory authority.

ii) Packaged Drinking Water (PDW) and Packaged Natural Mineral Water (PNMW); and

iii) Products for which licence is to be granted on the basis of factory testing (**Annexure-I**)

d) While exercising option 2, the applicant must first register itself on the IT software, wherein he will get a unique code. The applicant will have to submit this code to the third party testing laboratory (refer 4 e) below while submitting the samples for testing and get the receipt for the same. The receipt will be required to be uploaded on IT software after the submission of the sample(s) to the laboratory. The samples for testing shall be selected based on the grouping guidelines for the product (if any) made available by the Bureau and the varieties to be covered under the scope of the licence.

Laboratory

e) Test reports of the following laboratories shall be accepted:

i) Laboratories established, maintained or recognized by the Bureau for the product (including Group-2 labs as specified under the Laboratory Recognition Scheme of the Bureau);

ii) Government laboratories empanelled by the Bureau;

iii) Any other laboratories as decided by the Executive committee of the Bureau;

Test reports shall be the latest

f) The test reports of the product shall not be more than 90 days old. The period for counting 90 days shall be from the date of issue of the test reports to the date of receipt of the application in the BO. In case of multiple test reports for one product, the latest product test report shall not be more than 90 days old and the oldest product test report shall not be more than 180 days old.

g) If a BO is of the opinion that the test report(s) to be considered for Grant of Licence need to be accepted beyond specified time norms due to genuine reasons, the case may be put up for the approval of concerned DDGR with proper justification. DDGR after due consideration of the facts in the recorded justification, may take a decision whether to allow acceptance of the test report(s) which are not within the time limits specified above.

Conformity of Raw Material

h) Where ensuring conformity of raw materials is a mandatory requirement of the product standard being considered for certification, such conformity shall be established through any of the following:

i) Raw material is ISI marked;

ii) Test report from any laboratory as specified at 4 e) above;
iii) In case i) & ii) above are not possible, then raw material manufacturers' test certificate;
iv) In case i), ii) and iii) are not possible, then in-house Factory Test Report.

Where Indian standards for raw materials are referred to in the product standard for guidance or reference only, evidence of conformity of raw material should not be insisted upon. Ensuring conformity of raw material/components shall rest with the applicant.

Submission of Partial Test Report

i) (1) It is the responsibility of the applicant to ensure that the test reports submitted are complete in all respects and conforming to the relevant Indian Standard. In the event of submission of partial test report, applicant must submit reasons for test reports not being complete and proper justification to the satisfaction of Head (BO). Based on the reasons/justification received, the remaining test(s) shall be done in the laboratory of the applicant, with permission of Head (BO), as per procedure given at clause 4 i) (2) below.

(2) The factory testing for remaining tests will be carried out by the Bureau during verification visit, subject to:

A. Availability of complete testing facility in the lab of the applicant for the remaining tests to be done.
B. Payment of inspection fee for the visit.
C. Availability of sufficient material for carrying out the remaining tests from material of the same control unit of which the test reports were submitted along with the application. In case, material from the same control unit is not available, sufficient material from two fresh control units be made available.

Long Duration Tests

j) For product characteristic requiring **testing time 30 days (one month) and above** (like keeping property tests in paints, carbon paper, insulating tapes, various types of inks etc) evidence of conformity in the form of test reports from any laboratory, firm's own or outside (as per 4 e) above), should be made available for such tests. The applicant should also simultaneously produce evidence that the long duration test in any of the laboratories specified at 4 e) above, is in progress and the laboratory shall be able to issue the Test Report (TR) within a definite time period (indicating date), which shall be made available by the applicant to the Bureau.

Note: The provision of in-house/outside laboratory test report for long duration test(s) may be relaxed, in case the applicant firm located in India is newly established and duration of such test(s) is more than 6 months. The appropriate evidence for establishment and commencement of production shall be taken.

Undertakings

k) An **undertaking** (refer clause 5 (d) xi)) shall also be obtained from the applicant on its letterhead that, in the event of non-conformity of the sample in long duration test(s) or its inability to submit the test report immediately but not later than 30 days (one month) from the date of test report confirmed by the laboratory, the licence, if granted shall be processed for cancellation.

l) An **undertaking** (refer clause 5 (d) xii)) shall also be obtained from the applicant on the letterhead that the licence, if granted, shall be put under suspension if the sample(s) drawn during the factory visit by the certification officer(s) of the Bureau, do(es) not conform to the requirements of relevant Indian Standards.

Factory visit

5. **a)** Duration of the factory visit shall normally be one day in case of Indian manufacturers and two days in case of foreign manufacturers. In case more days are required, the decision in this regard may be taken by Head (BO).

b) In case the Grant of Licence is to be considered based on the complete testing of the product in the factory, the man-days required for such visits may be assessed and approved by Head (BO)

c) During the factory visit, the activities as per clause (c) of sub-paragraph (2) of paragraph 3 of Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations 2018 shall be carried out.

d) the following documents shall be taken and verified during the factory visit-

i) a self-evaluation cum verification report in the proforma, as given in **Annexure-II**
ii) Details of Quality Control Personnel
iii) Calibration Certificates of Testing Equipment to be verified during the visit
iv) Copies of Test Certificates of Raw Material, as applicable
v) Drawing of sample(s) of the Product and / or Components, as applicable
vi) Report of Hygienic Condition, if applicable
vii) Plant layout indicating the location of manufacturing area, storage area for raw material and finished product, testing laboratory etc.
viii) Location Plan of the factory
ix) For the tests which are permitted to be subcontracted and not available with the manufacturer, copy of the agreement or consent letter from the outside laboratory for which arrangement for sub-contracting is made
x) Inspection and Test Plan proposed to be followed, if different from Scheme of Inspection and Testing of the Bureau
xi) Undertaking for long duration test as per the template attached as **Annexure-III**, wherever applicable (refer clause 4 k) and 5 g)), and
xii) In case of option 2(refer Sl. No. 4), undertaking, as per the template attached as **Annexure-IV** (refer clause 4 l)).

Factory Testing

(e) i) Carry out Factory Testing (FT) for as many requirements, as possible. All subjective requirements like – workmanship, visual characteristics, surface defects, description, taste, flavor etc. shall be checked in the factory.

ii) Carry out factory testing on the remaining requirements (refer clause 4 i)(1) and 4 i)(2)) in case of partial test report(s) submitted by the applicant. **Inspection fee, as applicable, shall be collected** for the additional man-days required for such factory testing.

iii) In case of bulkier products, the dimensional measurements and other tests, for which complete product cannot be drawn and sent for third party testing (e.g. steel plates, sheets, steel pipes etc.) shall be carried out during factory testing.

iv) If, **during the factory testing, any non-conformity is observed**, no sample shall be drawn for testing in Third Party Laboratory. The applicant may be advised to carry out improvement, which is to be verified through another inspection and testing in the factory (inspection fee to be paid by the applicant for the visit).

v) **For ensuring conformity of the raw material(s) to the relevant requirement(s) of product standard, if applicable, refer 4 h) above.**

Drawl of Sample

(f) i) For option 1 - Draw sample(s) as per the guidelines for the product (if any) made available and the varieties to be covered under the scope of the licence. Draw a counter sample of the product and if applicable, of Raw Material(s) also.

ii) For option 2: Draw only one sample from the product variety to be covered under the scope of the licence.

iii) After ensuring proper packing of the sample, seal the sample and the counter sample. The guidelines issued by the Laboratory Policy & Planning Department shall be followed for sealing and dispatch of the sample to laboratory for testing.

Testing of Sample

(g) For product characteristic requiring **testing time 30 days (one month) and above** (like keeping property tests in paints, carbon paper, insulating tapes, various types of inks etc) evidence of conformity in the form of test reports from any laboratory, firm's own or outside (as per 4 e) above), may be accepted for such tests. In such cases, an **undertaking** (refer clause 5 (b) xi)) shall be obtained from the applicant on its letterhead that, in the event of non-conformity of the sample in long duration test(s) or its inability to submit the test report immediately but not later than 30 days (one month) from the date of test report confirmed by the laboratory, the licence, if granted shall be processed for cancellation.

Changeover from Option 2 to Option 1

6 The applicant may change his/her application from Option 2 to Option 1. The application shall then be processed as per option 1 only. The changeover from option 1 to 2 shall not be permitted.

Processing for GoL

7 **a)** Option 1: Process of grant of licence is expected to be completed within 120 days, except for all India first case where it may take 180 days, from the date of receipt of the application provided the documentation, assessment of the unit and conformity of the product is established satisfactory at first instance during various stages. A template of the letter to be sent for communication of Grant of Licence is attached as **Annexure-V**.

b) Option 2: The applicant shall submit the proof of delivery of the sample drawn during the factory visit to the concerned laboratory, wherever applicable, and the testing fee. Only after submission of such proof, the licence shall be granted by the competent authority. Process of grant of licence is expected to be completed within 30 days from the date of receipt of the application if factory visit is satisfactory and conformance of sample to the relevant Indian Standard(s) is established at the first

instance. A template of the letter to be sent for communication of Grant of Licence is attached as **Annexure-V**.

c) The licence to use Standard Mark shall initially be granted for not less than one year and upto two years.

Review of test report of in the Sample drawn in case of option 2

8 **(a)** In case of non-conformity of sample(s) drawn during the factory visit under option 2, Suspension of licence shall be imposed immediately. The licensee shall take necessary corrective actions and inform the same to the Bureau, and also confirm his readiness to offer fresh samples manufactured after taking the corrective actions. The revocation of suspension in such cases shall be considered only on the basis of conforming Testing Reports of the fresh samples from a Third Party Testing Laboratory. In case the fresh sample drawn by the Bureau for consideration of revocation of suspension shows non-conformity in third party laboratory testing, or the licensee does not inform corrective actions taken and does not offer improved samples within 30 days of the date of Suspension, the licence shall be processed for cancellation.

