

BUREAU OF INDIAN STANDARDS
(Central Marks Department - I)

Our Ref: CMD-I/2:4:1

19 January 2024

Subject: Clarification on the provisions of the product manuals - reg.

BIS issues product manuals as guidance documents for conformity assessment as per various Indian Standards. Many of these products are covered under the product certification scheme of BIS. These product manuals also incorporate Scheme of Inspection and Testing (SIT) specifying controls and checks to be exercised by the manufacturer.

- 2) These documents are intended to be guidance documents for BIS licensee and applicant manufacturers so as to facilitate them in operating BIS certification. In this context, following aspects may be taken note of:
 - a) The 'Levels of Control' given in the SIT are recommendatory in nature. The same is also reflected in the product manual as a Note given under the SIT Table for Levels of Control.
 - b) The manufacturer has the choice to define the control unit/batch/lot and their own Levels of Control with proper justification and inform the Head of the concerned Branch Office (BO) for further action.
 - c) In a few product manuals, the Levels of Controls prescribed in the SIT are mentioned as obligatory for the manufacturers. It is clarified that Levels of Control given in the SIT are recommendatory in nature in respect of products covered even in these Product Manuals.
 - d) This is not applicable, however, to the products such as LPG cylinder, High pressure cylinder including medical oxygen cylinder etc., where the Indian Standard itself prescribes the control unit/batch/lot.

- 3) As regards the SIT specifying the requirement of test as required in-house ('R') and to be subcontracted to outside laboratories ('S'), the following may be noted:
 - a) The tests specified as 'R' are fundamental to meeting the quality requirements of a product, as provided in the Indian Standard concerned. The compliance with the Standard in the absence of these in-house test facilities may become a challenge for the manufacturers.
 - b) Provisions for the sharing of the test facilities, including those in the category 'R' too, have already been made in the Annexure-X (Relaxation in test facilities) of the guidelines for Grant of Licence Ref: CMD-I/2:12:1 dated 06 March 2023, and the guidelines for the utilisation of cluster based test facilities by MSMEs Ref. CMD-I/2:12:8 dated 30 April 2021.

- c) To further facilitate the implementation of Standards and reduce the compliance burden on the MSME manufacturers opting for BIS certification under Scheme-I, the test facilities specified as 'R' in the SIT are also allowed to be subcontracted by MSME manufacturers to the outside laboratories recognised or empanelled by BIS. Additionally, MSME manufacturers may also utilise the NABL accredited laboratories as per IS/ISO/IEC 17025 for sub-contracting of tests categorised as 'R'.
- d) Similarly, for sub-contracting of tests categorised as 'S', the manufacturers may utilise the outside laboratories recognised or empanelled by BIS as well as NABL accredited laboratories as per IS/ISO/IEC 17025.
- e) The manufacturer shall inform the concerned BO of the tests in the category 'R' subcontracted to the outside laboratories and maintain complete records of the tests got done from outside laboratories.
- f) The frequency of factory and market surveillance in respect of the licensed manufacturers subcontracting even the tests in the category 'R' will be dynamically reviewed by BIS on the basis of risk-based approach.