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

हमारा सन्दर्भ: सीएमडी-I/2:12:6 **08 फरवरी 2021**

विषय: भारतीय मानक ब्यूरो (अनुरूपता निर्धारण) विनियम, 2018 की अनुसूची-II की अनुरूपता निर्धारण स्कीम-I के अंतर्गत लाइसेंस के संचालन के दौरान फैक्ट्री निगरानी के दिशानिर्देश - हेतु।

जैसा कि सूचित किया गया है, ओ०एम० सन्दर्भ: एचआरडी/19:5 दिनांक 12 अक्टूबर 2020 द्वारा, सक्षम प्राधिकारी ने नए सर्टिफिकेशन, सर्विलांस एवं मॉनिटरिंग विभाग (सीएसएमडी) बनाने का निर्णय लिया है, जिसका उद्देश्य संबंधित गतिविधि में बेहतर समन्वय तथा निगरानी है। यह एक निष्ठापूर्त नोडल विभाग है, जो कि पुरे भारत व्यापी स्तर पर सर्विलांस गतिविधियों की योजना, निष्पादन, निगरानी और समीक्षा कार्य करेगा एवं संपर्क का एकल बिंदु भी होगा। उपर्युक्त विषय पर सक्षम प्राधिकारी द्वारा अनुमोदित निम्नलिखित दिशानिर्देश सभी संबंधित पक्षों के कार्यान्वयन के लिए सलंग्न है।

2. संसाधनों की सुविधा और वृद्धि के लिए, बीआईएस नियम 2018 के नियम 33 के तहत उपलब्ध प्रावधानों के अनुसार, अपने निमित्त पक्ष से फैक्ट्री निरीक्षण गतिविधियों को करने के लिए बीआईएस द्वारा पांच एजेंटो को नियुक्त किया गया है। ये एजेंट निम्नलिखित है:

   i) टीयूवी एसयूडी साउथ एशिया प्राइवेट लिमिटेड
   ii) टीयूवी इंडिया प्राइवेट लिमिटेड
   iii) क्वालिटी ऑस्ट्रिया सेंट्रल एशिया पीवीटी० एलटीडी०
   iv) ब्यूरो वेरिटास (इंडिया) पीवीटी० एलटीडी०
   v) राइट्स एलटीडी०

3. फैक्ट्री निगरानी के लिए संशोधित व्यापक दिशानिर्देश, जिसमे हाल ही में हमारे आईटी सहायता विभाग द्वारा विकसित मोबाइल एप्प का विवरण भी है, को सक्षम प्राधिकारी ने अनुमोदित कर दिया है। यह निम्नलिखित कथित दिशानिर्देश सभी के कार्यान्वयन के लिए संलग्न है:

   i) सन्दर्भ: सीएमडी-I/2:12:6 दिनांक 25 जनवरी 2021 फैक्ट्री निगरानी के लिए

4. यह दिशानिर्देश 15 फरवरी 2021 से लागू होंगे तथा पूर्व दिशानिर्देश सन्दर्भ: सीएमडी-I/2:12:6 के फैक्ट्री निगरानी प्रावधानों दिनांक 28 अगस्त 2019 को प्रतिस्थापित करते हैं।

(मोहित जनोहिया)
वैज्ञ-'सी'/सीएमडी-I

<u>प्रमुख, सीएमडी-I</u>

<u>वैज्ञ-'जी' एवं उपमहानिदेशक (प्रमाणन)</u>

Bureau of Indian Standards

(Central Marks Department - I)

Our Ref: CMD-I/2:12:6 **08 February 2021**

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

As informed, vide O.M. Ref: HRD/19:5(2020) dated 12 October 2020, the competent authority has decided to create the new department Certification, Surveillance & Monitoring Department (CSMD) for better coordination and monitoring of concerned activity. This is a dedicated nodal department which shall be responsible and act as a single point of contact for planning, execution, monitoring and review of surveillance plans across India for product certification activity.

2. To facilitate and augment the resources at disposal, as per provisions available under Rule 33 of the BIS Rules 2018, five AGENTs have been appointed by BIS to carry out factory inspection activities on its behalf. These AGENTs are as follows:

   i) TUV SUD South Asia Private Limited
   ii) TUV India Private Limited
   iii) Quality Austria Central Asia Pvt. Ltd.
   iv) Bureau Veritas (India) Pvt. Ltd.
   v) RITES Ltd.

3. The revised comprehensive guidelines for factory surveillance incorporating details about recently developed mobile app has been approved by the Competent Authority. These said following guidelines are attached herewith for implementation by all concerned:

   i) Ref: CMD-I/2:12:6 dated 25 January 2021 for Factory surveillance

4. These revised guidelines shall come into effect from 15 February 2021 and supersede provisions of factory surveillance in earlier guidelines Ref: CMD-I/2:12:6 dated 28 August 2019.

(Mohit Janoiya)
Sc.C/CMD-I

Head, CMD-I

Sc.G & DDG (Certification)

परिचालित/circulated to:

सभी क्षेत्रीय कार्यालयों/ शाखा कार्यालयों
All ROs/BOs

सभी उपमहानिदेशक (क्षेत्रीय)
All DDGRs

अन्य सभी संबंधित पक्ष
All other concerned

प्रमुख, आई०टी०एस० विभाग - बी आई एस इंट्रानेट पर डालने हेतु।
Head, ITSD - with request to host on BIS Intranet

BUREAU OF INDIAN STANDARDS

(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/2:12:6 **25 January 2021**

