भारतीय मानक ब्यूरो
(केन्द्रीय मुहर विभाग - I)

हमारा सन्दर्भ: सीएमडी-I/2:12:9 **09 अगस्त 2021**

विषय: भारतीय मानक ब्यूरो (अनुरूपता निर्धारण) विनियम, 2018 की अनुसूची-II की अनुरूपता निर्धारण स्कीम-I के अंतर्गत उत्पाद वापसी तथा नमूनों की विफलता के कारण निलंबन, निरस्त या रद्द किये गए लाइसेंस की जानकारी प्रसार के दिशानिर्देश - हेतु।

उपर्युक्त विषय पर सक्षम प्राधिकारी द्वारा अनुमोदित दिशानिर्देश सभी संबंधित पक्षों के कार्यान्वयन के लिए सलंग्न है।

(मोहित जनोहिया)
वैज्ञ-'सी'/सीएमडी-I

प्रमुख, सीएमडी-I

उपमहानिदेशक (प्रमाणन)

Bureau of Indian Standards
(Central Marks Department - I)

Our Ref: CMD-I/2:12:9 **09 August 2021**

Subject: Guidelines for product recall and dissemination of information about licences put under suspension/ licences cancelled or expired due to failure of samples under conformity assessment Scheme – I of Schedule – II of BIS (Conformity Assessment) Regulations, 2018 - reg.

The guidelines on the above subject as approved by the Competent Authority is attached herewith for implementation by all concerned.

(Mohit Janoiya)
Sc.C/CMD-I

Head, CMD-I

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/2:12:9 **06 August 2021**

Subject: Guidelines for product recall and dissemination of information about licences put under suspension/ licences cancelled or expired due to failure of samples under conformity assessment Scheme – I of Schedule – II of BIS (Conformity Assessment) Regulations, 2018

This document stipulates the guidelines/standard operating procedure (SOP) for product recall and dissemination of information to common consumers as well as wider public and stakeholders in general, about the product certification licences (ISI) that have been put under suspension due to failure of sample(s) or licences cancelled/expired due to failure of sample(s). The failure of sample(s) includes but is not limited to results obtained from certification surveillance operations and complaint investigation.

Entry in online portal

1. **(i)** The Regional Offices (ROs)/Branch Offices (BOs) shall ensure that proper reasons including the parameters in which the sample has failed are entered in the online portal (e-BIS/ManakOnline) for any failure of sample and whenever a decision for suspension or cancellation/expiry of any licence is taken.

(ii) In case of suspension or cancellation of licence on account of establishment of complaint (in line with complaint management and enforcement guidelines framed under provisions of the BIS Act, 2016), the explicit reasons vis-a-vis findings of the complaint shall be clearly reflected in entries made in online portal.

Risk assessment

2. **(i)** Upon receipt of information about any non-conformity of products bearing Standard Mark(ISI), an assessment analysis shall be carried by the BO. For this purpose, Head BO should constitute a committee of officer(s) at BO level. The committee shall carry out the risk assessment and the recommendations of the committee shall be put up to Head BO for consideration. A guidance template to undertake assessment analysis of non-conformity by BO is enclosed as ***Annexure - I***.

(ii) If the risk assessment concludes that the product failure is going to have impact on public health/safety etc., in all such cases, the Head BO may order product recall in accordance with Sr. No. 3, 4 and 5.

(iii) Such cases shall also be notified in public domain including the failure aspects as well as its impact on public health/safety etc.

Notifying in public domain

(iv) The information about product certification licences (ISI) that have been put under suspension/ cancelled or expired due to reasons of failure of sample(s) or establishment of complaint will be made publicly available on the dashboard of e-BIS portal website and BIS Care app.

(v) Public advertisement must have the information that consumers can check the validity of the licence for a product using BIS Care app.

Product recall (failure of sample)

3. **(i)** The communication about nonconformity of product including instructions of product recall (if applicable) shall be informed to the licensee preferably within 15 days.