(b) In case of receipt of test report of any sample drawn after Grant of Licence [Factory Sample (FS) /Market Sample (MS)] prior to receipt of the test report for the sample drawn during factory visit during the applicant stage, the same shall be treated as a routine sample. However, on receipt of test report of the sample drawn at applicant stage which is found non-conforming, notwithstanding the conformity of the FS/MS drawn after GOL, **action as per clause 8 (a) above, shall be taken.**

Partial Test Report of sample drawn for Third Party Laboratory Testing

(c) In case of receipt of partial test report for the Sample drawn for Third Party Laboratory testing, the remaining test shall be carried out on the counter sample in a Third Party Laboratory (refer clause 4 e). If, in any case, it is difficult to test the remaining requirements in a Third Party Laboratory, the same may be carried out in the factory of the licensee with approval of Head, BO, provided such test facilities exist in the factory.

Review of test reports of Long Duration Test

(d) Case shall also be reviewed for the test report of long duration test, for which the applicant had submitted an undertaking (refer clause 4 j) and 5 f) above). If the test report for the long duration test is found non-conforming or the applicant fails to submit the test report by the stipulated time, the licence, if granted, shall be processed for cancellation.

All India first application

9. i) If the application is for a product for which no licence has been granted earlier, the application shall be processed by the concerned BO and sent to CMD through concerned DDGR.

ii) The Certification Officer concerned, who has carried out factory visit for all India first application, shall prepare draft product manual including draft scheme of inspection and testing, and marking fee, within 07 days of the factory visit / drawal of applicant sample for testing in third party laboratory.

iii) If there is no third party laboratory, the decision for processing the case for grant of licence may be taken up with the approval of Head of the Region.

Rejection of application

10. **a)** The application may be processed for rejection as per the sub-regulation (6) of regulation 4 of BIS (Conformity Assessment) Regulations, 2018. It may include one or more of the situations mentioned below:

i) Samples not offered for testing within 30 days of recording of application

ii) Sample drawn fails in an independent testing- In case of drawl of sample for multiple varieties, application may be processed for rejection if samples of all the varieties are found failing **for the second time**, else the scope may be restricted keeping in view the varieties found conforming and guidelines for the product

iii) Lack of testing facilities with the applicant

iv) Lack of technical personnel with the applicant

v) If corrective actions are not taken within the time period stipulated in discrepancy-cum-advisory report

vi) The firm has not been clearing the financial dues to the Bureau.

vii) The firm has tampered with documents in connection with the grant of the licence.

viii) The firm has indulged in unethical practices in the context of grant or operation of the licence.

ix) Major deviation is observed from the declared manufacturing facility during the factory visit.

x) Failure of firm in providing all assistance to certification officer in connection with carrying out factory visit

xi) If non-conformity in factory testing is found repeated during the second factory visit.

b) Before rejecting an application, a rejection notice of not less than 21 days shall be given to the applicant (template attached as **Annexure-VI)**. The applicant shall be given a reasonable opportunity of being heard either in person or through its representative. In case the facts or the explanation furnished by the applicant or its representative is not satisfactory, the application shall be rejected. The closing of application shall be communicated to the applicant (template of the letter attached as **Annexure-VII**.

Product specific guidelines

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

Additional features for foreign manufacturers

12. The additional requirements for foreign manufacturers are specified in **Annexure - VIII**.

Inspection fee

13. The inspection fee shall be payable, in advance, as per sub-paragraph (6) of paragraph 5 of Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018.

Testing fee

14. The testing fee of the samples shall be borne by the applicant.

Annexure - I

List of products operated on factory testing basis

Sl. No	IS No.	Title	TD
1.	458	Precast Concrete Pipes (with and without Reinforcement)	CED
2.	784	Pre-stressed Concrete Pipes (Including Fittings)	CED
3.	1592	Asbestos Cement Pressure Pipes and Joints -	CED
4.	1834	Hot Applied Sealing Compounds for Joints in Concrete - Specification	CED
5.	2095 Part 1	Gypsum Plaster Boards - Part 1 Plain Gypsum Plaster Boards	CED
6.	2096	Asbestos cement flat sheets	CED
7.	2098	Asbestos Cement Building Boards	CED
8.	2713 Part 1 to 3	Tubular Steel Poles for Overhead Power Lines	CED
9.	3829 Part 1	Horizontal Cylindrical and Horizontal Rectangular Steam Sterilizers, Pressure Type (for Hospital and Pharmaceutical Use)	MHD
10.	3829 Part 2	Steam Sterilizers - Part 2 : Horizontal Cylindrical High Speed Steam Sterilizers, Pressure Type	MHD
11.	3829 Part 3	Steam Sterilizers - Part 3 : Pressure Sterilizers, Vertical Cylindrical Type	MHD
12.	4266	Lockers, Bedside for Hospital Use	MHD
13.	5029	Bedsteads, Hospital, General Purposes	MHD
14.	5035	Sterilizers, Bowl and Utensil (Pedal Type)	MHD
15.	5291	Tables, Operation, Hydraulic, Major	MHD
16.	5446	Machine Chucking Reamers with Parallel Shanks - Specification	PGD
17.	5631	Trolley, Instrument, Plain and Curved	MHD
18.	6315	Floor springs (hydraulically regulated) for heavy doors	CED
19.	6452	Specification for high alumina cement for structural use	CED
20.	6685	Life Jackets	TED
21.	6908	Asbestos cement pipes and fittings for sewerage and drainage	CED

22.	7083	Trolley, Medicine	MHD
23.	7620 Part 1	Diagnostic Medical X-ray Equipment - Part 1 : General and Safety Requirements	MHD
24.	7898	Manually-Operated Chaff Cutter	FAD
25.	8110	Well Screens and Slotted Pipes	MED
26.	8229	Specification for Oil-well Cement	CED
27.	8471	Acetylene Generators - Requirements(Amalgamation of IS 8471(Part 1 to 5)	MED
28.	9020	Power Threshers - Safety Requirements	FAD
29.	9167	Ear Protectors	LITD
30.	9395	Bed, Intensive Care	MHD
31.	9972	Specification for Automatic Sprinkler Heads for Fire Protection Service	CED
32.	10238	Fasteners - Threaded Steel Fastener - Step Bolts for Steel Structures	PGD
33.	10264	Trolley, Hot Food, for Hospital and Industrial Canteens	MHD
34.	10617	Hermetic Compressors	MED
35.	11279	Braille Slate	MHD
36.	11378	Anesthetic Machines for Use with Humans	MHD
37.	11459	Power-operated Chaff Cutter	FAD
37.	11552	Liquid Nitrogen Vessels of Capacity up to 75 Liters	MED
38.	12709	Glass-fibre Reinforced Plastic (grp) Pipes Joints and Fittings for Use for Potable Water Supply	CED
39.	12866	Plastic translucent sheets made from thermosetting polyester resin (glass fibre reinforced)	CED
40.	13000	Silica-asbestos-cement Flat Sheets	CED
41.	13258	Welded Low Carbon Steel Cylinders Exceeding 5 Liter Water Capacity for Low Pressure Liquefiable Gas - Code of Practice for Inspection and Reconditioning of Used LPG Cylinders	MED
42.	14402	GRP pipes joints and fittings for use sewerage, industrial waste and water (other than potable)	CED

43.	14746	Respiratory Protective Devices - Half Masks And Quarter Masks	CHD
44.	14845	Resilient Seated Cast Iron Air Relief Valves for Water Works Purposes	CED
45.	14862	Fibre Cement Flat Sheets	CED
46.	14871	Products in Fibre Reinforced Cement - Long Corrugated or Asymmetrical Section Sheets and Fittings for Roofing and Cladding -	CED
47.	14951	Fire Extinguisher - 135 Liters Capacity Mechanical Foam Type	CED
48.	15155	Bar/Wire Wrapped Steel Cylinder Pipes With Mortar lining and Coating (Including Specials) --	CED
49.	15477	Adhesives for Use with Ceramic Tiles and Mosaics	CED
50.	15490	Cylinders for On-Board Storage of Compressed Natural Gas As a Fuel for Automotive Vehicles	MED
51.	16111	Elastic Bandage	TXD
52.	16127	Behind the Ear (BTE) Hearing Aids - Digital - Specification	LITD
53.	12950	Battery hydrometer portable syringe type for lead-acid batteries	CHD
54.	14806	Azospirillum Inoculants	FAD
55.	13692	Metalaxyl Mancozeb WP	FAD
56.	717	Carbon Disulphide, Technical	PCD
57.	10245 Part-3	Breathing Apparatus - Part 3 : Fresh Air Hose and Compressed Air Line Breathing Apparatus	CHD
58.	10245 Part-2	Respiratory protective devices - breathing apparatus Part 2 Open circuit breathing apparatus	CHD
59.	10592	industrial emergency showers, eye and face fountains and combination units	CHD
60.	7653	Manual blow pipes for welding and cutting	MTD
61.	16289	Medical Textiles Surgical Face Masks Specification	TXD
62.	11928 Part 1 & 2	Roundslings Made of Man-made Fibres for General Service - Parts 1 and 2	TXD
63.	5983	Eye-protectors	CHD
64.	15322	Particle Filters Used in Respiratory Protective Equipment	CHD

65.	14900	Transparent Float Glass	CHD
66.	14550	Hexaconazole, EC	FAD
67.	14613	Roasted Bengal Gram Flour (Channa Sattu)	FAD
68.	16131	Imidacloprid Suspension Concentrate (SC)	FAD
69.	15323	Gas Filters and Combined Filters Used in Respiratory Protective Equipment	CHD
70.	6901	Gas welding equipment - Pressure regulators for gas cylinders used in welding, cutting and allied processes up to 300 bar	MTD
71.	16585	Magnetic Materials - Specification for Individual Materials - Fe-Based Amorphous Strip Delivered in the Semi-Processed State	MTD
72.	15041	Textiles - Flat Woven Webbing Slings Made of Man-Made Fibres for General Services	TXD

Annexure - II

Self-evaluation cum verification report

1. **General information**
   a) Applicant's name
   b) Enclose plant layout:

2. **Raw materials**
   a) Raw Materials Used:

Sl. No	Raw material	Name of supplier	With/without BIS certification mark	Test certificate of the supplier	How received batches/lots nature of package

3. Packing and marking

a) Nature of packing
b) Quantity per package
c) Marking on article
d) Method of marking (printing, Stencilling, embossing etc)
e) Form of label(s), if any (enclose one set)
f) Batch or Code numbering for identification
g) In what manner marking differs from the provisions in the Indian Standard Specification

4. Details of Quality Control Staff:

Sl. No.	Name of person	Designation	Qualification	Experience

5. Brand Name(s)

Declaration of brand name/trademark proposed to be covered under certification

a) Brand Names/Trademark(s) being used:

Brand Names/Trademark(s) which would be marked on the product bearing the BIS Standard Mark (Give actual design depiction of the Brand Name/Trade Mark(s)	Owned by self or others	Registered/ Unregistered	Date of registration/ introduction
b)			

c) Other Brand Names/Trademark(s) used for the same product marketed without BIS Standard Mark. Give reasons.

d) In case Brand Names/Trademark(s) of any other party/manufacturer is being used for purposes of the above, give the design depiction of the Brand Names/Trademark(s) and copy of the agreement authorizing the use of the same.

e) I/We undertake to inform BIS in advance as and when we propose to use any other Brand Names/ Trademark(s) in conjunction with the operation of the BIS Certification Scheme I.

f) I/We also undertake that, as far as possible, the entire production which conforms to the specification shall be marked with the BIS Mark, irrespective of the Brand Names/Trademark(s) used.

g) I/We understand that the above has been given only as information to BIS, that BIS has no role in permitting/approving of any Brand Name or Trade Mark, that this is not in anyway be interpreted to mean that BIS has permitted/approved the use of the Brand Name(s) and Trade Mark(s) listed above, and that the responsibility is entirely mine/ours.

Declaration

The information given in this report are true to the best of my knowledge and belief. I shall be responsible if any misleading information has been given in this report and the application shall be liable for rejection if wrong information has been given. If the licence is granted on the basis of information which is found to be incorrect later, the licence shall be liable for cancellation.

Date:

(Signature)

Name &
Designation

Place:

Annexure - III
Undertaking for long duration test

(To be submitted on the letterhead of the firm)

The Head ……..(Branch Office)
Bureau of Indian Standards

Dear Sir/Madam,

I, ... (name of person), ... (designation) have applied for a licence on ..... (date of application as in the application form) to you for use of BIS standard mark on ..... (name of product) as per IS ..... (Indian Standard No.) being manufactured at our factory at ..... (give address).

I understand and agree that in event of failure of the sample drawn for the purpose of Grant of Licence to use and apply Standard Mark in the following type tests or my inability to submit the test report for following tests within 30 days (one month) of the date of completion of the test(s) as confirmed by the laboratory*, the licence if granted to me, shall be processed for cancellation:

Sl. No.	Type test	Duration of the test	Date of completion of the test(s) as confirmed by the laboratory, if applicable
1			
2			
3			

Further, I duly undertake that I shall abide by all the directions issued by the Bureau in this regard.

Date:

(Name)
(Designation)
(Seal)

*Strike out whatever is not applicable

Annexure - IV

Undertaking by applicant applying under option 2

(To be submitted on the letterhead by Member of Management/Authorized Signatory to concerned Head of the Branch office along with the Application and other documents)

The Head ……(Branch Office)
Bureau of Indian Standards

Dear Madam/Sir,

I, ... (name of person), ... (designation) have applied for a licence under Option - 2 on ..... (date of application as in the application form) to you for use of BIS standard mark on ..... (name of product) as per IS ..... (Indian Standard No.) being manufactured at our factory at ..... (give address).

I clearly understand and agree to the conditions that-

(i) the licence, if granted against the above application shall be put under suspension by BIS, if the sample drawn during the verification visit fails to conform to the relevant Indian Standard,
(ii) in such case of suspension, I shall take necessary corrective actions and inform the same to BIS within one month and offer fresh lot of product manufactured after taking corrective actions, from which sample(s) will be drawn by BIS for third party testing,
(iii) the revocation of suspension will be considered only on the basis of complete test report(s) of the fresh sample(s) offered, from third party testing laboratory,
(iv) the testing fee for testing of sample drawn for consideration of revocation of suspension shall be borne by me, and
(v) in case, the fresh sample drawn by BIS for considering revocation of suspension shows non-conformity, or I fail to inform corrective actions within 30 days from the date of suspension, the licence will be processed for cancellation.

Date:

(Name)
(Designation)
(Seal)

Annexure - V

Our Ref: **Dated:**

Subject: Grant of BIS Product Certification Licence No.- ..... as per IS .....

M/s

Dear Madam(s)/Sir(s),

With reference to your application, we are pleased to inform you that the Certification Marks Licence has been granted to you to use the Standard Mark in respect of the followings:

Product:

(i) Grade
(ii) Class
(iii) Type
(iv) Variety

As per IS …….

The licence is granted on the explicit condition that you will mark entire/substantial production which conforms to the Indian Standards.

2. The number assigned to this Licence is **CM/L- .....** which has been made operative from ..... and is valid up to ..... The licence number shall invariably be referred to in your future correspondence.

According to Sub-Paragraph (1) & (3) of Paragraph 5 of Scheme-I of Schedule-II under Bureau of Indian Standards (Conformity Assessment) Regulations, 2018, the annual licence fee of Rs.1000.00 and the marking fee for use of Standard Mark as per Annexure-I of Scheme-I of BIS (Conformity Assessment) Regulations, 2018 is payable by you with effect from ..... for the period of validity of the licence in advance.

3. Minimum Marking fee stipulated in Annexure-I of Scheme-I of BIS (Conformity Assessment) Regulations, 2018 is payable by you regardless of the fact whether you actually mark your product or not with the Standard Mark. Our Receipt No.**R/ .....** dated ..... for the licence fee and the minimum marking fee for the first operative period is already *issued/enclosed/being sent separately.

4. This advance minimum marking fee will be carried over to the next year on every renewal. The actual marking fee calculated on the unit rate on the production marked or the minimum marking fee, whichever is higher, shall be payable by you at the time of renewal.

5. With a view to streamlining the reporting of quantity marked, calculation and collection of marking fee on the unit rate basis, fees will be calculated on the production marked during the first nine months of operation of the licence at the time of first renewal, and on the production marked during twelve months comprising the last three months of the previous operative year and the first nine months of the current operative year, at the time of the second and

subsequent renewals. In case the licence expires, the entire production marked till the expiry date shall be taken into account for calculating the marking fee payable.

6. The Scheme of Inspection and Testing (SIT) submitted by you and agreed by BIS or the Scheme of Inspection and Testing as specified by BIS* will have to be implemented by your organization strictly and completely. This supervision of the operation of the Scheme shall be done by a person responsible for the quality control function in your organization. Kindly inform us the name and designation of the person who will be held responsible for the operation and maintenance of the Scheme. Any future change in this respect will have to be communicated by you to us as and when these take place.

7. We are enclosing a sheet giving the preferred dimensions of the Standard Mark to enable you to prepare the designs of the Standard Mark for marking the above product Photographic reduction in any size is permissible. This will ensure the relative proportions of the different dimensions maintained. Preferred dimensions be used as far as possible.

8. On commencement of marking of your product for which you are licensed, you may advertise your product with Standard Mark in various media only during the validity of your licence. The use of Standard Mark on letterheads and publicity literature will be permitted only on receipt of your assurance that in the event of cancellation or lapsing of your licence, the Standard Mark on your letterheads, publicity literatures etc. will be destroyed/obliterated.

9. This licence is granted for your manufacturing premises situated at (Address of factory) ..... Privileges under the licence shall not be exercised by any other firm company/factory etc. This licence is not transferable in the event of shifting the manufacturing and testing equipment from the licensed premises to some other place, use of Standard Mark shall be stopped till the new premises are inspected and found to be satisfactory by BIS in respect of manufacturing and testing facilities available there and the address of the new premises is endorsed in the licence.

10.* It may be noted that this licence is granted under option 2 which is subject to the condition that if samples drawn on **(Date of drawl of verification sample)** by BIS during the verification visit before grant of licence, fail to conform to the requirements of relevant Indian Standard (in any requirement), the licence shall be put under suspension, and in case fresh sample after corrective action is not offered within one month or fresh sample fails to conform to the requirement of relevant Indian Standard, in any requirement, the licence shall be processed for cancellation (Applicable for GOL under option 2).

Thanking you,

Signature of designated authority
(Name of designated authority)

Encl: As above.
(*strike out whichever is not applicable)

Annexure - VI

Our Ref.: Date:

Subject: Notice for Rejection of Application.

M/s

Dear Sir/Madam,

This is with reference to your application No.CM/A-……..for grant of licence to use the Standard Mark on your product …….as per IS…….

2. We regret to inform you that it has not been found possible to further process your application because of the following:

(BO to mention the reasons)

3. In view of above, it is proposed to reject your application. In case, you have anything to say in the matter, you may send your reply within 21 days of issue of this letter. If you desire to be heard by the undersigned in person or through a representative authorized by you on your behalf, you may seek an appointment for such a hearing with the undersigned, after submitting your written explanation.

4. In case no reply is received from your end within the stipulated period, we will process your application for rejection as per the sub-regulation (6) of regulation 4 of BIS (Conformity Assessment) Regulations, 2018 without any further notice to you.

Thanking you,

Signature of designated authority
(Name of designated authority)

Annexure - VII

Our Ref: ..... BO/A- Date:

Subject: Rejection of Application No. BO/A –

M/s

Dear Sir/Madam,

This is with reference to your Application No. A- …….. for grant of license to use the Standard Mark on your product of …… as per IS …….

2. Kindly refer to our letter of even number dated ……. In this letter we had informed you of our intention to reject your application for the following reasons:

(BO to mention the reasons for rejection of application, reference to reply from firm, its examination and consideration and also if any personal hearing is held, reference to the same needs to be indicated)

3. It has, therefore, been decided that the case relating to your above mentioned application be rejected. You may please apply afresh with applicable fee as and when you feel interested in future to get licence to use or apply Standard Mark on your product and are in position to comply with the above mentioned requirements.