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

1. This document stipulates the guidelines for surveillance by BIS w.r.t. monitoring operation of product certification licences and checking conformance of product as per applicable Standard(s) through inspection at manufacturing premises. These guidelines are to be read in conjunction with the BIS Act 2016 and Rules, Regulations framed thereunder. In particular, the provisions 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 undertakes various surveillance measures for its product certification scheme which aims to check conformance of certified products to applicable standard(s). These surveillance operations also provide inputs & opportunities for improvement to licensee. The various types of conformity assessment surveillance activities are as follows:

(1) Pro-active surveillance

(i) Pre-market surveillance activities
- (a) Factory surveillance visits
- (b) Pre-despatch inspection visits

(ii) Post-market surveillance activities
- (a) Procurement of product samples from open market
- (b) Feedback from buyers

(2) Re-active surveillance

(i) Surveillance based on consumer complaint or feedback

(3) Dynamic surveillance

3. A dedicated nodal department, named Certification, Surveillance and Monitoring Department (CSMD), has been set up at BIS HQ for effective monitoring of inspection and surveillance in product certification activities of BIS. CSMD shall be responsible for planning and preparation of surveillance plans across India, i.e. factory surveillance for domestic licensee. CSMD shall also be the single point of contact for:

(1) Domestic factory surveillance
- (i) Planning and communication to concerned AGENT(s) and ROs/BOs
- (ii) Invoice settlement of AGENT(s)

(iii) Monitoring of surveillance activities including review of target achievements and quality

4. The inspection and surveillance activities of foreign manufacturers shall be planned and prepared by Foreign Manufacturers Certification Department (FMCD) with approval of the competent authority. The factory inspection and surveillance activities of foreign manufacturers shall be undertaken by certification officers of BIS.

5. Pro-active surveillance:

(1) Factory surveillance:

Generally, one factory surveillance per year may be carried out for each licence for drawl of sample and its testing in third party laboratory(ies) subject to risk based assessment & dynamic surveillance.

(i) Quarterly factory surveillance plans on an All India basis shall be prepared by the Head CSMD and communicated to concerned AGENT(s) and ROs/BOs at least one month in advance. The AGENT(s) will in turn create monthly plans and share them with CSMD. CSMD will process the case and may update the submitted monthly plans including incorporation of any inspection(s) required to be carried out on urgent-basis.

(ii) Additionally, CSMD may raise a request to Head BO for conduct of factory surveillance inspection by certification officer(s) posted at respective BO which may also include evaluation of quality of factory inspection(s) undertaken by AGENT(s).

(iii) The planning of factory surveillance visits will be undertaken by CSMD through ManakOnline portal.

(iv) The mobile app and online portal have been developed for conduct of factory surveillance. Factory surveillance inspections will be operated through these app/portal and relevant access will be provided to the AGENT(s) and ROs/BOs for end-to-end management from planning, inspection report, test request generation, query resolution process and till settlement of invoice raised by AGENT(s).

(v) While making surveillance plans, risk based assessment on the basis of product category, overall product compliance level and individual performance of licensee will be taken into account. Additionally, various other relevant factors like seasonality of the product, available production schedule information, adherence to principle of rotation et cetera shall be followed. To ensure

adherence to principle of rotation, Head (CSMD) while finalizing the monthly/quarterly surveillance programme needs to ensure that:

(a) The visits are allocated equitably and inline with work order issued to AGENTs & their performance, as far as possible.

(b) Multiple visits to a single licensee are equitably rotated amongst all the AGENTs, as far as possible.

(c) No particular AGENT is allocated an unduly exceeding number of visits in respect to a specific licensee.

(d) Multiple licences operating from single premises may be allocated as a group for efficient utilisation of resources.

(e) CSMD shall ensure that personnel appointed by AGENT(s) to carry out factory surveillance on behalf of BIS are competent and are of relevant discipline.

(f) Head BOs shall also adhere to the principle of rotation for surveillance visits requested by CSMD to be carried out by certification officer(s) posted at BOs. As far as possible, the factory surveillance inspection visits by BOs shall be carried out by the officer of relevant discipline.

(vi) For submission of surveillance inspection reports, a mobile-app based system has been developed. All certification officers and personnel of AGENT(s) shall submit their surveillance inspection reports through this mobile-app only. A guidance document about usage of this mobile-app is enclosed as ***Annexure-I***.

(a) As detailed in this guidance document, the certification officer or personnel of the AGENT(s), as the case may be, would be required to carry pre-printed QR codes for scanning in mobile-app for samples sealed during factory visit.

(b) The factory surveillance samples duly marked, sealed by the certification officer (or personnel of AGENT(s), as applicable) carrying QR codes shall be left in safe custody of the licensee. Necessary instructions in the discrepancy-cum-advisory report shall be issued to the licensee for despatch of samples to the designated laboratory.

(c) It shall be the duty of the licensee to send and ensure deposition of such sample(s) in designated laboratory(ies). Certification officer or personnel of AGENT(s), as the case may be, shall follow-up with the licensee for receipt of proof of deposition of sample(s).

(vii) For the inspection(s) carried out by the AGENT(s), the BO concerned shall examine the submitted report(s) and review, process these report(s) for acceptance/non-acceptance within ten working days from the date of submission of inspection report by AGENT(s). BOs may seek any clarification on inspection report(s) from concerned personnel of AGENT(s) through ManakOnline portal and resolve it for acceptance or non-acceptance within ten working days from the date of submission of inspection report. In case, BO doesn't initiate any action on the inspection report within ten working days, then it shall be deemed accepted by the BO and accordingly payment shall be processed further by CSMD..

(viii) CSMD shall process the eligible monthly invoices submitted by the AGENT(s) for payment by BIS within 30 calendar days from the date of its submission, as per the terms and conditions of the signed contract agreement. The instances of non-acceptance of inspection report(s) and non-adherence to other service level criterion as per contract agreement shall be taken up by CSMD with AGENT(s) during quarterly review meetings.

