

भारतीय मानक ब्यूरो
(केन्द्रीय मुहर विभाग - I)

हमारा सन्दर्भ: सीएमडी-I/6:8

22 जून 2022

विषय: बीआईएस की ओर से फैक्ट्री निरीक्षण करने वाली पैनलबद्ध एजेंसियों के तकनीकी लेखा परीक्षकों (टीए) के प्रदर्शन के आकलन और निगरानी के लिए बीआईएस अधिकारियों द्वारा साक्षी अंकेक्षण एवं पुनःजांच दौरा

- 1) उपर्युक्त विषय पर सक्षम प्राधिकारी द्वारा अनुमोदित एसओपी दस्तावेज सभी संबंधित पक्षों के कार्यान्वयन के लिए संलग्न है।
- 2) समसंख्यक परिपत्र के साथ संलग्न पूर्व एसओपी दस्तावेज दिनांक 20 जनवरी 2022 तत्काल प्रभाव से संलग्न संशोधित एसओपी द्वारा प्रतिस्थापित किया जाता है।

(मोहित जनोहिया)
वैज्ञ-सी/सीएमडी-I

प्रमुख, सीएमडी-I

उपमहानिदेशक (प्रमाणन एवं सीएसएम)

Bureau of Indian Standards
(Central Marks Department - I)

Our Ref: CMD-I/6:8

22 June 2022

Subject: Witness Audits and Follow-up Visits by BIS officers for assessment and monitoring the performance of technical auditors (TAs) of empanelled agencies carrying out factory inspections on behalf of BIS

- 1) The SOP document on the above subject as approved by the Competent Authority is attached herewith for implementation by all concerned.
- 2) The earlier SOP document enclosed with circular of even number dated 20 January 2022 stands superseded by the enclosed revised SOP with immediate effect.

(Mohit Janoiya)
Sc.C/CMD-I

Head, CMD-I

DDG (Certification & CSM)

परिचालित/circulated to:

सभी क्षेत्रीय कार्यालयों/ शाखा कार्यालयों
All ROs/BOs

सभी उपमहानिदेशक (क्षेत्रीय)
All DDGRs

प्रमुख, सी०एस०एम० विभाग
Head, CSMD

अन्य सभी संबंधित पक्ष - बीआईएस इंटरनेट के माध्यम से
All other concerned - through BIS intranet

BUREAU OF INDIAN STANDARDS
(CENTRAL MARKS DEPARTMENT - I)

Our Ref: CMD-I/6:8

22 June 2022

Subject: SOP for Witness Audits and Follow-up Visits by BIS officers for assessment and monitoring the performance of technical auditors (TAs) of empanelled agencies carrying out factory inspections on behalf of BIS

BIS has started using the services of NABCB accredited (as per IS/ISO/IEC 17020) inspection agencies for carrying out factory inspections to support BIS in the Product certification scheme.

- 2) BIS, as certification body, with its overall responsibility towards successful operation of product certification scheme takes into account qualification and competence of personnel of outsourced inspection agencies. To ensure adequate competence of the OSA personnel carrying out BIS inspections, Technical Auditors (TAs) go through a classroom training session followed by two shadow inspections with BIS officers or experienced OSA auditors, before being deployed for independent inspections.

Their performance is regularly monitored by way of 100% evaluation of quality of inspection reports at BOs. Regular meetings/VCs are also being organised with OSA personnel for providing feedback and suggesting improvements in their reports.

- 3) **Objective:** In this regard, with a view to further improve this assessment and monitoring mechanism of TAs of OSA, and in line with practices followed for accreditation, a procedure for 'Witness audits' has been established to observe and review the competence of TAs while performing the Inspection activity.

The certification officer shall carry out a concurrent visit in the licensee's premises where surveillance inspection is being conducted by TA of OSA. During the visit, the BIS officer shall observe all the inspection activities carried out by the TA and submit a report, which shall include officer's comments on TA's technical competence, understanding of standard and Product Manual, thoroughness of inspection activities, comprehensiveness of report, their conduct and recommendations for overall improvement in performance.

- 4) **Planning of Witness Audits:**

- a) The planning of witness audits shall be carried out by the Regional Offices under the supervision of DDGRs.
- b) For the purpose of witness audits, each DDGR may identify 2-3 officers of each domain (MCM, EEE & FCT) in their region who are of relevant discipline and are

well-conversant and have experience with the surveillance activity of the product (Preferably products with adequate coverage under certification may be selected for witness audits).