4. 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.

Thanking You,

Signature of designated authority
(Name of designated authority)

Annexure – VIII

Additional requirements for Foreign Manufacturers Certification Scheme (FMCS)

The foreign manufacturers, who are having their factory location outside India, can apply under FMCS. Features of FMCS different from Indian manufacturers are as follows:

1) Applicant has to submit application form and other requisite documents in duplicate (presently, hard copies to be submitted) as per option 1 only.

2) All foreign manufacturers are considered as 'Large Scale' as per FMCS norms.

3) Nomination of Authorized Indian Representative (AIR) by foreign manufacturers (Applicants and licensee)

The applicant shall nominate AIR(s) in the Form – VI of Scheme – I for its operation of BIS licence for its group companies. For nominating an AIR, the applicant shall ensure the following:

a) AIR shall be an Indian resident.

b) AIR is representative of one manufacturing firm only and doesn't represent other foreign manufacturer(s) as AIR under the BIS Conformity Assessment schemes. However, in case of foreign manufacturers belonging to one group of companies and importers (related to the foreign manufacturer) nominated as AIR, the restriction shall not be applicable.

c) AIR(s) shall not have any conflict of interest with respect to their role as AIR with testing of sample(s) in third party laboratories.

d) AIR(s) shall be preferably at least graduate by qualification and shall understand the provisions of BIS Act, 2016 and rules, regulations framed thereunder and the implications thereof.

e) AIR(s) shall declare his/her consent to be responsible for compliance of the BIS Act, Rules, Regulations and Terms & Conditions as laid down in BIS Licence, Agreement, Undertaking etc. executed by or on behalf of the foreign manufacturer in connection with grant and operation of licence.

f) The name of AIR(s) is endorsed in the licence document.

4) The applicant shall confirm readiness for the inspection and should take all actions, like arrangement of air tickets, issuance of VISA and insurance, arrangement of transport in the foreign country, etc. for the officer, so that visit of the officer could take place at the earliest.

5) Responsibility for safe deposition of sample(s) to the labs and remittance of testing charges (directly to the OSLs in case sample is sent to OSLs and to BIS account. in case sample is sent to BIS Labs), lies with the manufacturer firm.

6) As provided under the provision of sub-regulation (11) of regulation 6 of BIS (Conformity Assessment) Regulations, 2018; the foreign manufacturer, after obtaining the licence, shall submit the details of consignment of goods bearing Standard Mark (giving details of Indian importer, distributor, dealer, retailer, final destination to whom goods or articles with Standard Mark is being supplied with estimated date(s) of entering Indian ports) to BIS online or through email as soon as these are despatched from the manufacturing premises..

7) Fees and charges

a) All payments are to be made in equivalent USD by applicants/ licensees of Non-SAARC Countries. All payments can be made either in Indian Rupees with GST (as applicable) or in equivalent USD by applicants/ licensees of the South Asian Association for Regional Cooperation (SAARC) Countries, i.e. Afghanistan, Bangladesh, Bhutan, India, Nepal, the Maldives, Pakistan and Sri Lanka.

b) Per-diem charges: Per diem charges for the officers shall be the same as applicable to "Scientist F" officer grade as per "Terms and conditions of service of employees Regulations of BIS". The applicant has to make accommodation arrangements during the visit. The applicant should pay 65% of the applicable per diem charges. The number of days of which per diem charges are to be paid by the applicant should be the number of inspection days plus one day.

c) Visit Charges: Applicant is also required to remit visit charges @ INR 7000 per day. The number of days of which visit charges are to be paid by the applicant should be the number of per diem days plus three days.

d) Contingency funds: Applicant is required to remit Contingency funds @ INR 10000 per licensee.

e) Agreement as mentioned in Form – IX and Indemnity Bond as mentioned in Form – X of Scheme – I are required to be executed and Performance Bank Guarantee (PBG), mentioned in Form – XI of Scheme – I, from any bank, having RBI approved branch in India are required to be furnished, after grant of licence. Performance Bank Guarantee shall have a validity of six months more than the validity of the licence.

BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:2 **08 August 2018**

Sub: Guidelines for Suspension (SUS) and Revocation of Suspension (ROS) of Licence – For Scheme I of Schedule II of BIS (Conformity Assessment) Regulations, 2018

These guidelines stipulate the procedure for imposition of Suspension on account of non-conformity of the product to the relevant Indian Standard or unsatisfactory performance or special situations. These are to be read in conjunction with BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018. In particular, the provisions for Suspension and Revocation of Suspension of a licence are addressed in Regulation 10 and Paragraph 11 of Scheme - I of Schedule - II of BIS(Conformity Assessment) Regulations, 2018. Any situation, in general, not covered in these guidelines are to be dealt as per the provisions of Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs).

A. SUSPENSION AND REVOCATION OF SUSPENSION IN CASE OF NON-CONFORMITY OF THE PRODUCT TO THE RELEVANT INDIAN STANDARD

Receipt of Test Reports

1. Each BO shall maintain record(s) for third party laboratory test reports received in BOs inline with Standard Operating Procedure for Processing and Payment of Testing Charges issued by Accounts Department. Maintaining the record and delivering the test reports to the concerned dealing officer (DO) shall be the responsibility of the person(s) designated by Head BO.

2. The DO shall examine the test reports and record 'Conforming/Non-conforming' on it with his signature, name and date. Incase of non-conforming sample, the DO shall record on the test report, the requirements in which the sample has shown non-conformity and also make necessary entry(ies) in BIS portal.

Non-conformity of Samples

3. When a sample is found non-conforming either in **Third Party Testing(TPT) or Factory Testing(FT)**, the dealing officer shall prepare "Review of Performance" (ROP) wherein she/he shall determine, in accordance with para 4 & para 5 whether it is a case of **first non-conformity** or **consecutive non-conformity**.

4. **First Non-conformity of sample:** The non-conformity of sample in Third Party Testing (TPT) or Factory Testing (FT) shall be treated as first non-conformity, if the previous test report (based on date of manufacturing or in its absence date of drawl) is found conforming.

5. **Consecutive Non-conformity of sample:** Any non-conformity of sample in TPT or FT shall be treated as a consecutive non-conformity if its date of manufacturing (in case date of manufacturing is not available, then date of drawl) is after the date of completion of corrective actions on first non-conformity and there is no **'conforming'** test report in between.

Note: In case any non-conforming test report pertains to the period prior to ROS, then it will not be considered for the purpose of review. However, non-conformity, if any, shall be communicated to the licensee.

Suspension due to non-conformity of samples

6. Suspension shall be imposed in the event of consecutive non-conformity of samples. However, in case of food products non-conforming in the requirement of toxicity or pesticide residues or radioactive residues or as per the product specific guidelines, suspension shall be imposed on first non-conformity itself. The DO shall recommend the case accordingly and put up the ROP to the Head BO.

7. In situations other than para 6 above, the non-conformity shall be communicated to the licensee **through email/speed post/IT Software with a copy of the test report** (template of the letter attached as **Annexure - I).** The licensee shall be advised to take corrective actions and submit its reply along with supporting evidence, as applicable, within 30 days (one month) from the date of communication.

8. (a) When the corrective actions as mentioned at para 7 above, are received within 30 days (one month), the DO shall put up the case to the Head BO for nominating an officer for verification of the corrective actions preferably within 90 days through a surveillance inspection.

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

9. However, if corrective actions as mentioned at para 7 are not received within 30 days (one month), the case may be processed for imposition of suspension.

Communication of Suspension

10. The decision of suspension shall be promptly communicated to the licensee **through email/speed post/IT Software** seeking its response (template of the letter attached as **Annexure - II)**. If response is received, then further action shall be taken as per para 11 and 12. If no response is received within 45 days from the date of communication of suspension, BO may arrange a visit to check any possible violation of the provisions of BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) regulations 2018. If there is still no response, licence may be processed for cancellation.

Inspection for Revocation of Suspension (ROS)

11. (a) On receipt of corrective actions, an inspection for considering ROS shall be organized by the Head BO preferably within 15 days. In case it is not possible to do so, the reasons for the same shall be recorded. During the inspection, the certification officer shall verify the corrective actions taken by the licensee.

(b) If all the requirements in which non-conformity was reported can be tested in the factory in a day or two, then sample from the lot offered shall be tested in the factory for all possible tests including the requirements in which non-conformity was observed.

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

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

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

Processing ROS 12. If the sample shows conformity in FT or TPT, as the case may be, ROS shall normally be processed within 7 days' time.

B. SUSPENSION (SUS) AND REVOCATION OF SUSPENSION (ROS) IN CASE OF UNSATISFACTORY PERFORMANCE

Unsatisfactory Performance of licence 13. Performance of a licence shall be treated as unsatisfactory in case of discrepancies observed in the operation of the licence. Such situations are not limited to, but may include the following:

a) Non-availability of testing personnel even as the Standard Mark is being used and product being dispatched/sold without testing
b) Use of Standard Mark on non-conforming products
c) Major deviations observed in the implementation of scheme of inspection and testing
d) Major modification(s) in the manufacturing process without prior evaluation of the Bureau
e) Unsatisfactory hygienic conditions in case of food products
f) Non-availability of manufacturing machinery and test equipments declared by the manufacturer

Inspection report indicating unsatisfactory performance

14. In case of unsatisfactory performance, the inspection report along with the DVR shall be submitted by the certification officer within 7 days from the date of inspection and necessary data entry shall be made by him/her in IT Software.

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

Suspension due to unsatisfactory Performance

16. In case of consecutive instances of unsatisfactory performance, suspension shall be imposed. However, suspension is not to be considered on the basis of combination of non-conformity of sample(s) in Third Party Testing/Factory Testing only and unsatisfactory performance.

17. In case of unsatisfactory performance due to the discrepancies mentioned at para 13 (d), (e) and (f) above, suspension may be imposed at the first instance itself.

18 In case of discrepancies mentioned at para 13, except 13 (d), (e) and (f), the reasons for unsatisfactory performance shall be communicated to the licensee **through email/speed post/IT Software with a copy of the DV report.** The licensee shall be advised to take corrective actions and submit its reply within 30 days (one month) from the date of communication.