(ii) An incident investigation shall be carried out by the licensee and the same shall be informed to BIS along with plan of action for product recall. The guidance template as per ***Annexure - I*** may also be utilised by the manufacturer.

(iii) Based on the assessment analysis of the non-conformity by the BO and incident investigation by the licensee, the decision on product recall shall be taken by the Head BO. For any differences or otherwise between the assessment carried out at BO and incident investigation by licensee, a meeting (virtual or in-person) may also be organised.

(iv) The information about recall of products bearing Standard Mark (ISI) sought from manufacturers shall be checked before any decision about reinstatement (revocation of suspension, cancellation proceedings etc.) of certification.

(v) Any inputs received about appropriate action as per Sr. No. 3(i), (ii), (iii) and (iv) above shall be verified to the extent possible during the next factory visit or dynamic surveillance visit. For non-compliance observed, if any, appropriate action shall be taken.

Product recall (complaint establishment)

4. **(i)** The following information sought from manufacturers about appropriate action about complaint redressal (in line with complaint management and enforcement guidelines) shall be checked before any decision about reinstatement (revocation of suspension, cancellation proceedings etc.) of certification:

(a) Recall of product bearing Standard Mark (ISI)

(b) Repair/Replacement/Reprocessing/Compensation to consumers who had already been sold product bearing Standard Mark (ISI)

(ii) Any inputs received about appropriate action as per Sr. No. 4(i)(a) above shall be verified to the extent possible during next factory visit or surveillance based on consumer complaint/feedback.

(iii) For any inputs received as per Sr. No. 4(i)(b), appropriate action shall be taken as per extant guidelines of complaint management and enforcement operations.

Dissemination of information in public and to consumers

5. **(i)** The ROs/BOs shall spread awareness about the publicly available information on BIS website, online portals and BIS care app. This shall include information on instructions issued for product recall, licences put under suspension/ cancelled or expired due to reasons of failure of sample(s) or establishment of complaint w.r.t. BOs under their respective jurisdiction.

(ii) While giving reference to the status of licences (including suspension/ cancellation or expiry) as reflected on the BIS website/portal/BIS care app, it shall be ensured that emphasis is made on the dynamic nature of information. The relevant details about how to access the real-time information from BIS website, portals and BIS care app shall also be shared and propagated during such informative campaigns/exercises. The impact of non-conforming product on the health/safety etc. shall also be highlighted during such activities.

(iii) The licensee manufacturers (especially MSMEs) shall also be made aware about the assessment procedures and documentation involved in procedures of product recall, incident investigation during the training programmes.

(iv) The information summary about non-conformity of product and decision(s) taken about product recall shall be informed by BOs to respective RO on a quarterly basis. Head of the Region shall review the findings of the BOs under their jurisdiction so as to ensure uniformity of practice within the Region to the extent possible.

(v) For any non-compliance towards instructions of the product recall, the case shall be brought to the notice of Head of the Region by Head BO. In such cases, Head of the Region shall issue appropriate media/news release and publicise findings about non-conformity of the product(s) manufactured by concerned manufacturer.

Annexure - I

Sr. No.	Aspect	Observations/Remarks
(i)	Identification of product and its non-conformity	
(ii)	Identify hazard(s), For example: a) Thermal hazards like explosion, flame, radiation, hot surfaces etc. b) Electrical hazards like live parts, short-circuits, overload etc. c) Mechanical hazards like vibration, instability, break-down during operation, moving parts susceptible to causing physical harm to the operator, falling or ejected objects, edges or corners etc. d) Chemical/Biological hazard like presence of toxins, expiry of product etc.	
(iii)	Identify subject at risk, For example, Human, plant, animal, environment etc.	
(iv)	Description of potential harm scenario(s) For example, absence of proper labelling and marking resulting in consumption of expired food product	
(v)	Describing the potential harm(s) For example, potential electrical shock/burn/loss of life due to leakage of current from electrical wire	
(vi)	Risk assessment Assessing severity of harm(s) and probability of its occurrence across production process	
(vii)	Need for product recall (Yes or No)	