

DOC : BIS/LRS/2018



भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

LABORATORY RECOGNITION SCHEME, 2018

1. Introduction

1.1 Bureau of Indian Standards (BIS), the National Standards Body of India, was established under The Bureau of Indian Standards Act, 1986 now revised to The Bureau of Indian Standards Act 2016. To protect the interest of consumers, BIS operates a variety of Conformity Assessment Schemes for manufacturers and service providers for a variety of goods and services. Under the Product Certification Scheme, the licensed manufacturers can use the Standard Mark, popularly known as the ISI mark, on their products which conform to the relevant Indian Standards. Under the Compulsory Registration Schemes, BIS registers the manufacturers for self-declaration of conformity whose products conform to the relevant Indian Standards as assessed through testing at BIS recognized laboratories. Both the Schemes require testing of products for quality evaluation against the respective Standards and therefore there is need for testing facilities. It is in this context that BIS has established a network of eight laboratories of its own in the country to cater to testing of samples generated from its Conformity Assessment Schemes.

1.2 BIS operates Laboratory Recognition Scheme which is governed by the provisions under Section 13 (4) of the BIS Act 2016 and Section 32 (2), (3) & (4) of the BIS Rules, 2018. These statutory provisions confer upon BIS, powers to recognize any laboratory in India or outside India for carrying out testing of samples in relation to conformity assessment and such other functions as the Bureau may assign to it. The Rules also provide for issuance of guidelines for suspension or withdrawal, revocation or renewal of recognized laboratories. BIS also maintains record of such laboratories as are recognized by it for testing of samples of articles or processes in relation to relevant Indian Standards. The delegation of powers for carrying out the activities for the operation of the scheme shall be as given in Annex A.

2. Objectives of Laboratory Recognition Scheme

It is neither physically possible nor economically viable for BIS laboratories to develop testing facilities for each and every product covered under various conformity assessment schemes of BIS. Accordingly, this Laboratory Recognition Scheme (LRS) has been formulated with the objective of having a sufficient number of outside laboratories in India and abroad, in addition to BIS labs to cater to the needs of various conformity assessment schemes of BIS.

3. Scope of BIS LRS

3.1 This Scheme lays down the criteria, terms and conditions of grant and operation of recognition, suspension or withdrawal of recognition, revocation or renewal of recognition, appeals, complaint handling mechanism, administrative instructions for testing & issuing test reports and charges relating to recognition of outside labs.

3.2 The Scheme covers recognition of laboratories in India and outside India.

3.3 The recognition in no way guarantees utilization of the recognized laboratories by BIS for testing of samples drawn under Conformity Assessment Schemes of BIS.

3.4 The schedule of Fees for Laboratory Recognition Scheme for Laboratories is given in Annex B of this scheme.

4. Grant of Recognition

Recognition is granted to such laboratories which meet the criteria for recognition and which are able to demonstrate availability of infrastructure, test facility and manpower required for testing of products covered or proposed to be covered under Conformity Assessment Schemes of BIS and payment of fees as prescribed by BIS.

4.1 Criteria for recognition – The laboratory desirous of seeking recognition under LRS shall meet the following criteria:

4.1.1 Accreditation - The laboratory shall be accredited to Laboratory Quality Management System as per IS/ISO/IEC 17025. The accreditation body, through which the laboratory is accredited, shall be a full member of International Laboratory Accreditation Co-operation (ILAC) and/or Asia Pacific Laboratory Accreditation Co-operation (APLAC) or any other regional cooperation body. All the test parameters as per the Indian Standard/s for which recognition is sought shall be covered under the scope of accreditation as per IS/ISO/IEC 17025, except for the test parameters for which no test method has been prescribed in the Indian Standard (ex visual examination, finish etc) due to which / or due to any other reasons it is not technically possible to obtain accreditation for the said parameter. BIS will take decision regarding exclusion of parameters from the scope of accreditation, if required.

Note: The standard IS/ISO/IEC 17025, wherever appears in this Scheme, would also mean ISO/IEC 17025 or the equivalent national standard of any other country.