19. (a) When the corrective actions are received within 30 days (one month), the DO shall put up the case to the Head BO for nominating an officer for verification of the corrective actions preferably **within 90 days through a surveillance inspection**.

(b) However, if complete and satisfactory reply is not received within 30 days (one month) from the date of communication of unsatisfactory performance, the case may be processed for suspension.

20. (a) The decision of suspension shall be promptly communicated to the licensee **through email/speed post/IT Software** seeking its response (template of the letter attached as **Annexure - II**). If response is received, then further action shall be taken as per para 21 and 22.

(b) In case no response is received within 45 days from the date of communication of suspension, BO may arrange a visit to check any possible violation of the provisions of BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) regulations 2018.

Inspection for Revocation of Suspension (ROS)

21. (a) On receipt of corrective actions, an inspection for considering ROS shall be organized by the Head BO preferably within 15 days. In case it is not possible to do so, the reasons for the same shall be recorded**. Wherever it is necessary for verification of corrective actions**, sample from one lot shall be tested in the factory for all possible tests in a day.

(b) In case of suspension due to major modification(s) in the manufacturing process without prior evaluation of the Bureau [Para 13(d)], sample shall be drawn for complete third party testing.

Processing ROS 22. (a) The action for ROS shall be completed preferably within three weeks' time from the date of receipt of corrective actions from the licensee. However, if the corrective actions are found to be insufficient, or if the sample shows non-conformity in factory-testing (where applicable), the licensee shall be advised to take corrective actions.

(b) In case of para 21(b), the action for ROS shall be completed within 7 days' time from the date of receipt of test report indicating conformity of the sample. However, if the sample shows non-conformity in TPT, the licensee shall be advised to take corrective actions**.**

C. <u>SUSPENSION (SUS AND REVOCATION OF SUSPENSION (ROS) IN CASE OF SPECIAL SITUATIONS</u>

Shifting of premises 23. When a licensee informs about shifting of the manufacturing facilities to a new premises, suspension shall be imposed. The decision on suspension shall be communicated to the licensee (template attached as **Annexure - II)** with an advise to also inform-

(i) The proposed new address to which the manufacturing facilities are being shifted,
(ii) Document for authentication of the new premises of manufacture,
(iii) Location map for the new premises,
(iv) The probable date for completion of the shifting process.
(v) All other relevant documents as taken during Grant of Licence.

Inspection for considering ROS 24. On receipt of information from the licensee about completion of shifting process, inspection shall be carried out at the old as well as the new premises to verify the same. During the inspection at the new premises, among other things, the certification officer shall –

(a) verify the manufacturing machinery, test equipment, plant layout and, if applicable hygienic conditions. If the Quality Control In-charge (QCI) has changed, the competence of QCI shall also be checked.
(b) verify the working condition of the manufacturing machinery and test equipment, a sample may be subjected to testing to ascertain the workability of manufacturing and testing equipment.
(c) in case of Packaged Drinking Water (PDW), draw a product sample for complete third party testing including radioactive residues, as change of source of water is involved. For other similar products product specific guidelines shall be followed, if any.

Processing ROS 25. (a) The process for ROS shall be completed preferably within 3 weeks from the date of receipt of information from the licensee about completeness of the shifting process. However, shifting of premises in case of PDW, the process for ROS shall be completed preferably within 7 days from the date of receipt

of satisfactory test report. The new address shall be endorsed in the licence as per the format attached as **Annexure - IV**.

(b) In case the licence does not confirm completion of shifting process for more than 90 days, a visit may be organized to both the new and existing premises to check any violation of the provisions of BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) regulations 2018.

Non-payment of fee

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

Non-implementation of revised Indian Standard

27. In case of non-implementation of revised Indian Standard, amendment to Indian Standard, suspension shall be imposed, if-
(a) Additional testing facilities are required and the licensee fails to develop the facility within the stipulated time;
(b) Non-submission of evidence of conformity to the revised provisions where it is a requirement as per the relevant BIS guidelines.

28. In case of SUS as at para 27,
(a) Where the licensee has to develop the additional testing facilities, ROS shall be permitted on confirmation of additional testing facility.
(b) Where evidence of conformity to the revised Indian Standard is not available, ROS shall be permitted on receipt of evidence of conformity of the product as per the new provisions.

Intentionally using Standard Mark on non-conforming goods

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

(b) If explanation is found to be satisfactory, the ROS shall be done as per as per para 11, 12.

Suspension on establishment of Complaint

30. If complaint regarding quality of any goods or article bearing the Standard Mark is established, the licence may be put under suspension and licensee shall be required to take corrective actions.

Revocation of Suspension done at para 30 above

31 The revocation of suspension shall be permitted only after successful verification of corrective actions as per para 11 & 12 above.

Suspension along with cancellation notice

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

Proceedings for cancellation

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

(b) Before cancelling a licence, a cancellation notice of not less than twenty one days shall be given to the licensee (template attached **Annexure - V)**.

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

Suspension in vogue for more than a year

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

Product specific guidelines

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

Inspection fee

36. 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

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

Annexure - I

Our Ref: ..... BO/CML- Dated:

Subject: Non-conformity of sample pertaining to CM/L-.....

M/s

Madam/Sir

Please refer to the BIS Certification Marks Licence No. CM/L-..... granted to you for use of BIS Standard Mark (ISI Mark) on..... (Product name) manufactured according to IS.....

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

Particulars of Sample:
Name of the Product: Date of Manufacturing:
Batch/C.U./Lot No.: Date of sampling:
Size/Variety/Type/Grade:
Source: Factory/Market Sample (purchase details)

Name of Laboratory	Test Report No	Requirement(s) in which sample is non-conforming

3. You are required to investigate the reasons for non-conformity by reviewing your quality assurance system and to take appropriate corrective actions. You may test the improved product after the corrective actions have been taken to ensure that the actions taken are appropriate to prevent recurrence of non-conformities observed.

4. You are further required to intimate BIS the details of corrective actions taken along with applicable supporting evidence within one month of the issuance of this letter, failing which your case may be processed for imposition of suspension. You are also required to inform the production schedule of the product as per the improved process for verification of corrective actions by BIS.

5. You are advised not to use Standard Mark on the non-conforming material and to take appropriate action to withdraw the non-conforming material pertaining to the Batch/Lot/C.U

number (refer paragraph 2 above) from market/dealer/distributor under intimation to this office.

6. In view of the non-conformity at paragraph 2, above, you are required to retest the available stock and ensure conformity to relevant standard before dispatch. Record of such retesting shall be maintained.

7. It may also be noted that, the Bureau may impose suspension according to the provisions of clause (a) of sub-paragraph (5) of Paragraph 11 of Scheme-I of Schedule-II under BIS (Conformity Assessment) Regulations, 2018 if any other sample (after completion of corrective action) is found not conforming to the standard.

8. Kindly acknowledge receipt and ensure compliance and reply as per para 4 above.

Signature of designated authority
(Name of designated authority)

Encl: as stated.

* ***Strike off whichever is not applicable***.

Annexure - II

Our Ref: ..... BO/CML- Dated:

Subject: Suspension of Licence CM/L---------- for---------- (Product name)

M/s

Kind Attn: (Name of the CEO/MD)

Madam/Sir,

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

2. In accordance with the provisions of clause (a) of sub-paragraph (5) of Paragraph 11 of Scheme-I of Schedule-II under BIS (Conformity Assessment) Regulations, 2018, it has been decided to put your licence under suspension with immediate effect due to the following reason(s):

(BO to mention reasons)

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 preferably by return speed post/e-mail. You are also advised to submit us the following details as on the date of receipt of fax/email:

a) Quantity of material with Standard Mark held in stock:
b) (i) Batch No(s). and date(s) of manufacture;
(ii) Brand;
(iii) size/type/grade/variety;
c) Packing details; and
d) Pending Orders for material with Standard Mark, if any with purchasers' names and addresses

4. Your reply with above stated details must reach us within 21 days of the issuance of this letter failing which it will be presumed that you do not have such material in stock. In case it is subsequently found that you have sold the material with Standard Mark after receipt of BIS instructions to suspension, it will be construed that the material so sold has been marked subsequently contravening 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.

5. *You are advised to take appropriate action to withdraw the material pertaining to the non-conforming Batch/Lot/C.U number..... from market /dealer/distributor, wherever possible, under intimation to this office.

6. Kindly note that, according to Paragraph 5 of Scheme-I of Schedule-II under BIS (Conformity Assessment) Regulations, 2018, the minimum marking fee as indicated in the Schedule of above mentioned licence is payable by you even during the period the licence is not in operation due to suspension.

7. You are required to take necessary corrective action in the context of the reasons for suspension as stated in paragraph 2 above and submit complete details of compliance with all supporting evidence, as applicable, for examination and verification. *You are advised to produce a fresh batch/lot/control-unit after taking corrective actions and confirm your readiness for the visit by BIS to consider revocation of suspension.

8. A sum of Rs…….shall be payable to BIS in advance towards this visit.

9. The reply with information sought under point 4 & 5 above should be sent immediately by return speed post/e-mail but not later than 21 days from the issuance of this letter. Further, complete reply with respect to Para 7 should reach BIS within 45 days failing which your licence will be considered for cancellation as per Regulation 11 of BIS (Conformity Assessment) Regulations, 2018.

10. Kindly acknowledge 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***

Annexure - III

Our Ref: ..... BO/CML- Dated:

Subject: Unsatisfactory performance pertaining to CM/L ----------

M/s

Madam/Sir,

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

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

3.* Also, during the inspection, 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.

Particulars of Sample:
Name of the Product: Date of Manufacturing:
Batch/C.U./Lot No.: Size/Variety/Type/Grade:

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

4.* You are advised not to use Standard Mark on the non-conforming material and to take appropriate action to withdraw the non-conforming material pertaining to the Batch/Lot/C.U number (refer paragraph 3 above) from market/dealer/distributor under intimation to this office.

5.* In view of the non-conformity at paragraph 3, above, you are required to retest the available stock and ensure conformity to relevant standard before dispatch. Record of such retesting shall be maintained.