- c) A plan of witness audits shall be created such that all the TAs working in their regions are assessed at least once in a year. While planning the audits, DDGRs may consult each other so as to avoid multiple audits of the same TA of OSA functioning across regions.
- d) Dates of witness audits can be decided using the 'Monthly surveillance plan' submitted by OSAs on ManakOnline, which contains the lists of licences allotted to TA along with corresponding dates of inspection. Audits shall be allotted to the identified officers by DDGRs.
- e) **Risk based approach:**
 - i) DDGRs may take inputs from BOs with respect to performance of the Technical Auditors (TAs) of OSA based on evaluation of Inspection reports. Based on the feedback, the witness audits for TAs can be prioritized and planned by DDGRs.
 - ii) After one round of completion of witness audits of all TAs, planning of audits may be carried out based on risk evaluation based on previous audit reports and feedback from BOs.
 - iii) Based on risk evaluation, more audits may also be planned for a Technical Auditor by BIS during a year.

5) Performing Witness audit:

- a) BIS Officer shall inform the Technical Auditor about the planned witness audit in advance. BIS Officer shall plan and prepare for effective execution of the witness audit.
- b) BIS Officer shall carry out the witness audit. The audit shall focus at assessing the understanding, competence and performance of the TA in carrying out the factory inspection activity.
- c) The officer shall be required to submit a report along with observations, if any (Template enclosed as *Annexure - I*). The observations requiring improvement in performance of TA shall also be informed to TA at the end of audit.
- d) The report of witness audit shall be submitted to DDGRs.

6) Evaluation and compilation:

- a) DDGRs shall evaluate the reports of witness audit. Any report requiring immediate attention and action by BIS shall be communicated to DDG (Certification) and CSMD immediately with comments and recommendations, as required.

- b) The details of witness audits (alongwith copy of reports) carried out in the region during the month alongwith observations of DDGR shall be communicated to DDG (Certification) and CSMD on a monthly basis (preferably by 5th of next month).

7) Evaluation and follow up with OSA:

- a) CSMD shall compile, evaluate and put up details from all regions to DDG(Certification)/DG on monthly basis (preferably by 10th of each month).
- b) CSMD shall also take up the observations of BIS with Project Incharge of respective OSA seeking corrective actions, as required.
- c) In case of a report requiring immediate attention forwarded by DDGR, CSMD shall put up for review immediately within 2 days to DDG(Certification)/DG.
- d) CSMD shall also take up the matter for immediate attention and action by the Project Incharge of respective OSA.

8) Planning of Follow-up Visits: In addition to witness audits, to keep a check over quality of inspections carried out by Technical auditors of OSA, follow-up visits may also be planned and organised by DDGRs through BIS officers in the region. The follow-up visit shall normally be undertaken within seven days of inspection completion by TA of OSA. The objective of the follow-up visits shall be to review that the inspection carried out and reported by OSA personnel is true and complete as required. The follow-up visit shall be a surprise visit. Any serious variations shall be clearly highlighted in the report by the BIS officers. DDGRs shall review these reports and send these to CSMD and DDG (Certification) with comments, as required. DDG (Certification) may also plan and organize follow up visit for any inspection.

9) The details of witness audit and follow-up visit outcomes of each OSA shall be compiled by CSMD and should form an input for the review and assessment of performance of OSAs to be carried out every six month by BIS.

10) This issues with the approval of DG-BIS.

(Mohit Janoiya)
Sc.C/CMD-I

Head, CMD-I

DDG (Certification & CSM)

circulated to:

- i) **All ROs/BOs**
- ii) **All DDGRs**
- iii) **Head(CSMD)**
- iv) **All other concerned** - through BIS intranet

Annexure – I

Bureau of Indian Standards

Witness Audit report

| <u>Part - I : General information</u> | | | Remarks |
|--|---|-------------------|---------|
| 1) | Name of technical auditor | | |
| 2) | Name of inspection agency | | |
| 3) | Name of manufacturer inspected | | |
| 4) | Address of the manufacturer inspected | | |
| 5) | Licence No. | | |
| 6) | Indian Standard No. | | |
| 7) | Product | | |
| <u>Part - II : Inspection details</u> | | | |
| 8) | Date(s) of inspection | | |
| 9) | Type of inspection (Surveillance/ Pre-despatch etc.) | | |
| 10) | Time of entry to inspection premises | | |
| 11) | Time of exit from inspection premises | | |
| 12) | Time spent in inspection (excluding breaks, if any) | | |
| 13) | a) Whether the inspection personnel was accompanied by any other person. b) If Yes, give details | Yes or No or N.A. | |
| <u>Part - III : Preparation for inspection</u> | | | |
| 14) | Relevant Standards were readily accessible to the inspection personnel (by physical or electronic means) | Yes or No or N.A. | |
| 15) | Product manual and relevant guidelines were readily accessible to the inspection personnel (by physical or electronic means) | Yes or No or N.A. | |