4.1.2 Indian Standards for recognition – Recognition shall be considered only for Indian Standards which are covered/proposed to be covered under the conformity assessment schemes of BIS \ and/or related standards for all the requirements in a particular IS. However for an IS, exclusion with respect to certain tests may be permitted as per the following:

- i) Exclusions of scope for IS will only be provided in case test facilities are not available in any laboratory in the country for the particular test for which exclusions are being sought .The exclusion of tests will not be as per the choice of the individual laboratories but will be considered for the IS as a whole in case of genuine difficulty /non availability or limited availability of the test facility for a particular requirement/possibility of conformance of the requirement on the basis of other test reports or documentary evidence/ the test which are not routinely required, e.g. radioactive test in packaged drinking Water ,Pull out test in HSD / TMT bars, Short Circuit test in case of Transformers, Photometry test for LED Luminaries, EMI/ EMC test for safety of Electrical Appliances etc .
- ii) These exclusions/restriction in scope will be specifically considered and allowed by BIS on merit of the case.
- iii) In case the laboratory is seeking exclusion of certain tests in the ISs while applying for recognition/inclusion, the same has to be mentioned in application form for applying for recognition/inclusion under LRS. The application in such cases will be recorded only once decision regarding exclusion of tests has been taken by BIS.
- iv) Recognition may be considered only for specialized tests prescribed in Indian Standards for which exclusions have been permitted to other laboratories and for which there is limited test facility available in the country as per the decision of Bureau for the individual IS, if required.

Note : The list of tests mentioned in (i) above is for guidance purpose only and not exhaustive.

4.1.2.1 For the purpose of certificate of conformity to be issued under the various conformity assessment schemes of BIS, if the report is to be issued for particular requirements only, in such cases the recognition can be granted for such particular requirements only.

4.1.3 Sub contracting of tests shall not be allowed.

Note: Subcontracting may be agreed in case of breakdown of existing test equipments and only for the samples which are already under test. The lab to which subcontracting of tests is to be carried out shall also be BIS recognised for the IS or IS/ISO/IEC17025 accredited for the IS.

4.1.4 The laboratory shall be carrying out all testing related activities in the same premises. For the purpose of this Scheme the term ‘same premises’ would mean one or more of the following:

- i) Single address
- ii) Premises comprising of number of buildings within the same perimeter of the address all of which under authorized ownership/lease rights of the laboratory.
- iii) In case of laboratory operating from different areas (within the same premises) which have different identifications (such as different flat no., plot no., wing, floor, etc) then all such areas should be part of the document authenticating the address of the premises.

Exemptions may be permitted for specialized tests like test for Fire performance of Fire extinguishers, short circuit test in case of transformers, Photometry test for LED Luminaries, EMI/ EMC test for safety of Electrical Appliances etc for which laboratory may have arranged separate premises at a different location as per the merit of the case by BIS and subject to the test at separate premises being covered under the scope of accreditation as per IS/ISO/IEC 17025:2017 of the laboratory. In such case, the laboratory has to mention the same in application form itself for applying for recognition under LRS. The application in such cases will be recorded only after decision regarding allowing functioning from a separate premise at different location has been taken by BIS.

4.1.5 Impartiality

As per the requirements of IS/ISO/IEC 17025, the following has to be ensured by the lab for the purpose of impartiality:

“ 4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5. If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk”.

4.1.5.1 The laboratory shall ensure the impartiality of testing on a ongoing basis, and shall submit an undertaking as part of the application in the prescribed format as given below.