6. You are advised to take appropriate corrective actions to avoid such discrepancies in future and intimate BIS the details of actions taken along with applicable supporting evidence within one month from the issuance of this letter.

7. Kindly note that in case, complete/satisfactory reply is not received within the stipulated period or performance during next surveillance visit is also found unsatisfactory, suspension

may be imposed in accordance with clause (a) of sub-paragraph (5) of Paragraph 11 of Scheme - I of Schedule - II under BIS (Certification) Regulations, 2018.

8. Kindly acknowledge receipt and ensure compliance under intimation to this office.

Thanking you

Signature of designated authority
(Name of designated authority)

Encl: As above

**** Strike off where not applicable***

Annexure - IV

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

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

Endorsement No. ..... Dated ....

Consequent to the shifting of the factory, the address of the licensee mentioned in the Licence has been changed to ..... with effect from .....

Other terms and conditions of the Licence remain the same.

Signature of designated authority
(Name of designated authority)

Annexure - V

Our Ref: ..... BO/CML- Dated:

Subject: Notice for Cancellation of BIS Product Certification licence No.CM/L ……for…….(Product Name) as per ……(IS No.)

M/s

Kind Attn: (Name of the CEO/MD)

Dear Sir/Madam,

This has reference to the BIS Product Certification Licence No. CM/L-…….. held by you to use the Standard Mark on your product…….as per IS……which is valid up to……..

2. The following serious discrepancies were observed with regard to the operation of the above licence which is violation of the provision of Regulation ..... of BIS (Conformity Assessment) Regulations, 2018.

(RO/BO to give the reasons for proposed cancellation in this space)

3. In view of the above, it is proposed to cancel the licence CM/L- .....held by you in accordance with the provisions under Section 13 of the BIS Act, 2016 read in conjunction with the provisions of Regulation 11 of BIS (Conformity Assessment) Regulations, 2018.

4. **In view of the above you are, henceforth, not permitted to use and apply Standard Mark and dispatch (including stock in hand) the above mentioned product with Standard Mark**. Your licence is, therefore, put under **suspension** with immediate effect & you are advised to confirm that you have stopped using and applying Standard Mark immediately preferably by returned speed post/e-mail. You are also advised to submit us the following details as on the date of receipt of speed post/email:

(a) Quantity of material with Standard Mark held in stock

(b) (i) Batch No(s) and date(s) of manufacture;

(ii) Brand;

(iii) size/type/grade/variety

(c) Packing details; and

(d) Pending Orders for material with Standard Mark, if any with purchasers' name and address

5. In case you have anything to say in this matter, you may submit your explanation to the Bureau within 21 days from the date of issue of this notice, failing which, it will be presumed that you are no longer interested in continuing the said licence and as such the licence will be processed for cancellation without any further reference to you.

This notice is being issued **without any prejudice to the right of this Bureau to take any legal action under section 29 of the BIS Act, 2016.**

6. If you desire to be heard in person or through a representative authorized by you on your behalf, you may seek an appointment for such a hearing with the undersigned, after submitting your written explanation.

7. Kindly acknowledge the receipt of this letter and ensure compliance.

Thanking You,

Signature of designated authority
(Name of designated authority)

Enclosed: As above

Annexure - VI

Our Ref: ..... BO/CML- Dated:

Subject: Cancellation of BIS Certification Marks Licence No. CM/L…… for……. (product name) as per IS……..

M/s

Dear Sir/Madam,

This has reference to BIS Product Certification Licence No……held by you for (product name) as per IS …….which was valid upto ……..

2. The Competent Authority has decided to cancel your Licence after …… as per the provision of Regulation ..... of BIS (Conformity Assessment) Regulations, 2018 due to the following reasons:

(BO to mention the reasons)

3. Your above mentioned licence, therefore, stands Cancelled w.e.f.…….You are therefore, NOT entitled to mark/ dispatch your product (product name) as per IS …… with BIS Standard Mark after …… or to claim in your advertisements or in any other publicity material that you are a licensee to use the ISI Mark on your product after …….

4. Any publicity material such as handbills, pamphlets, letterheads, etc. claiming that you hold BIS Product Certification Licence for your above mentioned product should be destroyed or such markings obliterated/defaced immediately. This should be confirmed by you at the earliest, positively within 15 days.

5. Further, you are advised to furnish a statement of (Product Name) with Standard Mark as follows:

a) Quality held in stock:
   i) Type or Grade
   ii) Variety
   iii) Brand, if any
b) Batch number/drum number
c) Packing
d) Pending order for ISI certified material, if any and purchaser's name and address

6. Please note that any material found marked with BIS Standard Mark after …….., will be deemed to be the violation of the provisions of the BIS Act 2016, and Rules and Regulations framed thereunder and action will be taken as per the BIS Act 2016, and Rules and Regulations framed thereunder.

7. You are advised to surrender the original licence along with all the attachments/endorsements sheets, etc. and also submit an undertaking to the fact that you have not retained photocopy of the said licence document and shall not produce it anywhere under any circumstances subject to prior permission from BIS in this regard.

8. If you are aggrieved by the above order, you may prefer an appeal to the Director General, Bureau of Indian Standards within ninety days from the date of the order with a fee of two thousand rupees as per provisions of section 34 of the BIS Act 2016 read along with Rule 37 of the BIS Rules 2018.

9. Please acknowledge receipt of this letter and confirm compliance within the stipulated period.

Signature of designated authority
(Name of designated authority)

BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:3 **08 August 2018**

Subject: Guidelines for Renewal of Licence (RoL) as per the conformity assessment Scheme – I of Schedule – II of BIS (Conformity Assessment) Regulations, 2018

These guidelines stipulate the procedure for renewal of licence (RoL). These are to be read in conjunction with BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018. In particular, the provision for RoL are addressed in Regulation 8 and Paragraph 9 of Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018. Any situation, in general, not covered in these guidelines are to be dealt as per the provisions of Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs). All the forms mentioned herein corresponds to those given in Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018

General principles for RoL

1. Licence may be considered for renewal for a period of minimum one year and upto five years on the request of the licensee, depending upon whether the application fee, licence fee, advance minimum marking fee and dues, if any, has been paid for requested duration along with the renewal application. For example, if the renewal has been requested for five years, licensee is required to submit licence fee and advance minimum marking fee for five years. The renewal of licence shall be endorsed as per Form - XIII.

Renewal application

2. The renewal application shall be made through BIS portal in Form - XII along with relevant documents, preferably two months prior to the validity date. For calculation of marking fee, production statement duly authenticated by chartered accountant/cost accountant (CA) shall be submitted as per the provisions of clause 5 of these guidelines.

Deferment of decision to renew the licence (for all cases)

3. **(a)** When renewal application along with the requisite fee (Renewal application fee, annual licence fee and applicable marking fee) and dues, if any, is not received within the validity period of the licence, the decision to renew the licence may be deferred for not more than 90 days from the date of validity of the licence.

(b) A communication shall be sent to the licensee by the BO (Template enclosed as Annexure - I) in this regard. The licence shall stand expired after 90 days from the date of validity if renewal application and requisite fee (including late fee) is not received from the licensee within this period.

Deferment of renewal of licence

4. **(a)** If the licence is under suspension at the end of validity period and the licensee has applied for renewal of licence, licence shall not be renewed till suspension is revoked.

(Where licence is under suspension)

(b) In such cases, the decision to renew the licence may be deferred for not more than 180 days from the date of validity. (see sub-regulation (6), (7) and (9) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018)

(c) In such a case, a communication shall be sent (Template enclosed as Annexure - II) to the licensee. If there is no response from the licensee or the response is not adequate within stipulated period, a communication shall be sent (Template enclosed as Annexure - III), preferably, two months prior to the last date till which decision of renewing the licence may be deferred.

(d) During this period, if all the actions for revocation of suspension are completed, the licence shall be renewed. However, if the revocation of suspension of licence is not done within the period of 180 days, the licence shall stand expired.

Calculation of actual marking fee

5. **(a)** For the payment of marking fee on actual basis before the end of the each operative year, firm shall submit the production statement of goods bearing standard mark for the period of last three months of previous operative year and first nine months of current year.

(b) Where volume of production is high, licensee may be directed to pay actual marking fee on quarterly basis.

(c) Production statement(s) of the licensee shall be obtained on the letter head of the chartered accountant/cost accountant (CA) indicating its membership number along with name of the unit, address and actual quantity produced for the said period.

Expiry of licence

6. In case of expiry of licence, applicable communication in the format (Template enclosed as Annexure - IV and Annexure - V) shall be sent by the BO.

Annexure-I

Our Ref: ..... BO/CML- Dated:

Subject: Provision of submission of renewal application with late fee within 90 days of validity - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. ……..... granted to you for use of Standard Mark on your product ……..... under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..... which was valid upto ……....

2. Please refer to our communication dated ..... about validity of your licence and requesting you to apply for renewal of your licence. Since, you have not submitted the renewal application with requisite fee till the validity date, the decision to renew your licence can be deferred for a maximum duration of ninety days from the date of its validity as per sub-regulation(4) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018,.

3. In view of the above, you have no right to mark and dispatch (including stock in hand) the above mentioned product with standard mark after the date of validity. You are, therefore, instructed to ensure stoppage of use of standard mark on the product with immediate effect and confirm the same giving the following details as on the date of issuance of this communication:

a) Quantity of material with Standard Mark held in stock:

b) (i) Batch/C.U./Lot no. and date of manufacture;
(ii) Brand(s);
(iii) size/type/ grade/variety;

c) Packing details; and

d) Pending orders for material with Standard Mark, if any with purchasers' names and addresses

4. Your reply with above stated details must reach us within 21 days of the issuance of this letter failing which it shall be presumed that you do not have such material in stock. In case it is subsequently found that you have sold the material with Standard Mark after receipt of these instructions, it will be construed that the material so sold has been marked subsequently contravening the provisions of the BIS Act, 2016. In such an eventuality, the Bureau reserves the

right to take such action against you as envisaged in the BIS Act, 2016, Rules & Regulations framed thereunder.

5. Please note that after the last date of validity, you shall not claim by any means that you would supply the material with the Standard Mark.

6. As per sub-regulation (5) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018, you may submit the renewal application form along with requisite fee, accompanied with late fee of rupees five thousand, within ninety days from the last date of validity, i.e. upto ..... It may be noted that, the marking fee as indicated in the schedule of the licence is payable by you for the complete period, including the period for which you have no right to use Standard Mark on your product.

7. **It may be noted that**, in case the renewal application along with requisite fee including late fee is not received within ninety days, then as per sub-regulation (4) of regulation 4 of BIS (Conformity Assessment) Regulations, 2018 your licence shall stand expired after the last date of its validity.

Thanking you.

Signature of designated authority
(Name of designated authority)

Annexure-II

Our Ref: ..... BO/CML- Dated:

Subject : Deferment of decision to renew licence in view of licence under suspension - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. ……..... granted to you for use of Standard Mark on your product ……..... under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..... which was valid upto ……....

2. As per sub-regulation (7) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018 the decision to the renew the above mentioned licence has been deferred as the licence is under suspension w.e.f. ....., which has been communicated to you vide our letter ref: ..... dated .....

3. Please note that from the date of suspension, i.e. ....., you are not authorized to claim by any means that you would supply the material with the Standard Mark as already advised.

4. You may also note that, if your licence gets renewed then the marking fee as indicated in the schedule of the licence is payable by you even for the complete period including the period for which you have no right to use Standard Mark on your product.

5. #You are required to take necessary action in the context of the reasons to defer the decision to renew the licence as mentioned at para 2 within .....

6. **It may be noted that**, in case necessary actions are not taken by you within the stipulated period, i.e. upto ..... or suspension is not revoked within one hundred and eighty days from the date of validity (whichever is earlier), then as per sub-regulation (7) and (9) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018 your licence shall stand expired after the last date of its validity.

Thanking you.

Signature of designated authority
(Name of designated authority)

BO to specify the applicable time period

Annexure-III

Our Ref: ..... BO/CML- Dated:

Subject : Notice for Expiry of licence due to licence under suspension

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. ……..... granted to you for use of Standard Mark on your product ……..... under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..... which was valid upto ……....

2. As per sub-regulation (7) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018 the decision to the renew the above mentioned licence was deferred as the licence is under suspension as communicated to you vide our letter ref: ..... dated ..... You were advised to take necessary action under intimation to BIS to enable revocation of suspension on or before .....

3. No response has been received from your side or the response has not been found adequate

(BO to specify the reasons)

4. In view of above, as your licence continue to be under suspension, decision to renew your licence cannot be taken as per sub-regulation (6) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018.

5. **It may be again noted that**, in case necessary actions are not taken by you within the stipulated period, i.e. upto ..... or suspension is not revoked upto one hundred and eighty days from the date of validity, then as per sub-regulation (7) and (9) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018 your licence shall stand expired after the last date of its validity.

6. In case, you have anything to say in the matter or you would like to be heard either in person or through a representative authorized by you in this behalf, kindly do so within 21 days of issue of this letter.

Thanking you.

Signature of designated authority
(Name of designated authority)

Annexure-IV

Our Ref: ..... BO/CML- Dated:

Subject : Expiry of BIS Certification Marks Licence No. CM/L- …… as per : IS …….

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

Please refer to our communication Ref ..... dated ..... regarding provision of submission of renewal application with late fee within 90 days of validity for the renewal of BIS Certification Marks Licence No. ……. held by you for your product under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..after ……..

2. Since, renewal application along with requisite fee (including late fee) has not been submitted within ninety days from the last date of validity of licence, then as per sub-regulation (4) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018 your above mentioned licence stands expired.

3. As informed earlier also, you are NOT entitled to mark/dispatch your product ……as per IS …….. with BIS Standard Mark or to claim in your advertisements or in any other publicity material that you are a licensee to use the Standard Mark on your product after ..... Any publicity material such as handbills, pamphlets, letterheads, etc. claiming that you hold BIS Certification Marks 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 21 days.

4. Please note that any material found marked with BIS Standard Mark after ....., will be deemed to be marked illegally violating the provisions of BIS Act, 2016 and Rules & Regulations framed thereunder and action will be taken as per applicable provisions.

5. Please acknowledge receipt of this letter and confirm compliance within the stipulated period.

Signature of designated authority
(Name of designated authority)

Annexure-V

Our Ref: ..... BO/CML- Dated:
Subject : Expiry of BIS Certification Marks Licence No. CM/L- …… as per IS …….

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

Please refer to our communication Ref: ..... dated ..... regarding deferment of decision to renew BIS Certification Marks Licence No. ……. held by you for your product under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..after ……..

2. Also, refer to the expiry notice Ref: ..... dated .....
(Reasons for licence under suspension even after one hundred and eighty days, reply from firm, its examination and consideration and also if any personal hearing is held, reference to the same needs to be indicated)

3. As the necessary actions were not taken by you within the stipulated period, i.e. upto ..... or suspension is not revoked upto one hundred and eighty days from the date of validity, then as per sub-regulation (7) and (9) of regulation 8 of BIS (Conformity Assessment) Regulations, 2018 your licence stands expired after .....

4. As informed earlier also, you are NOT entitled to mark/dispatch your product …… as per IS …….. with BIS Standard Mark or to claim in your advertisements or in any other publicity material that you are a licensee to use the Standard Mark on your product after ..... Any publicity material such as handbills, pamphlets, letterheads, etc. claiming that you hold BIS Certification Marks 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 21 days.

5. Please note that any material found marked with BIS Standard Mark after ....., will be deemed to be marked illegally violating the provisions of BIS Act, 2016 and Rules & Regulations framed thereunder and action will be taken as per applicable provisions.

6. 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 2017.

7. Please acknowledge receipt of this letter and confirm compliance within the stipulated period.

Signature of designated authority
(Name of designated authority)

BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:4 **08 August 2018**

Subject: Guidelines for Change in Scope of Licence (CSoL) and special situations as per the conformity assessment Scheme – I of Schedule – II of BIS (Conformity Assessment) Regulations, 2018

These guidelines stipulate the procedure for change in scope of licence (CSoL) and any special situations encountered during the operation of licence. These are to be read in conjunction with BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018. In particular, the provision for CSoL are addressed in Regulation 9 and Paragraph 10 of Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018. Any situation, in general, not covered in these guidelines are to be dealt as per the provisions of Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs). All the forms mentioned herein corresponds to those given in Scheme - I of Schedule - II of BIS (Conformity Assessment) Regulations, 2018

General Principles for CSoL

1. The scope given in the schedule of licence covers types, sizes, grades, varieties, etc. for which licence is granted by the Bureau to licensee to use standard mark for the product manufactured in accordance with relevant Indian Standard(s) mentioned in the schedule of licence. The change in scope of licence shall be endorsed as per Form - XV.

Application for CSoL

2. An application for change in scope of licence shall be made in the Form - XIV along with requisite fee and relevant documents. An amount of rupees five thousand shall be chargeable per variety or, where grouping guidelines are available, per group of varieties.

Test report (s) not required

3. If there is no change in infrastructure (including manufacturing machinery and test equipments) and change in scope of licence is in same group of sampling guidelines, then test report(s) from third party laboratory is/are not required for processing change in scope of licence.

Explanation - For any minor changes in infrastructure like jigs/fixtures/die/mould etc., third party laboratory test report(s) may not be insisted upon. The declarations regarding such changes shall be obtained in Form - I/Form - II and verified during next surveillance visit. However, in-house test report(s) excluding test(s) of duration more than 30 days shall be taken from the firm. Also, sample drawn during next surveillance visit shall preferably be of new variety added to the scope of licence.

Test report (s) required

4. **(a)** For cases other than those falling under sr. no. 3 of these guidelines, licensee may choose any of the options available under grant of licence

guidelines and all remaining relevant procedures regarding factory visit/ test report(s)/undertakings/product specific applicability of options etc. to be followed (unless otherwise specified to **deviate** here in this guideline).

(b) Under option 1 licensee shall submit

i) Declarations regarding changes in manufacturing machinery and test equipments, if any, in Form - I and Form - II

ii) Test Report/Test Certificates of **additional** raw materials/components, if required

(c) Under option 2 licensee shall submit (**available for foreign manufacturers also**)

i) Declarations regarding changes in manufacturing machinery and test equipments, if any, in Form - I and Form - II

ii) Test Report/Test Certificates of **additional** raw materials/components, if required

iii) Third party laboratory test report(s) complete in all aspects

(d) The test report(s), manufacturing machinery, test equipments declarations submitted along with application, shall be evaluated and if found satisfactory, change in scope shall be permitted. Endorsement to licensee shall be issued as per Form - XV for change in scope of licence.

(e) For option 2, factory visit is not required to be carried out. However, during the next surveillance inspection, all verifications such as additional requirements, raw materials, process requirements & controls, manufacturing machinery, test facilities, shall be verified and reported. Sample drawn during next surveillance visit shall preferably be from new variety added to the scope of licence.

Deficiencies

5. **(a)** In case of any deficiencies observed in the application for change in scope of licence, the same shall be communicated to firm for providing information within 21 days. In case of no reply/incomplete reply a rejection notice shall be issued (Template enclosed as Annexure - I).

(b) The decision on rejection shall be taken based on the merit of the case.

(c) In case, the application for change in scope of licence is rejected, the same shall be communicated to the licensee (Template enclosed as Annexure - II).

Reduction in scope of licence

6. If at any time, there is reason to reduce the scope of licence, a notice of one month shall be issued to the licensee (Template enclosed as Annexure - III). The change in scope of licence shall be informed (Template enclosed as Annexure - IV) and endorsed as per Form - XV.

Special situations

7. For any special situation arising during the operation of licence with regard to change of name, management, ownership etc., appropriate details with requisite documents as required at the time of grant of licence shall be collected. Such changes shall be duly endorsed in the licence. For guidance, following templates are enclosed

i) Change in name of licensee; Annexure - V

ii) Change in marking fee; Annexure - VI

iii) Change in Indian Standard; Annexure - VII

Annexure-I

Our Ref: ..... BO/CML- Dated:

Subject : Rejection notice of application for change in scope of licence - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. ……..... granted to you for use of Standard Mark on your product ……..... under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..... valid upto ……..... and your application dated ..... received at this office dated ..... for change in scope of licence.

