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No. 6/5/2017-BIS (Pt. I)
Government of India
Ministry of Consumer Affairs, Food & Public Distribution
Department of Consumer Affairs
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Krishi Bhawan, New Delhi.
Dated the 20th March, 2018.

OFFICE MEMORANDUM

Sub: Compulsory use of licence or certificate of conformity – reg.

The undersigned is directed to refer to section 16 and 25 (3) of the Bureau of Indian Standards Act, 2016 (11 of 2016) and to lay down the procedure to be followed by the concerned administrative ministries for making the use of a mark under licence or certificate of conformity compulsory, under section 16 (1) of the BIS Act 2016 to demonstrate that goods, article, process, system or service conform to the requirements of Indian standard or the essential requirements. This O.M. also covers the procedure for approving and authorizing any other agency, if required, in terms of section 16 (2) of the BIS Act 2016, for carrying out conformity assessment activities. In addition to the above, this procedure will be followed for making conformity assessment compulsory under section 25 (3) of the BIS Act 2016 for promotion, monitoring and management of quality of goods, articles, processes, systems and services and to protect the interests of consumers and various other stakeholders. This O.M. shall not be applicable to goods, article, process, system or service meant for export purposes.

2. In this O.M., unless the context otherwise requires,

(1) "Act" means the Bureau of Indian Standards Act, 2016 (11 of 2016);

(2) "accreditation body" means a body that performs third party attestation related to a conformity assessment agency conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

(3) "certification" means, third party attestation of conformity related to goods, article, process, system or service.

(4) "third party" means a person or body that is independent of the person or organization that provides goods, article, process, system or service for conformity assessment and has no user interest.

(5) All other words and expressions used which are not defined in this O.M. but defined in the BIS Act 2016 or the BIS Rules 2017 shall have the meanings respectively assigned to them in the Act and the Rules.

3. Procedure to be followed by concerned administrative ministry:

(1) Whenever use of a mark under licence or certificate of conformity is to be made compulsory to demonstrate that particular goods, article, process, system or service conform to the requirements of Indian Standard or the essential requirements, the concerned administrative ministry may:

a) identify the goods, article, process, system or service to be brought under compulsory certification, and the requirements of Indian Standard or the essential requirements it shall conform to.

b) satisfy itself that compulsory certification is necessary or expedient so to do in the public interest or for the protection of human, animal or plant health, safety of the environment, or prevention of unfair trade practices, or national security or for promotion, monitoring and management of quality of goods, articles, processes, systems and services or to protect the interests of consumers and various other stakeholders, as the case may be.

c) choose whether implementation would be through grant of licence by the Bureau or grant of certificate of conformity either by the Bureau or any other agency to be selected as per procedure given in para 4 of this O.M. In case the goods, article, process, system or service are vital to the national security, the implementing agency shall ordinarily be the Bureau.

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d) select the conformity assessment scheme from various schemes notified by the Bureau, or any combination of such schemes for ensuring conformity of goods, article, process, system or service. If required, the Bureau may be directed to notify any other scheme which thereafter may be used for ensuring conformity of goods, article, process, system or service. The selection of conformity assessment scheme should be based on the risk associated with the goods, article, process, system or service. The scheme may include but not be limited to (i) self – declaration, (ii) certificate of conformity based on type approval, testing or inspection, (iii) system certification, (iv) product/process/service certification, (v) any combination of the above. The cost burden of compliance on the impacted stakeholders shall be factored in while selecting the scheme.

e) the concerned administrative ministry shall prepare the draft Quality Control Order and send it to BIS for comments and publish on its website for public consultation. The concerned administrative ministry shall ensure that the information regarding the proposed notification reaches the stakeholders including WTO members. The comments and suggestions received on the draft notification shall be reviewed and considered on merit by the concerned administrative ministry.

(2) Subsequently Quality Control Order shall be notified in the Gazette by the concerned administrative ministry.

4. Procedure for approving and authorizing any other agency for conformity assessment:

(1) Following procedure may be followed for approval of any other agency for conformity assessment:

a) The concerned administrative ministry may invite, through wide publicity, expression of interest from the agencies which shall be either

i. accredited for carrying out conformity assessment activities from National Accreditation Board for Certification Bodies (NABCB) or;

ii. accredited or recognized by the Bureau.

b) The expression of interest so received shall be scrutinized in respect of

i. the capability and competency of the agency to certify manufacturers, providers or importers of goods, article, process, system or service, carry out surveillance and provide necessary assistance to authorities in enforcing the implementation of the scheme under para 3 (1) (d).

ii. fee and other charges that the agency would be collecting from certified bodies for certification.

(2) After evaluating the proposals received, the concerned administrative ministry shall issue a letter of approval to the agency for a period of 2 years which may be extended for a further period of 2 years on the basis of successful review that shall initially be done after one year from the issue of authorization and subsequently as decided by the concerned administrative ministry. This letter may contain detailed terms and conditions of operation.

(3) The procedure for grant of certificate of conformity by the agency shall be approved by the concerned administrative ministry.

(4) In case the outcome of the review is not satisfactory or some serious complaint against the agency regarding conduct of business has been received, the concerned administrative ministry shall ask the agency to take corrective actions. The administrative ministry may cancel the authorization if corrective actions taken are not to its satisfaction.

5. Issue of quality control order: The quality control order issued for any goods, article, process, system or service by the concerned administrative ministry shall inter -alia specify the following:

(1) the authority responsible for enforcing compliance to the quality control order.

(2) the essential requirements as per Explaination (ii) of sub-section (1) of Section 16 of the Act.

(3) the conformity assessment scheme required to be followed for carrying out conformity assessment activities which may include the requirements of testing, inspection, surveillance etc.,

(4) the conformity assessment agency responsible for carrying out conformity assessment activities to ensure compliance to the quality control order.

(5) the quality control order shall have adequate provisions related to the obligations of the certified bodies. The obligations of the certified bodies include prohibition to manufacture, import, store or exhibit for sale, sell, distribute goods, article, process, system or service without complying with the conditions of the quality control order.

(6) a provision stating that any technical clarification relating to Indian Standard shall be provided by the Bureau and relating to the essential requirements by the concerned administrative ministry, as applicable.

(7) whenever required, a provision, enabling the concerned administrative ministry for allowing exemption, for any consignment of such variety/type/grade/size of material which is covered in the Indian Standard specified in the quality control order but not manufactured in the country.

6. Follow up action: Subsequent to issue of the quality control order, the concerned administrative ministry shall

(1) provide copy of the quality control order to Director General of Foreign Trade, Central Board of Excise & Custom and to conformity assessment agency specified under para 5 (4) above.

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(2) publish the name of the conformity assessment agency specified under para 5 (4) and conformity assessment scheme specified under para 5 (3) on its website.
(3) publish details of the certified bodies with the scope of their certification on its own website and direct conformity assessment agency specified under para 5 (4) to publish such details on its website.

7. Review of Quality Control Order: The concerned administrative ministry may review any difficulty faced by the affected manufacturers, importers or conformity assessment agency specified under para 5 (4), and evaluate the need for necessary changes in the standard, essential requirements, the conformity assessment scheme specified under para 5 (3) or conformity assessment agency specified under para 5 (4).

8. Appeal: In cases where bodies other than the Bureau are authorized to certify and enforce conformity, in the event of rejection of application or cancellation of certification, the applicant or the certified body shall have the right to appeal to the concerned administrative ministry against any decision of the conformity assessment agency specified under para 5 (4), and the decision of the concerned administrative ministry shall be final in this regard.

9. This issues with the approval of Hon'ble Minister CA,F&PD.

(A. K. Pandey)
Under Secretary to the Govt. of India
Tel: 23381120

To

Secretaries of all administrative Ministries/Departments as per standard list.

Copy to: The DG, BIS for information.

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