(2) Pre-despatch/lot inspection:

(i) 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 by Head BO. For such inspections, licensee shall make arrangements 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 (₹ 10,000/-) as specified in Scheme - I of BIS (Conformity Assessment) Regulations.

(ii) In addition to adherence to principle of rotation given below, Head BOs shall rotate the visits for consequent production week equally amongst all the available certification officers (or agents, if applicable) in the Branch as far as possible.

(a) The visits are allocated equally amongst all the available certification officers in the Branch as far as possible.

(b) Multiple visits to a single licensee are rotated amongst all the available certification officers equally as far as possible.

(c) No particular certification officer is allocated unusually large number of visits in respect to a specific licensee

6. Surveillance based on consumer complaint/feedback:

(1) Head BO may allot visit(s) to certification officer(s) posted at respective BOs for undertaking complaint investigation visit (including factory surveillance) of the licensee based on consumer complaint or based on feedback/information available through any other means.

7. Post surveillance activities:

(1) 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 2016 and Rules, Regulations framed thereunder and guidelines issued for suspension and revocation of suspension of licence.

(2) For any instance noticed which casts doubt on ethics and integrity of the AGENT(s) shall be reported and submitted by the Head BO to DDG (Certification) through DDGR for further appropriate action.

(i) Quarterly plans on an All India basis shall be prepared by the Head CSMD for random cross-verification of factory inspection visit(s) undertaken by AGENT(s) by the deputed teams.

8. Dynamic Surveillance:

(1) The review of surveillance activities for a licensee may be used as an input to risk based analysis and BO may, if required, also raise a request to CSMD for carrying out factory surveillance visit of the licensee by AGENT(s) in addition to the norm(s)/plan(s).

9. Code of ethics:

(1) The certification officers of BIS shall adhere to Central Civil Services (Conduct) Rules, 1964. The AGENT(s) and its personnel shall also uphold the commitments of BIS so as to maintain the trust and respect of its stakeholders and the public at large through unquestionable integrity, honesty, behave professionally, objectively and ethical business conduct. A code of ethics guidance document is enclosed as ***Annexure - II***.

Annexure - I

Guidance on App based Surveillance Inspection Report

The surveillance inspection allocated to a CO/Agent will reflect in Factory Surveillance Assigned tab after logging in the application. After reaching the premises of licensee the CO/Agent will select the name of factory and proceed to fill the report. The application will prompt 'Upload Selfie' option before opening the report section. Uploading at least one image is required for activating the reporting module and the CO/Agent can upload a maximum of 3 selfies. In case the CO/Agent is accompanied by another CO/Agent, image of second CO/Agent is also to be uploaded.

Pre populated details:

Firm information:

This section will appear as pre filled with information from manakonline server. Details such as Firm name, Validity of license, Indian Standard & Product for which the license is operative, variety (scope of license), address of factory and firm. The visiting CO/Agent is requested to verify these details.

Location of factory: This sub-section is also envisaged to be prefilled. However for cases where the location is not appearing in the mobile app, the first time entry will be captured during the surveillance. The application will capture these details for the first time entry. Care should be exercised to fill location details only after entering the premises of licensee.

Previous inspection:

This section provides history details on last two inspections that were carried out at the premises of licensee. The data in the table will be prefilled and the CO/Agent has to identify if any unsatisfactory visit history is reflected in the history. In applicable cases the CO/Agent will enquire on status of corrective actions taken by the licensee and report on the adequacy and effectiveness of such actions in the subsequent sections of report.

Result of last 2 sample:

This section provides history details on last two samples of the licensee. The samples could be Market Sample, Factory Sample, Verification sample etc. In case any failure is being reflected in the sample history the CO/Agent will enquire on status of corrective actions taken by the licensee and report on the adequacy and effectiveness of such actions in the subsequent sections of report.

Action taken by firm on advice on previous visit/any other communication/failure of sample:

This section will show the actions taken by licensee for the discrepancies/advises of previous inspection, sample failure communication, Suspension or any other communication sent to licensee by BIS.

The Certification Officer (CO) /Agent has to verify the actions of licensee with two aspects that is whether the licensee has completed the required actions and whether actions taken by licensee are

adequate to address the observation/communication. After the verification CO/Agent is required to record his/her observations in this section.

A few situations which may be encountered are as follow:

(i) DVR issued during last inspection: The CO/Agent will be required to verify and report his/her point wise observations on correctives actions taken by firm.

(ii) Suspension of license: In some cases the license may have been under suspension under instructions of BO. The CO/Agent will verify the compliance of suspension order by checking if the factory has produced and marked their production with ISI mark during the said period by going through the production record/test records/dispatch records/stock verification etc. For products under compulsory certification suspension of license results in stopping of production altogether. Any observed non-compliance is required to be reported by CO/Agent through the Discrepancy-cum-Advisory report.

(iii) Failure of sample(s): Licensees are required to investigate causes of failure of their samples (factory/market), take suitable corrective actions and communicate the same to BIS. The CO/Agent will verify and report the corrective actions reported by the licensee and draw improved samples (manufactured after taking corrective actions) for independent testing and factory testing, as far as possible.

(iv) Switchover/Revision/Amendments of Standard: These cases may require creation of additional testing facilities by the licensee to meet the requirement of new/revised/amended standard. The CO/Agent will verify all such changes and report the same as per cl. 9 (b) of inspection report.

The surveillance report format is divided in to multiple sections from 'General Information' to 'Advice to the Firm'. The mobile application displays a Progress Report Screen where individual sections and percentage of completion for that particular section is shown. The CO/Agent will submit the report by filling the sub-sections and clauses provided in individual sections. A preview page is displayed on the app while moving from one section to the next one. The CO/Agent can either Edit or Save the entries from this preview screen. It is advisable to use Save option to store information already entered for each section. In case of no internet connectivity the application will save the data on user' device and it will be uploaded to sever when the internet connectivity is available again. The CO/Agent is required to complete all the sections/sub-sections during the inspection itself. The application by design will not allow postdated entries.

General Information:

1. Date of Inspection: The app will show the current date in this option by default. In case visit is scheduled for multiple days, the CO/Agent can select multiple dates using the calendar option.

2. Name & Designation of CO: As the CO/Agent will login to the app using his/her credentials these details will appear automatically in the app.

3. Second Certification Officer: Chose applicable here in case the inspection is being undertaken with a second CO/Agent.

4. In case the CO/Agent is accompanied by a second CO/Agent, name of designation of second officer is to be filled in this section.

5. Person (s) Contacted:

This section will show Name & Designation of individuals associated with the firm. The CO/Agent will select Yes/No option in third column of the section for each individual based on their availability during the inspection. An option to add persons may be utilized to include name(s) of individual who were contacted during the visit but whose details are not getting reflected in the application.

Manufacturing Process

6. Verification of Raw Materials used

The first four columns listed in format will be pre-populated with the information submitted by licensee while filing the application. Officer observation section of Raw Material table will be filled by the visiting CO/Agent.

CO/Agent has to identify if the product standard/manual or SIT has any requirement of compliance for the Raw Material and check the conformity accordingly.

Example 1: Cl 9.4.11 of IS 996 (Single phase a.c. induction motors for general purpose) states, Capacitors where used shall comply to IS 2993. Thus the conformity of capacitors (if used) to IS 2993 has to be verified by CO/Agent*. Further as IS 2993 is also under compulsory certification vide Electrical Capacitors Quality Control Order 2017, a.c. motor capacitors have to compulsorily carry ISI mark under a license form Bureau.*

Example 2: Cl. 4.1 Material of IS 694 requires, the conductor shall be composed of annealed, bare or tinned high conductivity copper wires complying with IS 8130. IS 8130 in turn requires as per cl. 4.2 for Copper, The conductors shall be made from high conductivity copper rods complying with IS 613. Now Cl. 8.1 of IS 613 states the material shall have chemical composition as given in for grades ETP, FRHC of IS 191 (Part 5) or IS 191 (Part 6) respectively. Thus ultimately the Copper Conductors used in manufacturing of product as per IS 694 shall have purity as specified in IS 191. The SIT of IS 694 requires each consignment of Conductor to conform to purity requirements of IS 191, so the licensee is required to establish this conformity. Further as the SIT permits subcontracting of Purity Test requirements so the licensee of IS 694 can establish conformity by producing a test certificate from third party laboratory for each of their consignments of copper conductors.

Example 3: Skimmed milk powder used in manufacturing of Milk-cereal based weaning foods as per IS 1656 shall be ISI marked as per IS 13334 (Part 1) or IS 13334 (Part 2) as Skimmed Milk Product is under compulsory certification.

Example 4: As per cl. 4.1 of IS 3196 (part 1) the steel used in the manufacture of cylinders shall conform to IS 6240 or IS 15914. Further as both these standards are notified for compulsory certification the steel used shall be ISI marked as per IS 6240 or IS 15914.

The CO/Agent will record his/her observations for each of the Raw Materials given in the table. Remarks in case of No/Not available/Not conforming/partially available will become NC.

For the licenses which were granted prior to implementation of new application format in Manakonline portal, Raw Material data may not be available in the system. Provisions are being made to provide the licensees a facility to enter this data through their manakonline account. In all such situations the CO/Agent will advise the licensee to fill the raw material details through their account then proceed to record their observation as explained above.

7. Verification of Details regarding Manufacturing Process

a. Variety being manufactured at the time of Inspection: CO/Agent to verify the manufacturing activity on the day of visit and record their observations. The variety can be selected from the drop down or entered in the text box provided after selecting 'Any other' from dropdown. Care should be exercised to confirm that the variety(s) on which ISI mark is being used by licensee are covered in the existing scope the licensee. Any observed non-compliance is required to be reported by CO/Agent through the Discrepancy-cum-Advisory report.

In case the app displays all the varieties of license together in the drop down menu, the CO may select 'Any other' option from drop down and enter the actual variety in the text box.

b. Verify any changes intimated by firm or made since last inspection about manufacturing process, if yes, confirm acceptability: This section requires the CO/Agent to verify and report any changes implemented by licensee in their manufacturing or processing stage. CO/Agent can use the download icon provided against the requirement in app to check the document submitted by firm, if any. The reporting has to be done keeping in mind the effect of these changes on conformity of final product. In some products changes in process may also require the licensee to provide evidence of conformity through a third party test report. *For example Annexure G of Packaged Drinking Water Manual (PM/ 14543/ 3 July 2020) requires the licensee to get the processed water produced from such changed process shall be tested for conformity to IS 14543 from BIS recognized outside lab.*

c. whether any major manufacturing process change without intimation or approval: Response to this field has to be provided after evaluating the changes as per b above. In case the response is Yes. The CO/Agent has to describe the same in remarks column and same will be recorded as a NC.

d. Verify the compliance to manufacture clauses and requirements of ISS which can be checked only at manufacturing stage, if any specified in Indian Standard and indicate conformity: In this section CO/Agent will be required to verify and report in process controls/tests which may a part of manufacturing setup itself. For example as per cl. 10.4 of IS 694, Spark Test is carried out on single core unsheathed cables during the processing stage itself. So the CO/Agent will have to verify the test parameters for this test during the visit by checking the manufacturing process.

e. Verify the "Layout Plan of factory" if any change is intimated or made by firm since last inspection: CO/Agent can use the download icon provided against the requirement in app to check the revised layout plan submitted by firm, if any. In case of changes communicated by licensee or observed during the visit CO/Agent has to verify and report the same. Layout plan is a simple

pictorial representation of factory working area. In general the layout should show location of plant and machinery, testing laboratory, raw material storage, finished goods storage, entry and exit etc. In case the layout plan is not uploaded in the system the CO/Agent will request the licensee to upload their latest layout plan using their manakonline dashboard.

f. <u>Any change in the Manufacturing Machinery since last inspection including for inclusion, revision of standard, shifting etc and uploaded revised list of machinery:</u> In this section the CO/Agent will evaluate and report any changes required in Manufacturing Machinery on account of situations mentioned in section heading. After verification of revised list confirmation for same will be recorded in the format by the CO/Agent. In case the update is required in the machinery list but the same has not been uploaded by the licensee, the CO/Agent will request the licensee to upload the latest updated manufacturing machinery list in the manakonline portal. A major change in manufacturing machinery may require updating the manufacturing process. The CO/Agent will request the licensee to update the same in manakonline portal.

Example 1. Inclusion of new variety: Inclusion of higher sizes and cores for cable products (IS 694, IS 7098 (part 1), IS 1554 (part 1) etc.) are approved by BIS BOs based on conforming test reports from BIS recognized labs without a verification visit. For manufacturing of these higher sizes the licensee will be required to install dies & nozzles of higher sizes. Similarly for bunching of bigger number of cores together, the licensee may require a bigger core laying machine. The visiting CO/Agent *will be required to verify these additions in manufacturing machinery.*

Example 2. Packaged drinking water licensees are required to install automatic filling machines for filling water in plastic cups, tumbler, pouch are required to be filled only through automatic machines. Thus this change in manufacturing infrastructure needs to be verified and reported by visiting CO/Agent*, if applicable.*

Example 3. Revision of Standard: Amendment No. 2 to IS 2061 (BICYCLES — FRONT FORKS —SPECIFICATION) vide Cl. 5.1 has prescribed joint shall be made either by Tungsten Inert Gas (TIG) welding or Metal Inert Gas (MIG) welding or shall be properly brazed with solder conforming to Grade B of IS 2927 : 1975. Earlier to the amendment only solder was allowed for making the joints thus the visiting CO/Agent *will be required to verify these changes in manufacturing machinery if implemented by the licensee.*

<u>g. If Outsourcing some process, verify the outsource agreement:</u> Outsourcing of a part of manufacturing process is permitted by BIS on product specific basis. The outsourcing arrangement is verified and approved during Grant of License. CO/Agent visiting for surveillance inspection is required to check if the outsourced process is operating adequately as approved during GoL.

Example. Product specific guidelines for IS 3854, IS 1293, IS 371 & IS 1258 (Switches, Plugs & Sockets, Ceiling Roses, Bayonet Lamp Holders) permit molding of plastic body part at locations outside the factory of licensee. This arrangement is clearly indicated in the Process Flow Chart at the time of GOL. During surveillance visit the CO/Agent *will verify the agreement between the molding unit and licensee and record any changes observed*.

h. Verify Controls being exercised by the firm on outsourced process for adequacy: The responsibility of ensuring compliance to specifications for the process(s) which are outsourced lies with the licensee. The CO/Agent is to verify the intermediate product received from outside vendor by the licensee to applicable requirements, if any.

i. Hygienic Conditions, if applicable (As per Relevant IS & Format specified): This requirement is product specific and is generally applicable to Packaged Drinking Water, Food products etc. Wherever applicable the CO/Agent will verify and report the compliance to hygienic conditions requirement. For example for PDW and PNMW a hygienic checklist has been developed which has to be filled with visiting CO/Agent' observation during the visit.

j. Technical Comments on manufacturing capabilities and in-process controls: After verifying the manufacturing process of the factory the CO/Agent will indicate observed deficiencies, if any, in this section. For some products the manufacturing process or intermediate controls to be exercised are mentioned in the standard. In all such cases the CO/Agent will verify and report the compliance to such requirements of the standard.
*Example: Clause 4.1 of IS 13428: 2004 (Packaged Natural Mineral water) provides Treatments and Handling permitted for manufacturing of this product. The visiting CO/*Agent *will check whether the firm is using only the allowed treatments as per the standard and report.*

Packaging and Marking:

8. Verification of Packaging and Marking:

a. Nature of Packing as declared & satisfactory as per IS, where specified: Nature of Packing of products is specifically provided in some Indian Standards. Further in products like PDW specific packaging type, process and size are approved at the time of GOL and mentioned in the scope of license.
The CO/Agent will verify the nature of packing with respect to requirement of ISS and report under this head.

Example: Cl. 6 of IS 14543 (Packaged Drinking Water) provides requirement of packing. Here the licensee is required to ensure compliance of packing materials given in the standard to the respective standards.

b. Check Marking on Article as per IS & SIT and report conformity: This section requires compliance to the marking clause of ISS/SIT. The CO/Agent is required to verify and report whether all the items mandated to be marked on the product as per the marking clause of IS/SIT are being followed by the licensee. The legibility of marking is also to be kept in mind while reporting.

Example 1: Cl. 11 (marking) of IS 269 (Ordinary Portland Cement) requires the manufacturer to mark 9 items on each bag/drum of Cement. Batch No. has to be marked in the format of Weak/Month and Year in BLACK color only.

*Example 2: Cl. 3.2.1 of SIT of IS 14543 (PDW) prescribes requirement of size of ISI mark to be used on the product to ensure legibility. Thus the visiting CO/*Agent *has to verify the dimension of ISI mark in addition to requirements of marking clause.*

c. Check Method of marking: The CO/Agent has to specify the means of marking employed by the licensee in the text box provided. Some examples of method of marking are, Printing, Stenciling, Moulding, Embossing, Labels/Stickers, Laser marking, and Itching etc.

d. Form of label(s): Specify the format of label, if any being used by the licensee. Same can also be uploaded in image option.

e. Batch or Code numbering for identification: This section requires reporting on ways adopted by the licensee to ensure traceability of final products manufactured by them. Each ISI marked product has to undergo internal testing as per frequency and levels of control provided in the SIT of that standard. Now the CO/Agent can verify the traceability of finished product from Batch/Code/Serial No to the manufacturing and in-house testing stages.

Testing and Inspection:

9. Laboratory and Inspection

a. Details of Technical Management/Quality Assurance/Control Staff: The first six columns listed in format will be pre-populated with the information submitted by licensee while filing the application. Observations of CO/Agent are to be filled in the remaining columns. Availability of testing personnel as declared by licensee has to be verified and entered in the app. In case the listed person(s) has left the organization the CO/Agent has to record the same in the relevant column. To ensure continuous testing of products as per ISS and SIT the licensee has to arrange competent manpower in the factory as replacement. The competency of testing personnel is verified through discussions, interview, and verification of previous test record & through witness testing. In case the CO/Agent is recording a testing person as incompetent he/she is required to clearly record the reasons for such assessment in the remarks column of format.

For the licenses which were granted prior to implementation of Manakonline portal, Testing Staff data may not be available in the system. Provisions are being made to provide the licensees a facility to enter this data through their manakonline account. In all such situations the CO/Agent will advise the licensee to fill the details as per given format, through their account then proceed to record their observation as explained above.

b. Test Equipment Details

b. Any change in the Testing Equipment since last inspection including changes intimated for inclusion, revision of standard/AMENDMENT TO STANDARD, shifting etc and uploaded revised list of testing equipment: These cases may require creation of additional testing facilities by the licensee to meet the requirement of new/revised/amended standard. The CO/Agent will verify all such changes and report the same in the app. In case data on test equipment list is not available CO/Agent will advise the licensee to fill the details as per given format, through their account then proceed to record their observation. In cases where the firm has expanded its production capacity a commensurate increase in testing capability is also required. For example in case of PDW number of glassware, petri-dishes etc. are dependent on production capacity. Thus

CO/Agent has to analyze whether the testing infrastructure is adequate for testing of current production.

The format of test equipment list requires the firm to declare Least Count of equipment. The CO/Agent will verify if the LC of available equipment in the factory are adequate for the intended measurement as per the ISS.

c. Verify arrangement indicated for sub-contracting of tests as per SIT provision: Table 1 (Levels of Control) of SIT specify Test Equipment Requirement as R: required (or) S: Sub-Contracting permitted. For the Requirements categorized as R, licensee is required to have complete in-house test facilities whereas for the Requirements categorized as S the licensee has an option to either have in-house test facilities or utilize the services of BIS recognized laboratory for testing as per frequency prescribed in the SIT. The sub-contracting arrangement is approved at the time of GOL and the licensee has to submit a consent letter from BIS recognized laboratory from where they intend to get these tests done. During the surveillance visit, the CO/Agent has to check and report if the firm is following the permitted sub-contacting arrangement and test reports from outside lab are available as per the frequency of SIT. In case any changes are observed in this arrangement, for example change in laboratory, the CO/Agent is required to verify and report the same

Example: SIT of IS 14543 (PDW) permits sub-contracting for tests having frequency of monthly, six monthly, yearly & biennial. The licensee who has opted for sub-contracting arrangement for these tests is required to produce test reports from recognized laboratory for the verification by CO/Agent.

d. Confirm acceptability of Accuracy of instruments and arrangements for calibration: The test equipment available with firm should be accurate for the requirements of measurement. Periodic & regular calibration of test equipment is required for achieving this aim. The CO/Agent is required to check for availability of evidence of calibration available in the factory.

e. Verify Calibration certificates of the equipment(s) with traceability to National/ International Standards: The calibration of equipment is carried out either by an external agency or internally through a master calibrator. In the first case the calibrator used by external agency should have traceability to National/International standards. In the second case the firm is required to get their master equipment calibrated from outside agency with traceability to National/International standards. In India, calibration certificates issued by NABL accredited labs ensure traceability to National/ International Standards.

Further Certified Reference Material (CRM) wherever used shall be traceable to National/International standards.

In case of few products the SIT may also prescribe requirements on calibration schedule/methods. Same has be verified by CO/Agent.

Example 1: SIT of IS 269 (Ordinary Portland Cement) requires the manufacturer to prepare a calibration plan for the test equipment used in the laboratory. Further the calibration frequency and method is also prescribed for five test equipment.

f. Whether complete Testing Equipment are available as per Indian Standard including sub-contracting arrangement: For the Requirements categorized as R, licensee is required to have complete in-house test facilities whereas for the Requirements categorized as S the licensee has an option to either have in-house test facilities or utilize the services of BIS recognized laboratory for testing as per frequency prescribed in the SIT. The CO/Agent will verify and report whether the licensee has arranged complete testing facility for all the requirements of approved scope as per the ISS including sub-contracted tests.

g. Whether Test equipment are in working order: During the surveillance visit, the CO/Agent has to check and report if the testing facilities available with licensee is functioning according to its nature and purpose. Working is verified through measurements during factory testing. In case any equipment is out of order CO/Agent has confirm if alternate arrangement has been made by the firm. In case any changes are observed, the CO/Agent is required to verify and report the same. Further some products require specific environmental condition of the test room. The visiting CO/Agent is required to ensure compliance to these requirements.

Example 1: In the product PDW (IS 14543) Microbiology section of in-house test lab is required to have Air Conditioners installed for maintenance of environmental condition. Also this section should also have a refrigerator available. Accordingly these will have to be verified in-addition to the test facilities of the product.

Example 2: Clause 5.3.3 of IS 2641 (Electric Welding Accessories) requires the temperature rise test to be carried out in a drought free room. So along with test facilities of temperature rise test availability of Drought free room/chamber has to be ensured by the licensee.

c. Product Conformity verification & Compliance to Scheme of Inspection & Testing:

i. All in-house tests being carried out as per SIT frequency, records being maintained & compliance of product to IS ensured: The CO/Agent is required to verify in-house test records maintained by the firm to confirm compliance to this requirement. During the verification compliance to the requirements of standard has to be checked by verifying if the test results obtained are conforming as per standard.

ii. Sub-contracted tests carried out as per SIT frequency from BIS recognized lab, reports available & compliance of product to IS ensured: During the surveillance visit, the CO/Agent has to check and report if the firm is following the permitted sub-contacting arrangement and test reports from outside lab are available as per the frequency of SIT. In case any changes are observed in this arrangement, for example change in laboratory, the CO/Agent is required to verify and report the same

Example: SIT of IS 14543 (PDW) permits sub-contracting for tests having frequency of monthly, six monthly, yearly & biennial. The licensee who has opted for sub-contracting arrangement for these tests is required to produce test reports from recognized laboratory for the verification by CO/Agent.

10. Details of stock available for Inspection and Testing: Manakonline dashboard of licensee has a provision to upload stock position of ISI marked products available in factory. The visiting CO/Agent will request the licensee upload the stock available in the factory on the day of inspection. Samples for factory testing and independent testing will be drawn on the basis of stock position in the factory.

In case of nil availability of stock in factory the licensee has to declare the same in their portal. In such situation the CO/Agent has to advice the firm to intimate their production schedule to BIS so that a subsequent visit can be planned.

Factory Testing:

11. Testing in factory Conducted: CO/Agent will select the applicable radio button regarding Factory Testing. In case No is selected, the same will be recorded in Discrepancy-cum-Advisory report. CO/Agent is required to clearly state the reasons for not carrying out FT in the remarks column.

i) If Yes, Is Factory Testing required on multiple: Chose Yes in this section in case FT is witnessed on more than one sample. Usually FT is carried out on only one sample during the inspection however in some case where testing on raw material is also required this option can be utilized. If the CO/Agent selects Yes in this section, dashboard of licensee in manakonline will permit filling of multiple otherwise only one FTR can be filled by the licensee.

Factory Test Report: The QCI/testing person of licensee will perform the testing in front of CO/Agent. The test report format as given in licensee dashboard is to be filled immediately after the testing. The uploaded report will reflect in mobile app after it is filled by the licensee. CO/Agent will verify and accept individual test parameters. In case the sample is non-conforming in one or more requirements the final result will be populated as non-conforming.

Whether all possible tests in a day (as per Product Manual) done: Tests possible in day are mentioned in product specific manuals. The CO/Agent is required to ensure that FT is carried out for all the parameters on the selected sample.

In case of any variance chose the No option and mention the reason for same. This will be recorded in the Discrepancy-cum-Advisory report by the application.

ii) If complete test facility is not available at any lab or it is not possible to draw samples for lab testing for some requirements, these requirements to be tested in the factory: In some products samples for complete independent testing in third party outside lab are not drawn due to size/dimensions/nature of products. In such situations tests for which samples could not be not be drawn are carried out in factory itself and sample is sent to lab for remaining tests. For example in some steel products physical parameters such as dimensions, weight, crown etc. are carried out in factory itself and samples for chemical testing from the same coil are sent to outside lab.

For all such products in-house testing for parameters whose samples were not drawn is to be witnessed by CO/Agent in the factory. In case of variance CO/Agent is required to select No option and write the reasons for same in the remarks column.

12. Sample Drawn of Product for Independent Test: If samples are drawn for independent testing yes is to be selected otherwise the No option. CO/Agent is to record reasons for not drawings samples and same will recorded in Discrepancy-cum-Advisory report. An option has been provided in dashboard of licensee to upload declared parameters pertaining to the selected sample.

Example: IS 996 (Single phase ac induction motors) samples require product related parameters declaration for testing of product. Format for declaration is provided in Annex-D of product manual (PM/ IS 996/ 3/ September 2020).

Sample Details: The CO/Agent has to select applicable requirements related form the sample from the drop down options provided in the app. wherever entry of a text is required provisions have been made in the application. In the date of manufacturing field the available date/month/week is to be filled. If complete date is applicable and same is required for calculating the shelf life it is to be entered in the format DD-MM-YYYY. The CO/Agent will affix two preprinted QR codes, one on sample and second on packaging, and scan the same in the mobile app. Sample codes will be auto generated by the system. CO/Agent is not required to write any physical code on the sample. In case the QR code is not being scanned in the app, its unique number is to be filled in the application.

While drawing the sample for independent testing all related accessories/loads/attachments etc. are also to be drawn to enable the laboratory for complete testing of product.

Example: IS 996 (Single phase ac induction motors) samples require Fan Load if the type of motor is declared as Fan type.

13. Counter sample: Most of the details in the section will be prefilled from the information selected in for the Factory Sample. CO/Agent can change editable fields in case of change in Si No. As explained above the CO/Agent will affix two preprinted QR codes on the counter samples.

14. Storage Facilities: The CO/Agent will enter relevant remarks in this field based on the requirement of product. For example in case of IS 14543 (PDW) verification of storage area is essential as the finished product is required to be kept in the premises of factory for at least 48 hours after filling as in-house tests require 48 hours for completion. Further the illumination and hygienic conditions have to be verified for the PDW storage area.

Product (ISS) Specific Standard Details:

15. ISS Specific field's verification: This section is under development in the mobile application. If applicable, this section will list particular requirements applicable to some products. CO/Agent will report as per the requirement of individual products.

16. Advise to the firm on: This section covers directions which CO/Agent issues to the licensee as per sub-sections given in the app.

CO/Agent has to advise the licensee to dispatch samples drawn to selected independent lab within 48 hours of inspection and submit the proof of dispatch to BIS.

Counter samples retention are intended to be retained safely with form till the factory sample is tested and complete test reports are available.

Additional Observation: This section can be utilized to issue any specific advice to the firm which is not already defined in subsection headings.

Dashboard of licensee in manakonlione has been provided with a facility for uploading production details periodically. CO/Agent will request the licensee to upload their monthwise production marked with standard mark in this module. As the production figures are also utilized in calculating Marking Fee for renewal of license, CO/Agent is requested to guide the licensee so that there is no mismatch in the production details uploaded in this section and details submitted at the time of renewal.

Licensee is required to upload Name and complete address of their customers/buyers/consignees to whom standard marked products have been supplied to. CO/Agent will advise the licensee to upload correct and complete details in this field.

After discussing with firm regarding present installed production capacity, CO/Agent will advise the firm to update the latest capacity in case of changes.

17 Generate Discrepancy-cum ADVISORY Report:

The mobile app for surveillance has been designed to capture discrepancies from all applicable sections based on findings of CO/Agent. This section will display all such discrepancies at one place. The CO/Agent has to provide necessary clause reference to ISS/PM against each discrepancy and verify once again the contents of the report before issuance. In case firm is able to produce evidence for clearing any discrepancy during the inspection itself then CO/Agent will go back to the relevant section of report and clear the applicable discrepancy. After finalizing the contents of Discrepancy-cum-Advisory report, CO/Agent will submit issue button in app which will communicate the Discrepancy-cum-Advisory report to the licensee. An OTP received by licensee is to be entered in app for proceeding further. In case OTP is not available for 10 minutes, the CO/Agent can proceed for completing the report.

The entries in Discrepancy-cum-Advisory report should be self-contained with justification and context. Summary statements like No available/unsatisfactory/absent without reasoning should be avoided.

18 Any other observation/comments: This section is designed to capture any information/observation/remarks which CO/Agent wishes to record apart form information filled above. Suggestions of licensee can also be submitted here.

19 Conclusion: After completing all other sections of report the CO/Agent will conclude the inspection by selecting the options from drop down menu. In case the visit is concluded Unsatisfactory by the CO/Agent a further drop down menu will be enabled from where the applicable reasons are to be selected by the CO/Agent.

20 Recommendations: The CO/Agent will chose the applicable entry from the drop down menu as his/her final recommendation.

After entering the recommendations a preview option will be available to the CO/Agent for going through the contents of the filled report. In case any changes are required in the report the

CO/Agent has make such changes before the final submission as the report cannot be edited after final submission.

Annexure - II

Code of ethics for BIS certification officers and AGENT(s) for factory inspection

While discharging its duties under the BIS Act 2016, BIS is committed to maintain the trust and respect of its stakeholders and the public at large through unquestionable integrity, honesty, behave professionally, objectively and ethical business conduct.

The AGENT(s), including personnel involved, appointed for BIS shall uphold dedication to the basic corporate ethic. In addition to the requirements of conduct stated herein, the AGENT(s) shall comply with the applicable national and state laws and regulation applicable to them in the territory they are working. The certification officer of BIS shall also adhere to this code of ethics, as applicable, in addition to the Central Civil Services (Conduct) Rules, 1964.

Professional Behaviour

(i) The AGENT(s) shall act honestly, in good faith and in the best interests of BIS, not engaging in conduct likely to bring discredit upon the Bureau

(ii) **Impartiality**- AGENT(s) shall disclose their past and present association with the entity to be assessed or the group of companies to which it belongs.

(iii) **Conflict of Interest** - AGENT(s) shall inform BIS of any conflicts, of potential conflicts of interest, arising out of fulfilment of his/her duties and the responsibilities of an AGENT. The agent shall not witness assessments of those organizations where he/she has been engaged as Consultant in at least the past 2 years. Any association with the organization to be witnessed shall be brought to the notice of Branch Head of the BIS.

(iv) The AGENT(s) shall not accept benefits, pecuniary or otherwise, from manufacturers (BIS applicants/licensees).

(v) The AGENT(s) shall not use accommodation and transport facility from any manufacturers (BIS applicants/licensees).

(vi) The AGENT(s) shall not indulge in consumption of intoxicant substances during inspection visits and in any case not indulge in such consumptions during the inspection or charge it to manufacturers (BIS applicant/licensee).

(vii) No personal expenses of the AGENT(s) shall be charged to the manufacturers (BIS applicants/licensees).

(viii) AGENT(s) shall have no association with any manufacturers (BIS applicants/licensees), and no financial dealing shall take place between AGENT(s) and any manufacturers (BIS applicants/licensees).

Confidentiality

(ix) AGENT(s) shall remain bound by confidentiality even after opting/retiring from the BIS's panel.

(x) AGENT(s) shall contact the concerned Branch Head of the BIS if he/she is in doubt with regards to a specific business conduct question or would like to report an infraction.

(xi) AGENT(s) shall not market their association with BIS for gaining work or misuse their position while interacting with manufacturers (BIS applicants/licensees).

Objectivity

(xii) AGENT(s) shall act impartially ensuring that he/she is independent in judgement and actions and takes all reasonable steps to be satisfied as to the soundness of all decisions taken.

(xiii) AGENT(s) shall use due care and diligence in fulfilling its functions and exercising any powers attached therewith.

BIS will promptly investigate any alleged non-compliance including this Code of Ethics. Each of the personnel of the AGENT(s) working for the project shall adhere to above guidelines.