2. We regret to inform you that it has not been found possible to further process your change in scope of licence application because of the following:

(BO to give the reasons in this space)

3. In view of the above, it is proposed to reject your application. In case, you have anything to say in the matter or you would like to be heard either in person or through a representative authorized by you in this behalf, kindly do so within 21 days of issue of this notice. In case, no reply is received from your end within the stipulated period, we will process closure of your application without any further notice to you.

Thanking you.

Signature of designated authority
(Name of designated authority)

Annexure-II

Our Ref: ..... BO/CML- Dated:

Subject : Rejection letter of application for change in scope of licence - reg.
M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. ……..... granted to you for use of Standard Mark on your product ……..... under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..... valid upto ……....

2. Kindly refer to our rejection notice Ref: ..... dated ..... In this notice you had been informed of our intention to reject your application for change in scope of licence.

3. Your reply to our rejection notice was due by ....., but we have not received any reply from you till date.

(or)

The reply received with your letter Ref: ..... dated ..... has not been found satisfactory due to following reasons:

(Reference to reply from firm, its examination and consideration. Also, if any personal hearing is held, reference to the same needs to be indicated)

4. It has, therefore, been decided that the case relating to your above mentioned application for change in scope of licence be rejected. You may apply afresh with requisite fee as per our procedure.

5. 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 2017.

Thanking you.

Signature of designated authority
(Name of designated authority)

Annexure-III

Our Ref: ..... BO/CML- Dated:

Subject : Notice for reduction in scope of licence - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. ……..... granted to you for use of Standard Mark on your product ……..... under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..... valid upto ……....

2. It is proposed to reduce the scope of your licence from present scope of ..... to revised scope of ..... due to the following :

(BO to mention reasons)

3. In case, you have anything to say in the matter or you would like to be heard either in person or through a representative authorized by you in this behalf, kindly do so within 30 days of issue of this notice.

Signature of designated authority
(Name of designated authority)

Annexure-IV

Our Ref: ..... BO/CML- Dated:

Subject : Reduction in scope of licence - reg.

M/s

(Kind Attn. Name of CEO/MD)

Dear Madam(s)/Sir(s),

This has reference to BIS certification mark licence No. ……..... granted to you for use of Standard Mark on your product ……..... under Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018 as per IS ……..... valid upto ……....

2. Kindly refer to our reduction in scope of licence notice Ref: ..... dated ..... In this notice you had been informed of our intention to reduce the scope of licence for the following reasons.

(Reference to reply from firm, its examination and consideration. Also, if any personal hearing is held, reference to the same needs to be indicated)

3. The revised endorsement for the reduction in scope of licence is enclosed herewith this letter.

4. 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 2017.

Signature of designated authority
(Name of designated authority)

Annexure - V

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

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

Endorsement No. ..... Dated ....

Consequent to the change in the name of the firm, the name of licensee in the schedule of the licence has been changed to ..... with effect from .....

Other terms and conditions of the licence remain the same.

Signature of designated authority
(Name of designated authority)

Annexure - VI

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

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

Endorsement No. ..... Dated ....

Consequent upon the revision of rate of marking fee in the Schedule of the licence have been revised as under with effect from ..... :

₹ ...../- per unit for the first ..... units, ₹ ...../- per unit for the rest of the units with a minimum marking fee of ₹ ...../- during an operative period of one year

Unit: .....

Other terms and conditions of the Licence remain the same.

Signature of designated authority
(Name of designated authority)

Annexure - VII

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

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

Endorsement No. ..... Dated ....

Consequent upon the revision of IS ..... as IS ..... the Indian Standard number specified in the schedule of the licence stands revised as under with effect from .....:

.....

Other terms and conditions of the Licence remain the same.

Signature of designated authority
(Name of designated authority)

BUREAU OF INDIAN STANDARDS
(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:5 **08 August 2018**

Subject: Guidelines for coding and retesting of sample(s) for the conformity assessment Scheme – I of Schedule – II of BIS (Conformity Assessment) Regulations, 2018

These guidelines stipulate the procedure for coding of sample drawn by certification officers and retesting of those samples or counter samples. These are to be read in conjunction with BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018. In particular, the provision for drawal of samples are addressed in sub-paragraph 6 of paragraph 3 of Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018.

Coding of Samples:

1. The sample(s) drawn by the certification officers may be coded in the following manner:

   Branch Office/Employee No./Sample drawl date/Type of sample/Serial number

2. Branch Office refers to jurisdiction under which manufacturer is located.

3. Date of drawl of sample in the format YYYYMMDD.

4. Type of samples:

Applicant sample (option 1)	AS
Applicant sample (option 2)	VS
Complaint sample	CP
Change of scope sample	IN
Market sample	MS
Factory sample	FS (operative licence sample)
Counter sample	CS
Revocation of suspension sample	RM
Enforcement sample	ES

5. Serial number is sequential number of the test request finalized by employee no on that date.

6. For enforcement operations sample, employee no. of enforcement team leader to be used

Retesting of Sample or Counter Sample:

7. Head BOs may also allow testing of counter samples when the original sample is damaged or lost in transit due to bonafide reasons. No additional charge for such samples be levied.

8. When any sample drawn is found non-conforming in a third party laboratory testing, the firm may challenge the test results and submit justification in this regard. Firm may request for the testing of counter sample or the testing on remnants of sample, if feasible.

9. Head BO may allow all such reasonable requests. However, in case of refusal of such requests, the matter shall be decided by Head of the Region.

10. The testing charges for retesting of the remnants or counter sample at the request of firm shall be twice the rates charged for normal testing and shall be borne by firm.

11. For witnessing the test(s), a separate charge of rupees ten thousand per day, cost of travel, boarding and lodging for the BIS official to witness the testing shall be payable by the firm. The concerned officer incharge and QA officer shall also be personally remain present and witness such testing either in BIS laboratory or in OSLs.

12. In case, the firm requests for retesting of only non-conforming requirements:

a) For testing on remnants of already tested sample: testing of other parameters may be foregone by BO, if felt technically appropriate

b) For testing on counter sample: testing of other interrelated parameters shall not be foregone, such decisions to be taken by BO based on the nature of the product

BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:6 **08 August 2018**

Subject: Guidelines for Surveillance during operation of licence for the conformity assessment Scheme – I of Schedule – II of BIS (Conformity Assessment) Regulations, 2018

1. These guidelines stipulate the requirements of surveillance by BIS for monitoring the operation of product certification licences by Branch offices. These are to be read in conjunction with BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018. In particular, the provision of surveillance are addressed in sub-paragraph (6) of paragraph 3 of Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018.

2. BIS shall carry out both pro-active surveillance and reactive surveillance under the product certification scheme which aims to check conformance to standards by the licence holder on continuous basis and may provide inputs & opportunities for improvement. Pro-active surveillance will involve both pre-market surveillance activities (like surprise factory surveillance) and post market surveillance activities (like market sample drawl and testing, obtaining feedback from organized buyers) and follow up activities. Re-active surveillance will involving attending to consumer complaints, its investigation and follow up activities.

3. Pro-active surveillance:

(1) Pre-market surveillance:

(i) BIS shall carry out factory surveillance at the premises of the licensee based on risk assessment of the product category and the licensee. In this regard, BOs will be required to follow guidelines for risk assessment issued by Central Marks Deptt (CMD).

(ii) Quarterly/monthly factory surveillance plans shall be prepared by the Head of BOs ensuring the spread of surveillance throughout the year. While planning surveillance, the various relevant factors like seasonality of the product, available production schedule information, adherence to principle of rotation of certification officers (or agents, if applicable) etc shall be followed.

(iii) For products under lot inspection where the licensee requests for issuance of test certificate based on pre-despatch inspection (e.g. Gas cylinder/valve/regulator etc.), normally not more than two inspections per licence may be planned every week. For such inspections, licensee shall make arrangement for travel and stay of the certification officer, as applicable. Otherwise, the payment towards travel and stay (for boarding and lodging per night stay) on actual basis shall be charged in addition to inspection charges (Rs. 10,000/-) as specified in Scheme I of BIS (Conformity Assessment) Regulations.

(2) Post-market surveillance:

Procurement of Product samples from Market:

(i) BIS shall procure market samples of the standard mark products based on risk assessment of the product category and the licensee. In this regard, BOs will be required to follow

guidelines for risk assessment issued by Central Marks Deptt (CMD). Generally, two samples per year may be procured for each licence from the market for independent testing in laboratory.

(ii) Samples of certified products shall be normally purchased from market. The same may also be procured from organized buyers or from any point in the supply chain including port of entry. In case, it is not possible to procure sample from any point in the supply chain, it may be drawn from despatch point. However, the certification officer (or agent) may draw the sample from despatch point with relevant details of consignee, invoice no and date etc.

(iii) Head of BO shall ensure planning for procurement of market samples ensuring the spread throughout the year and the market regions.

Feedback from Organized buyers:

(iv) For identified products (where sample is costing more than Rs. 10,000/-, licence is operated on factory testing basis, transportation is extremely difficult, etc.) BO shall obtain feedback about certified products from organized buyers specifically in the Govt sector. Feedback from organized buyers may also be obtained in addition to procurement of market samples.

4. Reactive surveillance:

(i) BO may carry out factory surveillance of the licensee based on consumer complaint (including for complaint investigation) or based on feedback/information available through any other means.

5. Post surveillance activities:

(i) BO shall ensure appropriate follow up for all surveillance activities based on review of reports (Factory visit reports, Test reports from labs, complaint investigation reports etc.) as per laid down provisions of BIS Act, Rules, (Conformity Assessment) Regulations and guidelines.

6. Dynamic Surveillance:

(i) The review of surveillance activities for a licensee may be used as an input to risk based analysis and BO may review the frequency of pre-market surveillance based on the same for a licensee.