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|--|---|-------------------|--|
| 16) | Inspection personnel was conversant with the requirements of relevant Standard(s) | Yes or No or N.A. | |
| 17) | Inspection personnel was conversant product manual and concerned requirements of relevant guidelines | Yes or No or N.A. | |
| 18) | Information about scope, status, past 2 years performance history of licence were available and understood by the inspection personnel | Yes or No or N.A. | |
| <u>Part - IV : Conduct of inspection</u> | | | |
| 19) | Familiarisation of manufacturing premises was undertaken including verification of manufacturing process/ production line | Yes or No or N.A. | |
| 20) | Conversant with various raw materials and components used in production | Yes or No or N.A. | |
| 21) | Certificates and test records of applicable raw material and components were verified | Yes or No or N.A. | |
| 22) | Able to comprehend relevance of certificates and test records of applicable raw materials and components as prescribed in relevant Standard(s) | Yes or No or N.A. | |
| 23) | Production details and material in stock was verified | Yes or No or N.A. | |
| 24) | Infrastructure (including adequacy of machinery and test equipments) was verified | Yes or No or N.A. | |
| 25) | Any change in infrastructure and/or representative from management/ quality control was verified and recorded (including competency criteria in case of quality control representative) | Yes or No or N.A. | |
| 26) | Any change in manufacturing process was verified and recorded | Yes or No or N.A. | |

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|---|--|-------------------|--|
| 27) | Follow-up actions (where applicable) for pending matters (like previous inspection, communication from BIS branch office etc.) were taken up with the manufacturer | Yes or No or N.A. | |
| <u>Part - V : Technical assessment</u> | | | |
| 28) | Test records as per scheme of inspection and testing were verified | Yes or No or N.A. | |
| 29) | Labelling and marking requirements were checked and recorded | Yes or No or N.A. | |
| 30) | Functioning and calibration status of test equipments were verified | Yes or No or N.A. | |
| 31) | Factory testing was assessed in a comprehensive manner | Yes or No or N.A. | |
| 32) | Hygienic conditions (where applicable) were assessed in a comprehensive manner | Yes or No or N.A. | |
| 33) | Competency of quality control personnel of manufacturer was assessed in an objective manner | Yes or No or N.A. | |
| <u>Part - VI : Drawl and sealing of sample(s)</u> | | | |
| 34) | Sampling was done randomly without any external influence | Yes or No or N.A. | |
| 35) | Proper packing and applicable sealing of sample (marked for dispatch to outside laboratory) was ensured | Yes or No or N.A. | |
| 36) | Proper packing and applicable sealing of counter sample (left for custody of manufacturer) was ensured | Yes or No or N.A. | |
| 37) | Test request covers all the required aspects | Yes or No or N.A. | |
| 38) | Laboratory selection was done inline with BIS guidelines without any external influence | Yes or No or N.A. | |
| <u>Part - VII : Conclusion of inspection</u> | | | |

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|---------------------------------------|---|--------------------|--|
| 39) | The manufacturer was provided with copy of test request | Yes or No or N.A. | |
| 40) | The DVA report was comprehensive covering all points and shared with manufacturer | Yes or No or N.A. | |
| 41) | The manufacturer was informed and made to understand about actions required post inspection | Yes or No or N.A. | |
| <u>Part - VIII : Code of ethics</u> | | | |
| 42) | The inspection personnel was compliant with code of ethics during the witness audit | Yes or No or N.A. | |
| <u>Part - IX : General attributes</u> | | | |
| 43) | Conduct and behaviour | Rating from 1 to 5 | |
| 44) | Effectiveness of communication | Rating from 1 to 5 | |
| 45) | Punctuality and focus on work | Rating from 1 to 5 | |
| 46) | Overall rating of technical auditor | Rating from 1 to 5 | |

Note 1: If the reply to any of the above questions is 'No', kindly give specific details.

Note 2: The ratings are on a scale of 1 to 5 with 5 being best.

Note 3: An overall rating of 2 and below will not be acceptable and technical auditor would be required to undergo training.

47) Issues to be highlighted to technical auditor for improvement: (To be recorded in **Observation sheet** and also informed to technical auditor)

48) Any other remarks for better appraisal of witness audit report:

Signature:
Name of BIS officer:
Designation:
RO/BO:
Date:
Place:

DDGR

Bureau of Indian Standards

Witness Audit report – Observation Sheet

| <u>Part - I : General information</u> | | |
|---------------------------------------|--|--|
| 1) | Name of technical auditor | |
| 2) | Name of inspection agency | |
| 3) | Name of manufacturer inspected | |
| 4) | Address of the manufacturer inspected | |
| 5) | Licence No. | |
| 6) | Indian Standard No. | |
| 7) | Product | |
| 8) | Date(s) of inspection | |
| 9) | Type of inspection (Surveillance/ Pre-despatch etc.) | |
| 10) | Observations, if any | |
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Signature:
Name of BIS officer:
Designation:
RO/BO:
Date:
Place: