BUREAU OF INDIAN STANDARDS

16 Jun 2017

Subject: Draft BIS (Conformity Assessment) Regulations, 2017

Draft BIS (Conformity Assessment) Regulations, 2017 framed under the provisions of the new Bureau of Indian Standards Act, 2016 have already been hosted on BIS website on 09 June 2017 for information and comments from stakeholders.

The revised Draft BIS (Conformity Assessment) Regulations, 2017 are being hosted on the website incorporating "PART IV – GENERAL"

Comments, if any may be sent to <u>scgc@bis.gov.in</u> through E-mail by 21 June 2017.

DDG(Certification) Tel: 011-23231120

Enclosure: As above

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09 Jun 2017

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THE BUREAU OF INDIAN STANDARDS (CONFORMITY ASSESSMENT) REGULATIONS, 2017

G.S.R. ------In exercise of the powers conferred by Section 39 of the Bureau of Indian Standards Act, 2016 (11 of 2016), read with Sections 12 and 13, the Executive Committee of the Bureau of Indian Standards, with the previous approval of the Central Government, hereby makes the following Regulations, namely:

1. SHORT TITLE AND COMMENCEMENT

(1) These Regulations may be called the Bureau of Indian Standards (Conformity Assessment) Regulations, 2017.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. DEFINITION OF TERMS

In these Regulations, unless the context otherwise requires -

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

(2) "Applicant" means any person who applies to the Bureau for a Licence or Certificate of Conformity;

(3) "Audit" means systematic, independent, documented process for obtaining evidence of conformity;

(4) "Bureau" means the Bureau of Indian Standards;

(5) "Certification audit" means audit carried out independently for the purpose of certifying the management system;

(6) "Consignment" means a specific batch of articles or goods for export, import or domestic use;

(7) "Rules" means the Bureau of Indian Standards Rules, -----; and

(8) All other words and expressions that have been used in these Regulations and not defined, but defined in the Act or the Rules shall have the same meaning as assigned to them in the Act or the Rules.

<u>Part I</u>

GRANT, OPERATION, SUSPENSION, RENEWAL, NON-RENEWAL AND CANCELLATION OF LICENCE

3. General

(1) For grant of Licence to use or apply a Standard Mark on any article or goods notified under the Conformity Assessment Schemes specified in Schedule-I of these Regulations, application shall be made to the Bureau, if the articles or goods conform to an Indian Standard or specified requirements. The manner, fee, terms and conditions for grant, operation, suspension, renewal, non-renewal and cancellation of such Licences are as specified in these Regulations.

4. Application

(1) Any person engaged in manufacturing of any article or goods may apply to the Bureau for grant of Licence. Every such applicant shall make a separate application for different article or goods manufactured at the same location unless otherwise specified by the Bureau. For Scheme E as specified in Schedule-I of these Regulations, separate applications shall be made by the manufacturer for each brand name used on the same article or goods manufactured at the same location, unless otherwise specified by the Bureau or single application may be made by the brand owner or the user of the brand for each brand name owned or used by him in relation to the same article or goods manufactured at different locations.

(2) The application shall be made in prescribed form along with necessary documents and fee as specified by the Bureau from time to time. The hard copy of application along with necessary documents may also be submitted to the Bureau, wherever required, within the stipulated time period. Whenever the applicant is required to submit test report(s) along with application, he shall be responsible for the authenticity of such test report(s). The applicant shall also be responsible that the article or goods for which the Licence is applied for conforms to the relevant Indian Standard or specified requirements.

(3) All applicants located outside India shall nominate an Authorized Indian Representative subject to the conditions specified by the Bureau.

(4) The application form shall be signed or e-validated by the management or any person duly authorized by the management.

(5) The Bureau may call for required documents and/or any supplementary information and/or any documentary evidence from the applicant in support of or to substantiate any statement made in the application, within such time as may be directed by the Bureau and non-compliance with such direction may result in the application being summarily rejected by the Bureau. If the documents and/or information and/or evidence furnished by the applicant are found to be satisfactory, the application may be processed for grant of Licence.

(6) The applicant shall, within reasonable time, arrange for inspection of the manufacturing premises as specified for the Schemes in the Schedule.

(7) Before granting a Licence, the Bureau may -

(a) require evidence to be produced by the applicant that the article or goods in respect of which a Licence has been applied for conform to the relevant Indian Standard or specified requirements;

(b) make such inspections and/or take such samples of any article or goods or any material or substance used in relation to any article or goods from the applicant as may be necessary to ascertain whether the articles or goods conform to the relevant Indian Standard or specified requirements and may test such samples in the factory and/or may direct the applicant to submit such samples for testing to such laboratory as the Bureau may consider appropriate and bear such expenses as specified by the Bureau;

(c) require all reasonable facilities to be provided to the Certification Officer or any other authorized representative of the Bureau in case of inspection of the manufacturing premises, office, workshop, testing laboratory, godown or any other premises relating to manufacturing and testing activities or for drawal of samples and testing.

(d) require the applicant to carry out such alterations or additions on the basis of scrutiny of the documents under regulation 4(7)(a) or on the basis of inspection carried out under regulation 4(7)(b).

5. Fee

(1) Every application for grant of Licence shall be accompanied by application fee. The following fee or charges shall be payable before grant of Licence as prescribed by the Bureau from time to time:

- (a) processing fee, wherever applicable;
- (b) inspection charges, wherever required;
- (c) testing charges, wherever applicable;
- (d) Licence fee;
- (e) advance minimum marking fee, as applicable.

(2) The Licence holder shall pay to the Bureau a marking fee prescribed by the Bureau for every article or goods. The marking fee shall be at the rate corresponding to total annual production of the article or goods covered by the Standard Mark or a minimum marking fee, whichever is higher.

(3) The marking fee determined by the Bureau from time to time shall be in the form of a schedule showing the unit rate and minimum marking fee for each product.

6. Grant of Licence

(1) The Licence to use or apply the Standard Mark shall be granted -

(a) if the application is complete,

(b) on payment of such fee and charges as specified by the Bureau from time to time,

(c) if the Bureau is satisfied that the applicant having regard to requisite skill, equipment, systems, resources, previous performance and antecedents relevant to the issuance of the Licence has necessary infrastructure and competence for carrying out manufacturing and testing of articles or goods as per the relevant Indian Standard or specified requirements and having established the evidence of conformity of articles or goods to the relevant Indian Standard or specified requirements, is fit to use the Standard Mark on such articles or goods,

(d) on acceptance of marking fee and Scheme of Testing and Inspection, where applicable.

(2) The grant of Licence shall be subject to the terms and conditions as given in regulation 11.

(3) The Bureau shall grant the Licence to the applicant in the format as specified by the Bureau and shall be valid for a period as specified in the Licence.

(4) The particulars of all Licences granted shall be suitably maintained by the Bureau and hosted on its website.

7. Standard Mark

(1) The Standard Mark in relation to the Conformity Assessment Schemes shall be of such design and contain such particulars as may be specified by the Bureau.

8. Rejection of Application

(1) The Bureau may reject an application, if -

(a) the application is submitted before expiry of such cooling period, as applicable, in case of conviction under provisions of the Act as specified in regulation 16(1) or cancellation or non-renewal or surrender of Licence as specified in regulation 16(2) or regulation 16(3).

(b) the application is found to be incomplete or is without necessary documents or requisite fee or does not fulfill the requirements specified by the Bureau.

(c) hard copy of application along with necessary documents is not submitted to the Bureau, wherever required, within the stipulated time period.

(d) the documents and/or information and/or any documentary evidence sought by the Bureau is not satisfactorily furnished.

(e) the applicant does not have the necessary infrastructure and competence for carrying out manufacturing and testing of articles or goods as per the relevant Indian Standard or specified requirements.

(f) the applicant has not co-operated with or not provided such reasonable facilities to the Certification Officer or any other authorized representative of the Bureau to enable him to discharge the duties during inspection or visit as may be required by the Bureau.

(g) at any time during processing of application, any declaration given is found to be incorrect or any documents or Test Reports submitted are found to be false.

(h) at any time during processing of application, the applicant or Authorized Indian Representative is found to be indulging in any unethical practices or any other malpractices or violation of any provisions of the Act or the Rules or the Regulations framed thereunder for which he is liable to be prosecuted under the Act.

(i) at any time during processing of application, the applicant has relocated the manufacturing premises, without informing the Bureau or made significant modification(s) in manufacturing process, plant or machinery without the prior evaluation and approval of the Bureau.

(j) the applicant has not implemented the amendment to Indian Standard or revised Indian Standard upon issue of amendment or revision, within the stipulated time period as specified by the Bureau.

(k) the articles or goods is not conforming to the relevant Indian Standard or specified requirements.

(l) the applicant has not accepted the terms and conditions as given in regulation 11.

(m) the applicant has failed to comply with any instructions issued by the Bureau or for any other specific reason not covered under regulation 8(1)(a) to regulation 8(1)(l).

(3) Before rejecting any application, the Bureau shall give the applicant a written notice of not less than fourteen days, through email or any other suitable means of communication, informing its intention of rejection of application along with the grounds, with a provision for submitting his written explanation and for personal hearing, if sought, to the applicant or Authorized Indian Representative.

(4) In case of non-receipt of a written explanation within a period of fourteen days from the date of issue of the notice the Bureau may reject the application.

(5) If an explanation is submitted, the Bureau may take into consideration the explanation so submitted and give a personal hearing, if sought, to the applicant or Authorized Indian Representative before taking a decision in this regard.

(6) The decision of the Bureau for rejection of application as per regulation 8(4) or regulation 8(5) shall be communicated to the applicant through e-mail or any other suitable means of written communication along with the grounds thereof.

9. Surveillance

(1) The surveillance under the Conformity Assessment Schemes shall be as specified in Schedule-I of these Regulations, except in cases like investigation of complaints, inclusion of variety, non-availability of market samples and under such situations warranting verification, visit to the factory may be carried out even for the products covered under Scheme D and Scheme C.

(2) When a Certification Officer or any other authorized representative of the Bureau proposes to inspect the premises of a Licence holder, he may not give any notice to the Licence holder.

(3) The Bureau may make such inspections and/or take such samples of any article or goods or any material or substance used in relation to any article or goods from the Licence holder as may be necessary to ascertain whether the articles or goods to which a Standard Mark has been used or applied conform to the relevant Indian Standard or specified requirements and may test such samples in the factory and/or may direct the Licence holder to submit such samples for testing to such laboratory as the Bureau may consider appropriate under the relevant Scheme.

(4) The Bureau or its authorized representative or any person authorized by the Central Government may take such samples of any article or goods of the Licence holder from distribution points, point of entry, in transit or places where the articles or goods are sold or stored or exhibited for sale or from the consignee or from the open market to ascertain whether any article or goods to which the Standard Mark has been used or applied conforms to the relevant Indian Standard or specified requirements.

10. Drawal of Sample

(1) The following procedure shall apply in case of drawal of samples in respect of any article or goods-

(a) if the Certification Officer or any other authorized representative of the Bureau takes one or more samples of any article or goods or material or substance used in relation to such article or goods from the manufacturing premises or storage place of the manufacturer during an inspection, he shall do so in the presence of the applicant or the Licence holder or a responsible person belonging to the establishment of the applicant or the Licence holder and jointly seal and label each sample under their signature. Wherever it is not possible to seal such samples, the Certification Officer or the authorized representative of the Bureau and the applicant or the Licence holder or a responsible person belonging to the establishment of the authorized representative of the Bureau and the applicant or the Licence holder or a responsible person belonging to the establishment of the authorized representative of the Bureau and the applicant or the Licence holder or a responsible person belonging to the establishment of the applicant or the authorized representative of the Bureau and the applicant or the Licence holder or a responsible person belonging to the establishment of the applicant or the authorized representative of the Bureau and the applicant or the Licence holder or a responsible person belonging to the establishment of the applicant or the Licence holder shall jointly put their signature in an appropriate manner as a token of authentication of the sample so drawn.

(b) in all such cases, in addition to the samples drawn, another sample from the same batch or lot may also be drawn as counter sample, sealed, labeled and jointly signed in a manner as given in regulation 10(1)(a) and left with him for safe custody. In the eventuality of any loss or damage to the sample or under any circumstances to the satisfaction of the Bureau, the Certification Officer can direct the applicant or the Licence holder to send the counter sample for testing in the specified laboratory.

(2) The sample drawn from distribution points, point of entry, in transit or places where the articles or goods are sold or stored or exhibited for sale or from the consignee or from the open market shall be treated as market samples and shall be drawn by the Bureau or its authorized representative. The sample so drawn shall be sealed by the Certification Officer under his signature. Wherever it is not possible to seal such samples, the Certification Officer shall put his signature in an appropriate manner as a token of authentication of the sample so drawn.

(3) The samples drawn under regulation 10 (1) or regulation 10(2) shall be sent for testing to the laboratory as the Bureau may consider appropriate along with a test request as prescribed by the Bureau indicating that the sample shall be tested with respect to the relevant Indian Standard or specified requirements.

11. Terms and Conditions

(1) The Licence shall be valid for a period as specified by the Bureau and as mentioned in the Licence.

(2) No Licence holder shall use or apply the Standard Mark on any article or goods unless the article or goods in respect of which the Licence has been granted conforms to the relevant Indian Standard or specified requirements.

(3) The Standard Mark shall be used or applied to only such types, grades, classes, varieties, and sizes of the articles or goods in respect of which Licence has been granted.

(4) The Standard Mark shall be used or applied in such a manner that it may be easily visible as a distinct mark on the articles or goods. Wherever it is not possible to do so, it shall be applied on the covering or packaging or test certificates relating to such articles or goods which cannot be labelled or covered or packed.

(5) No person, without having a valid Licence from the Bureau, shall make a public claim, through advertisements, sales promotion leaflets, price lists or the like, that his articles or goods conform to an Indian Standard or specified requirements or make such a declaration on the articles or goods.

(6) The Licence holder shall -

(a) at all times, be responsible for conformance of articles or goods in respect of which Licence has been granted and which carries the Standard Mark.

(b) institute and maintain, to the satisfaction of the Bureau, a system of control so as to ensure that the articles or goods in respect of which Licence has been granted and carrying the Standard Mark conform to the relevant Indian Standard or specified requirements.

(c) implement the Scheme of Testing and Inspection as indicated in the Licence and maintain complete record of tests and inspection and such other data as specified in the Scheme of Testing and Inspection so as to establish, to the satisfaction of the Bureau, that the required control of production process is being satisfactorily maintained. Such records shall, on demand, be made available to the Certification Officer or any other authorized representative of the Bureau.

(d) co-operate with and provide such reasonable facilities to the Certification Officer or any other authorized representative of the Bureau to enable him to discharge the duties during any visit as may be required by the Bureau from time to time.

(e) inform the Bureau of any changes in management of the firm, Authorized Indian Representative, manufacturing location, manufacturing machinery, manufacturing process, test equipment or breakdown of any major test equipment or conditions which were declared by him.

(f) ensure that the articles or goods carrying the Standard Mark fulfill any other marking and labeling requirements as specified by the Bureau including marking of date/month and year of manufacturing.

(g) implement the amendment to Indian Standard or revised Indian Standard upon issue of amendment or revision, within the stipulated time period as specified by the Bureau.

(h) supply to the Bureau such information and samples of any article or goods or any material or substance used in relation to any article or goods as may be necessary to ascertain whether the articles or goods to which Standard Mark has been used or applied conform to the relevant Indian Standard or specified requirements.

(i) supply to the Bureau the consignee details on a regular basis and also whenever required by the Bureau.

(j) pay all such fee, charges and dues as may be specified by the Bureau within the time specified in that regard.

(k) not use or apply the Standard Mark in case the operation in the premises cannot be carried out due to natural calamities such as flood, earthquake or the like or lockout declared by the management or closure of operations as directed by competent court or statutory authority or relocation of manufacturing premises and shall intimate the Bureau of such eventualities and such operation shall be resumed only after taking prior approval of the Bureau.

(1) comply with any directions issued by the Bureau from time to time including directions for recall of non-conforming articles or goods.

(7) Wherever Authorized Indian Representative has been nominated, he shall fulfill all responsibilities under the Scheme, meet all outstanding financial dues to the Bureau that may arise at any stage before or during operation of Licence and meet all liabilities and obligations on behalf of the manufacturer, with respect to violation of any provisions of the Act or the Rules or the Regulations framed thereunder.

(8) The Licence holder or his Authorized Indian Representative shall not engage in any activity which shall be in conflict with independent testing of samples.

(9)The Bureau may, during the period of validity of the Licence, amend by giving one month's notice to the Licence holder the terms and conditions of the Licence.

(10) Any violation of the terms and conditions of the Licence may lead to cancellation of the Licence.

12. Extension or Reduction in Scope of Licence

(1) A Licence holder may apply for extending or reducing the scope of the Licence to include or exclude types, grades, classes, varieties and sizes of the article or goods and may submit such details as sought by the Bureau.

(2) The fee for such an extension or reduction of scope shall be as decided by the Bureau.

13. Renewal of Licence

(1) The Licence holder shall apply for renewal, at least thirty days before expiry of the validity of Licence, in prescribed form along with required details and fee as specified by the Bureau from time to time. The hard copy of renewal application along with required details may also be submitted to the Bureau, wherever required, within the stipulated period.

(2) In case the Licence holder does not apply for renewal before expiry of the period of validity or deposit requisite fee or provide required details, renewal of Licence may be deferred for a period of thirty days from the date of validity after which the Licence may expire. If, during the period of deferment of Licence, an application is made seeking time for depositing requisite fee or providing required details, the same may be considered by the Bureau and a time not exceeding ninety days from the date of validity of the Licence may be allowed. In case renewal application along with requisite fee and details is not received within such period of deferment, the Licence shall stand expired.

(3) In case renewal application along with requisite fee and required details is received before expiry of the period of validity or within the period of deferment, the Licence may be renewed for a period as specified by the Bureau except when any complaint is being investigated or Licence is under suspension or considered for suspension, non-renewal or cancellation, till such time a decision is taken by the Bureau.

(4) The decision taken by the Bureau under regulation 13(2) or regulation 13(3) shall be communicated to the Licence holder through e-mail or any other suitable means of written communication along with reasons thereof. In all such cases where renewal of Licence is deferred, the Licence holder shall suspend operation of Licence and stop using or applying the Standard Mark till such time a decision is taken to renew the Licence.

(5) When renewal of any Licence has been deferred or Licence renewed or expired, the Bureau shall host the status of such Licences on its website.

14. Suspension of Licence

(1) If, at any time, the Bureau has sufficient evidence that the articles or goods for which the Licence has been granted may not be conforming to the relevant Indian Standard or specified requirements, the Bureau may suspend the Licence and direct the Licence holder to stop using or

applying the Standard Mark. Such evidence is not limited to, but may include one or more of the following –

(a) using or applying Standard Mark on non-conforming articles or goods,

(b) non-implementation of the provision(s) of Scheme of Testing and Inspection,

(c) relocation of manufacturing premises, without prior intimation to the Bureau,

(d) significant modification(s) in manufacturing process, plant or machinery without the prior evaluation and approval of the Bureau,

(2) The Bureau may suspend the Licence and direct the Licence holder to stop using or applying the Standard Mark if the Licence holder -

(a) has made false declaration in relation to the Licence or indulged in falsification of records or unethical practices,

(b) has failed to co-operate with the Bureau or its authorized representative or any person authorized by the Central Government for any such visits as may be required during the operation of Licence,

(c) has violated any terms and conditions of the Licence,

(d) has not paid the requisite fee, testing charges or any dues as may be specified by the Bureau.

(3) The decision taken by the Bureau under regulation 14(1) or regulation 14(2) shall be communicated to the Licence holder through e-mail or any other suitable means of written communication along with reasons thereof except under regulation 14(2)(d) where a written notice of not less than fourteen days shall be given to the Licence holder before suspension of Licence.

(4) The Licence holder whose Licence has been placed under suspension shall take corrective actions and inform the Bureau. On receipt of information on action(s) taken, an inspection, if required, may be carried out by the Bureau to verify such action(s).

(5) The Bureau may revoke the suspension after satisfying itself that the Licence holder -

(a) has taken corrective actions with sufficient evidence to the Bureau to establish conformity of the articles or goods to the relevant Indian Standard or specified requirements,

(b) in case of suspension under regulation 14(2)(d), has deposited the requisite fee, testing charges or the dues.

(6) When any Licence has been suspended, the Bureau shall host the status of such Licences on its website.

15. Cancellation or non-renewal of Licence

(1) The Bureau may cancel or not renew a Licence, if the Licence holder –

(a) has used or applied the Standard Mark and/or offered for sale or sold articles or goods with the Standard Mark during the period of suspension,

(b) has made false declaration in relation to the Licence or indulged in falsification of records or unethical practices,

(c) fails to control repeated non-conformance to the relevant Indian Standard or specified requirements,

(d) fails to submit acceptance of marking fee and Scheme of Testing and Inspection on their revision,

(e) has relocated the manufacturing premises, and has resumed operations at the new premises without the evaluation and approval of the Bureau.

(f) has violated any terms and conditions of the Licence.

(2) Before cancellation or non-renewal of any Licence, the Bureau shall give the Licence holder a written notice of not less than fourteen days, through email or any other suitable means of communication, informing its intention of cancellation or non-renewal of Licence along with the grounds, with provision for submitting his written explanation and for personal hearing, if sought, to the Licence holder or Authorized Indian Representative. If the Licence is not already under suspension, the notice shall also contain instructions to Licence holder directing him to stop the operation of Licence and stop using or applying the Standard Mark or offering for sale articles or goods bearing the Standard Mark.

(3) In case of non-receipt of a written explanation within a period of fourteen days from the date of issue of the notice the Bureau may cancel or not renew the Licence.

(4) If an explanation is submitted, the Bureau may take into consideration the explanation so submitted and give a personal hearing, if sought, to the Licence holder or Authorized Indian Representative before taking a decision in this regard.

(5) The decision taken by the Bureau for cancellation or non-renewal of Licence under regulation 15(3) or regulation 15(4) shall be communicated to the Licence holder through e-mail or any other suitable means of written communication along with the grounds thereof and specifying the cooling off period, if applicable.

(6) When an Indian Standard is withdrawn and not superseded by any other Indian Standard, any Licence granted in respect thereof shall be deemed to have been cancelled from the date of withdrawal of such Indian Standard and any such Licence shall be surrendered to the Bureau by the Licence holder forthwith. For such cancelled Licences, part of the marking fee paid in advance, proportionate to the unutilized period of the Licence, may be refunded if applicable.

(7) When any Licence has been cancelled or not renewed or surrendered, the Bureau shall host the status of such Licences on its website.

16. COOLING OFF PERIOD

(1) A person who has been convicted under the provisions of the Act shall not be eligible to apply for Licence again before expiry of a cooling off period of minimum six months from the date of such conviction. The period of disqualification shall be determined by the Bureau having regard to the facts and circumstances of each case and the cooling off period shall not exceed a period of one year.

(2) In case of cancellation or non-renewal of Licence for reasons under regulation 15(1)(a) or regulation 15(1)(b) or surrender of Licence in apprehension of cancellation or non-renewal due to such reasons a person cannot apply again for grant of Licence before expiry of a cooling off period of one year from the date of passing of such order.

(3) In case of cancellation or non-renewal of Licence for other reasons, a person cannot apply again for grant of Licence before expiry of a cooling off period not exceeding three months from the date of passing of such order. The period of disqualification shall be determined by the Bureau having regard to the grounds on which the Licence has been cancelled or not renewed.

<u>Part II</u>

CERTIFICATE OF CONFORMITY

17. General

(1) For grant of Certificate of Conformity by the Bureau for a process or consignment of articles or goods under the Conformity Assessment Scheme specified in Schedule-II of these Regulations, application shall be made to the Bureau, if the process or the consignment of articles or goods conform to the relevant Standard or specified requirements. The manner, fee, terms and conditions for grant of such Certificates of Conformity are as specified in these Regulations.

18. Application

(1) Any person, for the purpose of obtaining Certificate of Conformity, shall initially register with the Bureau in a manner as specified and obtain a unique Registration number.

(2) Any person having a valid Registration number from the Bureau may apply for grant of Certificate of Conformity for a process or a consignment of article or goods conforming to the relevant Standard or specified requirements. Every such applicant shall make a separate application, for each process or consignment of article or goods, in the prescribed form along with necessary documents and fee as specified by the Bureau from time to time. The application form shall be signed or e-validated by the management or any person duly authorized by the management. The hard copy of application along with necessary documents may also be submitted to the Bureau, wherever required, within the stipulated time period.

(3) The Bureau may call for any supplementary information and/or any documentary evidence from the applicant in support of or to substantiate any statement made in the application, within such time as may be directed by the Bureau and non-compliance with such direction may result in of the application being summarily rejected by the Bureau.

(4) The applicant shall also be responsible for ensuring the conformity of the process or the consignment of article or goods to the relevant Standard or specified requirements and the authenticity of all information provided by him.

(5) Before granting a Certificate of Conformity, the Bureau may –

(a) require evidence to be produced by the applicant that the process or the consignment of articles or goods in respect of which a Certificate of Conformity has been applied for conform to the relevant Standard or specified requirements;

(b) make such inspections of any process or take samples from any consignment of articles or goods or any material or substance used in relation to the consignment of article or goods from the applicant as may be necessary to ascertain whether the process or the consignment of articles or goods conform to the relevant Standard or specified requirements and may direct the applicant to submit such samples for testing to such laboratory as the Bureau may consider appropriate and bear such expenses as specified by the Bureau;

(c) require all reasonable facilities to be provided to the Bureau or its authorized representative in case of inspection of the process or drawal of sample and testing.

19. Fee

(1) Every application for Certificate of Conformity shall be accompanied by application fee. The following fee or charges shall be payable before grant of Certificate of Conformity as prescribed by the Bureau from time to time:

- (a) processing fee;
- (b) inspection charges;
- (c) testing charges, wherever applicable;
- (d) overhead expenses;
- (e) certification fee at the time of grant of certificate.

20. Drawal of Sample

(1) The following procedure shall apply in case of drawal of samples in respect of any article or goods -

(a) if the Certification Officer or any other authorized representative of the Bureau takes one or more samples of any article or goods or material or substance used in relation to such article or

goods during an inspection, he shall do so in the presence of the applicant or a responsible person belonging to the establishment of the applicant and jointly seal and label each sample under their signature. Wherever it is not possible to seal such samples, the Certification Officer or the authorized representative of the Bureau and the applicant or a responsible person belonging to the establishment of the applicant shall jointly put their signature in an appropriate manner as a token of authentication of the sample so drawn.

(b) in all such cases, in addition to the sample drawn, another sample from the same consignment may also be drawn as counter sample, sealed, labeled and jointly signed in a manner as given in regulation 20(1)(a) and left with him for safe custody. In the eventuality of any loss or damage to the sample or under any circumstances to the satisfaction of the Bureau, the Certification Officer can direct the applicant or the Licence holder to send the counter sample for testing in the specified laboratory.

(2) The samples drawn under regulation 20(1) or regulation 20(2) shall be sent for testing to the laboratory as the Bureau may consider appropriate along with a test request as prescribed by the Bureau indicating that the sample shall be tested with respect to the relevant Standard or specified requirements.

21. Grant of Certificate of Conformity

(1) The Certificate of Conformity shall be granted in the format as specified by the Bureau -

(a) if the application is found to be complete,

(b) on payment of such fee and charges as specified by the Bureau from time to time,

(c) if the Bureau is satisfied that process or the consignment of articles or goods conforms to the relevant Standard or specified requirements.

(2) The Grant of Certificate of Conformity shall be subject to terms and conditions as given in regulation 23.

(3) The particulars of all Certificates of Conformity granted shall be suitably maintained by the Bureau and will be hosted on its website.

22. Rejection of Application

(1) The Bureau may reject an application, if -

(a) the application is found to be incomplete or is without necessary documents or requisite fee or does not fulfill the requirements specified by the Bureau.

(b) hard copy of application along with necessary documents is not submitted to the Bureau, wherever required, within the stipulated time period.

(c) the documents and/or information and/or any documentary evidence sought by the Bureau is not satisfactorily furnished.

(d) at any time during processing of application, any declaration given is found to be incorrect or any documents or Test Reports submitted are found to be false.

(e) at any time during processing of application, the applicant is found to be indulging in any unethical practices or any other malpractices or violation of any provisions of the Act or the Rules or the Regulations framed thereunder for which he is liable to be prosecuted under the Act.

(f) the application is submitted before expiry of such cooling period under regulation 16, or in case of conviction under provisions of the Act or cancellation of registration under regulation 24(6).

(g) the applicant has not accepted the terms and conditions as given in regulation 23.

(h) the applicant has not co-operated with or not provided such reasonable facilities to the Certification Officer or any authorized representative of the Bureau to enable him to discharge the duties during any visit as may be required by the Bureau.

(i) the process or the consignment of articles or goods is not conforming to the relevant Standard or specified requirements.

(j) the applicant has failed to comply with any instructions issued by the Bureau or for any other specific reason not covered under regulation 22(1)(a) to regulation 22(1)(i).

(3)Before rejecting any application, the Bureau shall give the applicant a written notice of not less than fourteen days, through email or any other suitable means of communication, informing its intention of rejection of application, along with the grounds, with a provision for submitting his written explanation and for personal hearing, if sought, to the applicant.

(4) In case of non-receipt of a written explanation within a period of fourteen days from the date of issue of the notice the Bureau may reject the application.

(5) If an explanation is submitted, the Bureau may take into consideration the explanation so submitted and give a personal hearing, if sought, to the applicant, before taking a decision in this regard.

(6) The decision of the Bureau for rejection of application as per regulation 22(4) or regulation 22(5) shall be communicated to the applicant through e-mail or any other suitable means of written communication along with the grounds thereof.

23. Terms and Conditions

(1) The Certificate of Conformity shall be valid only for the process or the consignment of articles or goods which are mentioned in the Certificate and shall not be used for any other process or consignment of articles or goods. The Certificate of Conformity shall be valid for a period as specified by the Bureau in the Certificate.

(2) The holder of Certificate of Conformity shall -

(a) at all times, be remain responsible for conformance of the process or consignment of article or goods in respect of which Certificate of Conformity has been granted.

(b) not make false declaration or indulge in falsification of records or unethical practices.

(3) The Bureau may impose any other terms and conditions depending upon the process or article or goods before grant of Certificate of Conformity.

(4) The registration shall lapse in case of inactivity for three consecutive years.

(5) Any violation of the terms and conditions may lead to cancellation of registration.

24. Cancellation of registration

(1) Before cancellation of registration, the Bureau shall give the person a written notice of not less than fourteen days, through email or any other suitable means of communication, informing its intention of cancellation of registration, along with the grounds, with provision for submitting his written explanation and for personal hearing, if sought, to the person.

(2) In case of non-receipt of a written explanation within a period of fourteen days from the date of issue of the notice, the Bureau may cancel the registration.

(3) If an explanation is submitted, the Bureau may take into consideration the explanation so submitted and give a personal hearing, if sought, to the person before taking a decision in this regard.

(4) The decision taken by the Bureau for cancellation of registration under regulation 24(2) or regulation 24(3) shall be communicated to the person through e-mail or any other suitable means of written communication along with grounds thereof and specifying the cooling off period, if applicable.

(5) When any registration has been cancelled, the Bureau shall host the status of such registrations on its website.

(6) A person who has been convicted under the provisions of the Act or whose registration has been cancelled shall not be eligible to apply for registration again before expiry of a cooling off period of minimum six months from the date of such conviction or cancellation of registration. The period of disqualification shall be determined by the Bureau having regard to the facts and circumstances of each case and the cooling period shall not exceed a period of one year.

<u>Part III</u>

GRANT, OPERATION, RECERTIFICATION, SUSPENSION, AND CANCELLATION OF LICENCE FOR MANAGEMENT SYSTEMS

25. General

(1) For grant of Licence to use a Standard Mark for any Management System notified under the Management Systems Certification Scheme specified in Schedule-III of these Regulations, application shall be made to the Bureau if the system conforms to the relevant Indian Standard. The manner, fee, terms and conditions for grant, operation, recertification, suspension and cancellation of such Licences are as specified in these Regulations.

26. Application

- (1) Any person engaged in manufacturing or processing of articles or goods or involved in sales thereof or providing services can apply for Management System certification Licence against relevant standard(s). Every such applicant shall make separate application for different Management Systems.
- (2) Every application for the grant of Licence for Management Systems certification shall be made to the Bureau in the prescribed form(s) along with necessary documents and fee as specified by the Bureau from time to time. The applicant shall be responsible for the conformity of the Management System to the relevant Indian Standard for which the Licence is applied for.
- (3) The application form(s) shall be signed or e-validated by Management or any person duly authorized by the Management.
- (4) The Bureau may call for required documents and/or any supplementary information and/or any documentary evidence from the applicant in support of or to substantiate any statement made in the application, within such time as may be directed by the Bureau and non-compliance with such direction may result in the application being summarily rejected by the Bureau. If the documents and/or information and/or evidence furnished by the applicant are found to be satisfactory, the application may be processed for grant of Licence.
- (5) The applicant shall, within reasonable time, arrange for certification audit(s) of the premises as specified for the scheme in the Schedule-III.
- (6) Before granting a Licence, the Bureau may
 - (a) require evidence to be produced by the applicant that the management system in respect of which a Licence has been applied for conforms to the relevant Indian Standard;

- (b) make such audits as may be necessary to ascertain whether the management system conforms to the relevant Indian Standard and require the applicant to bear such expenses as specified by the Bureau;
- (c) require all reasonable facilities to be provided to the auditor;
- (d) require the applicant to carry out such alterations or additions on the basis of scrutiny of documents under Regulation 26(6)(a) or on the basis of audit carried out under Regulation 26(6)(b)

27. Fee

- (1) Every application for grant of Licence shall be accompanied by application fee. The following fee or charges shall be payable before grant of Licence as prescribed by the Bureau from time to time:
 - (a) Assessment charges
 - (b) Licence fee

28. Grant of Licence

- (1) The Licence to use the Standard Mark shall be granted:
 - (a) if the application is found to be complete;
 - (b) on payment of such charges as specified by the Bureau from time to time; and
 - (c) if the Bureau is satisfied that the applicant has implemented the Management System requirements as per the relevant Indian Standard and having established the evidence of conformity through certification audit(s) as per the relevant Indian Standard.
- (2) The grant of Licence shall be subject to terms and conditions as given in Regulation 32.
- (3) The Bureau shall grant Licence to the applicant in the format as specified by the Bureau and shall be valid for a period as specified in the Licence.
- (4) The particulars of all Licences granted shall be suitably maintained by the Bureau.

29. Standard Mark

(1) The Standard Mark in relation to this Conformity Assessment scheme shall be of such design and contain such particulars as may be specified by the Bureau and shall be used in a manner specified by the Bureau.

30. Rejection of application

- (1) The Bureau may reject an application, if
 - (a) the application is submitted before expiry of such cooling off period, as applicable, in case of conviction under provisions of the Act as specified in Regulation 16(1) or cancellation or non-renewal of Licence as specified in Regulation 16(2) and Regulation 16(3) of Part I of these Regulations;
 - (b) the application is found to be incomplete or is without necessary documents or requisite fee or does not fulfill the requirements specified by the Bureau;
 - (c) the documents and/or information and/or any documentary evidence sought by the Bureau is not furnished to the satisfaction of the Bureau;
 - (d) the applicant has not co-operated with or not provided such reasonable facilities to the auditor(s) to enable him/them to discharge the duties during audit as may be required by the Bureau;
 - (e) at any time during processing of application, any declaration given is found to be incorrect or any documents submitted are found to be false;
 - (f) at any time during processing of application, the applicant is found to be indulging in any unethical practices or any other malpractices or violation of any provisions of the Act or the Rules or the Regulations framed thereunder for which he is liable to be prosecuted under the Act;
 - (g) the applicant has not accepted the terms and conditions as given in Regulation 32;
 - (h) the applicant has failed to comply with any instructions issued by the Bureau or for any specific reasons not covered under Regulation 30(1)(a) to 30(1)(g)
- (2) Before rejecting any application, the Bureau shall give the applicant a written notice of not less than fourteen days through e-mail or any other suitable means of communication, informing its intention of rejection of application along with the grounds, with a provision for submitting his written explanation and for personal hearing, if sought, to the applicant.
- (3) In case of non-receipt of a written explanation within a period of fourteen days from the date of issue of the notice the Bureau may reject the application.
- (4) If an explanation is submitted, the Bureau may take into consideration the explanation so submitted and give a personnel hearing, if sought, to the applicant before taking a decision in this regard.
- (5) The decision of the Bureau for rejection of application as per Regulation 30(3) and Regulation 30(4) shall be communicated to the applicant through e-mail or any other suitable means of written communication along with the reasons thereof.

31. Surveillance

(1) The surveillance under this Conformity Assessment scheme is specified in the Schedule-III of these Regulations and assessment charges for such surveillance audits shall be paid in advance by the Licence holder.

32. Terms and Conditions

- (1) The Licence shall be valid for a period as specified by the Bureau and as mentioned in the Licence.
- (2) The Licence holder shall
 - (a) at all times, remain responsible for conformance of the system in respect of which Licence has been granted.
 - (b) not use the Licence in any manner which in the opinion of the Bureau may be misleading or use or apply the Standard Mark in any manner not permitted by the Bureau;
 - (c) upon expiry of its period of validity, suspension or cancellation of the Licence, discontinue its use forthwith and withdraw all promotional and advertising material which contains any reference thereto;
 - (d) return the Licence document to the Bureau in the event of Licence being surrendered, suspended or cancelled;
 - (e) inform the Bureau of any changes in management or address of the firm or conditions which were declared by him;
 - (f) implement the provisions of amendment to Indian Standard or revised Indian Standard upon issue of amendment or revision within the stipulated time as specified by the Bureau;
 - (g) facilitate and cooperate with the team appointed by the Bureau for the purpose of audit;
 - (h) inform the Bureau in writing of discontinuance of operations exceeding three months;
 - (i) pay all such fee, charges and dues as may be specified by the Bureau within the time as specified in this regard.
 - (j) comply with any directions issued by the Bureau from time to time.
- (3) The Bureau may, during the period of validity of the Licence, amend by giving one month's notice to the Licence holder the terms and conditions of the Licence.

(4) Any violation of terms and conditions of the Licence may lead to cancellation of Licence.

33. Extension or Reduction in Scope of Licence.

- (1) A Licence holder may apply for extending or reducing the scope of the Licence and may submit such details as sought by the Bureau.
- (2) The fee for such an extension or reducing of scope shall be as decided by the Bureau.

34. Recertification

- (1) The Licence holder shall submit an application for recertification in the prescribed form(s) to facilitate completion of recertification within the time frame as specified by the Bureau.
- (2) The following fee or charges shall be payable before grant of recertification as prescribed by the Bureau from time to time
 - (a) Assessment charges;
 - (b) Licence Fee.
- (3) The recertification of the Licence to use the Standard Mark shall be granted:
 - (a) if the recertification application is found to be complete;
 - (b) on payment of such charges as specified by the Bureau from time to time; and
 - (c) if the Bureau is satisfied that the applicant has implemented the Management System requirements as per the relevant Indian Standard and having established the evidence of conformity through recertification audit(s) as per the relevant Indian Standard.
- (4) The provisions under Regulation 28(2) to Regulation 28(4) shall be applicable for recertification of Licence.

35. Suspension of Licence

- (1) If, at any time, the Bureau has sufficient evidence that the Management System for which the Licence has been granted may not be conforming to the relevant Indian Standard, the Bureau may suspend the Licence and direct the Licence holder to stop using the Standard Mark. Such evidence is not limited to, but may include one or more of the following –
 - (a) using or applying Standard Mark in a manner not permitted by the Bureau;
 - (b) discontinuance of operation for more than three months;

- (c) corrective actions are not taken within the time frame specified by the Bureau;
- (d) Relocation of premises, without prior intimation to the Bureau.
- (2) The Bureau may suspend the Licence and direct the Licence holder to stop using or applying the Standard mark if the Licence holder -
 - (a) has made false declaration in relation to the Licence or indulged in falsification of records or unethical practices;
 - (b) failed to cooperate with the Bureau or its authorized representative for any such audits as may be required during the operation of the Licence;
 - (c) has violated any terms and conditions of the Licence
 - (d) has not paid any requisite fee, charges or dues as may be specified by the Bureau
- (3) The decision taken by the Bureau under Regulation 35(1) and 35(2) shall be communicated to the Licence holder through e-mail or any other suitable means of written communication along with reasons thereof, except under Regulation 35(2)(d) where a notice of not less than fourteen days shall be given before suspension of Licence.
- (4) The Licence holder whose Licence has been placed under suspension shall take corrective actions and inform the Bureau. On receipt of information on action(s) taken, a special audit, if required, may be carried out by the Bureau to verify such action(s).
- (5) The Bureau may revoke the suspension after satisfying itself that
 - (a) the Licence holder has taken corrective actions with sufficient evidence to the Bureau to establish conformity of the Management System to the relevant Indian Standard;
 - (b) in case of suspension under Regulation 35(2)(d), the Licence holder has deposited the requisite fee, charges or the dues.

36. Cancellation or refusal for recertification of Licence

- (1) The Bureau may cancel or refuse recertification of a Licence, if the Licence holder -
 - (a) has indulged in misuse of Standard Mark;
 - (b) has made false declaration in relation to the Licence or indulged in falsification of records or unethical practices;
 - (c) suspension exceeds more than six months
 - (d) has relocated the premises and has resumed operation of the Licence at the new premises without approval of the Bureau;

- (e) has violated any terms or conditions of Licence.
- (2) Before cancellation or refusal of recertification of Licence, the Bureau shall give the Licence holder a written notice of not less than fourteen days through email or any other suitable means of communication, informing its intention of cancellation or refusal of recertification of Licence, along with the grounds, with provision for submitting his written explanation and for personal hearing to the Licence holder, if sought. If the Licence is not already under suspension, the notice shall also contain instructions to Licence holder directing him to stop operation of the Licence and stop using the Standard Mark.
- (3) In case of non-receipt of a written explanation within a period of fourteen days from the date of issue of the notice, the Bureau may cancel or refuse to recertify the Licence.
- (4) If an explanation is submitted, the Bureau may take into consideration the explanation so submitted and give a personal hearing, if sought, to the Licence holder or his authorized representative before taking a decision in this regard.
- (5) The decision taken by the Bureau for cancellation or refusal of reaccreditation under Regulation 36(3) or Regulation 36(4) shall be communicated to the Licence holder through e-mail or any other suitable means of written communication along with the grounds.
- (6) When an Indian Standard is withdrawn and not superseded by any other Indian standard, any Licence granted in respect thereof shall be deemed to have been cancelled from the date of withdrawal of such Indian Standard and any such Licence shall be surrendered to the Bureau by the Licence holder forthwith. For such cancelled Licences, part of the Licence fee if paid in advance, proportionate to the unutilized period of the Licence, may be refunded if applicable.

	Conformity Assessment Schemes for Products					
	Scheme A	Scheme B	Scheme C	Scheme D	Scheme E	
MARK	Preliminary Factory Inspection	Preliminary Factory Inspection	Preliminary Factory Inspection	Preliminary Factory Inspection		
GRANT OF LICENCE TO USE STANDARD MARK	Initial Evidence of Conformity through Testing of Samples in Factory by the Bureau	Initial Evidence of Conformity through Testing of Samples in Factory by the Bureau and in Laboratory owned or as approved by the Bureau	Initial Evidence of Conformity through Testing of Samples in Factory by the Bureau and in Laboratory owned or as approved by the Bureau	Initial Evidence of Conformity through Test Report of Samples submitted by Applicant from Laboratory owned or as approved by the Bureau and Testing of Samples in Factory by the Bureau	Initial Evidence of Conformity through Self-Declaration and Test Report of Samples submitted by Applicant from Laboratory owned or as approved by the Bureau	
SURVEILLANCE	Periodic Factory Inspection	Periodic Factory Inspection	Factory surveillance as permitted under the regulations	Factory surveillance as permitted under the regulations		
	Testing of Samples in Factory	Testing of Samples from Factory				
		Testing of Market Samples		Testing of Market Samples	Testing of Market Samples	
			Certification of Lot			

SCHEDULE - II

	Conformity Assessment Scheme for Certificate of Conformity
IITY	Registration
F CONFORM	Inspection
GRANT OF CERTIFICATE OF CONFORMITY	Evidence of Conformity through Testing of Samples of articles or goods in Laboratory owned or as approved by the Bureau
GRANT O	Right to use Certificate of Conformity for a process or a consignment of article or goods
SURVEILLANCE	

SCHEDULE - III

	Conformity Assessment Scheme for Management Systems
GRANT OF LICENCE	Initial evidence of conformity through Certification Audit
SURVEILLANCE	Surveillance Audit
RECERTIFICATION	Recertification Audit

PART IV

GENERAL

37. (1) If the Licence Holder is prosecuted under Section 32 of the Act for any violation under Section 29(3) of the Act, the Licence shall be placed under suspension and/or not renewed, as the case may be.

(2) The Bureau shall cancel the Licence, if the Licence Holder is convicted under the provisions of the Act.

38. The Appeals against any decision of the Bureau shall be made under the provision of Section 34 of the BIS Act, 2016 and the Rules made thereunder.