

# **BUREAU OF INDIAN STANDARDS**

## **(CENTRAL MARKS DEPARTMENT - I)**

**Our Ref: CMD-I/2:12:6**

**28 August 2019**

**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 involve 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. To ensure adherence to principle of rotation, Head of BOs while finalizing the monthly/quarterly inspection programme of the Branch needs to ensure that:
      - (a) The visits are allocated equally amongst all the available certification officers (or agents, if applicable) in the Branch as far as possible.
      - (b) Multiple visits to a single licensee are rotated amongst all the available certification officers (or agents, if applicable) equally as far as possible.
      - (c) No particular certification officer (or agents, if applicable) is allocated unusually large number of visits in respect to a specific licensee.
  - For any deviation in surveillance plans, reasons shall be recorded by Head of BOs under intimation to DDGR. DDGR shall monitor, review and issue appropriate directions, if any.

**(iii) Pre-despatch/lot inspection:**

- (a) 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 (₹ 10,000/-) as specified in Scheme - I of BIS (Conformity Assessment) Regulations.
- (b) In addition to adherence to principle of rotation (Refer paragraph 3(1)(ii)), 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.

**(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, if applicable) 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 ₹ 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 the procurement of market samples.

**4. Reactive surveillance:**

- (1) 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. The principle of rotation shall be adhered to in reactive surveillance activities as well (Refer paragraph 3(1)(ii)).

**5. 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, Rules, (Conformity Assessment) Regulations and guidelines.

**6. Dynamic Surveillance:**

- (1) 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.