UNDERTAKING

We, M/s _____ (OSL Code - _____/Laboratory applying for recognition under BIS LRS 2018), located at _____

_____ ,
a BIS recognized laboratory under the Laboratory Recognition Scheme of the Bureau of Indian Standards / an applicant lab under the Laboratory Recognition Scheme of the Bureau of Indian Standards , do, hereby, undertake that:

- i) We shall not encourage “agent culture” (either through direct contract or collection representative) for obtaining business and shall deal professionally with the organizations submitting samples with our laboratory for independent testing under any conformity assessment scheme of the Bureau. We shall not indulge in payment of a sales commission or other inducement for the referral of new customers
- ii) Neither members of management of the laboratory nor any employee of the laboratory shall, in any way, act as authorized Indian representative for any foreign manufacturer under the Foreign Manufacturers’ Certification Scheme and / or Compulsory Registration Scheme/ any other Conformity assessment scheme of the Bureau; and
- iii) Family members of management of the laboratory or sister unit of laboratory are not acting as authorised Indian representative for any foreign manufacturer under the Foreign Manufacturer’s Certification Scheme and/or Compulsory Registration Scheme/ any other conformity assessment scheme of the Bureau; and if at any time in future family members of management of the laboratory or sister unit of laboratory poses any risk to impartiality as stated above, we shall inform BIS about the identified risks.
In such a situation, we undertake that we shall not test samples of these manufacturers in our laboratory to maintain impartiality as per requirement of terms and conditions of BIS recognition.

Or

Family members of management of the laboratory or sister units of the laboratory are acting as authorized Indian representative for any foreign manufacturer under the Foreign Manufacturers’ Certification Scheme and / or Compulsory Registration Scheme/ any other conformity assessment scheme of the Bureau. The details of the manufacturers are as below:

We undertake that we shall not test samples of these manufacturers in our laboratory to maintain impartiality as per requirements of terms and conditions of BIS recognition.

- iv) All of our relationships based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding) shall not present any threat to the impartiality of our laboratory.
- v) We hereby also declare that the above mentioned information is true to the best of our knowledge. We are also aware that any deviation to the above-mentioned declarations or any information submitted, if found incorrect by BIS at any stage, may lead to rejection of our application without any further reference and if found after grant of recognition, Withdrawal of recognition of the laboratory.

Date:

Name:

Place:

Designation:

Signature

Seal:

Note: *The undertaking shall be furnished, signed and sealed by Proprietor or Director or Partner of the BIS recognized laboratory /applicant laboratory on laboratory's official stationery (letter-head). For Government labs, the undertaking may be given by the local heads of the Lab.*

Family members as per above undertaking shall mean anyone who is related to another, if :

- (a) they are members of a Hindu Undivided Family;
- (b) they are husband and wife; or
- (c) if he or she is related to another in the following manner, namely:
- (i) Father including step-father. (ii) Mother including step-mother (iii) Son including the step-son (iv) Son's wife (v) Daughter (vi) Daughter's husband (vii) Brother including the step-brother (viii) Sister including the step-sister.

4.2 Submission of Application

4.2.1 Any laboratory fulfilling the criteria as laid down under clause **4.1** may apply for recognition in the prescribed application form (BIS/ LRS/ F-01) along with the requisite documents and fees.

4.2.2 The following documents, duly authenticated, shall be submitted along with the application form:

- a) Legal Identity of the laboratory – any one or more of the following documents
 - i) Certificate of Registration by Company Registrar and Memorandum of Articles in case laboratory is a Limited Company
 - ii) Partnership Deed in case laboratory is a Partnership entity
 - iii) Certificate from Chartered Accountant establishing the proprietorship or Affidavit on Non-Judicial Stamp Paper of Rs.100/- by Proprietor that he is the sole Proprietor, duly attested by Notary Public in case of laboratory being a proprietorship business entity
 - iv) Certificate of registration under shop and establishment act
 - v) Certificate of registration under Goods & Service Tax Act.
 - vi) For the purposes of legal identity, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.
 - vii) Documents authenticating legal identity of overseas laboratory: Any document from local authority/ Government, establishing legal identity of the laboratory as per law of the country

- b) Authenticating premises of the laboratory - any one or more of the following documents clearly indicating and covering all the areas where laboratory activities are carried out and which are proposed to be covered under recognition:
 - i) Certificates from Registrar of Firms or Directorate of Industries or Industries Centre
 - ii) Municipal Corporation/Local Body/Central Insecticides Board or Drug Controller/ Pollution Control Board or any such BIS indicating premises of the applicant laboratory
 - iii) Rent Agreement, duly notarised.
 - iv) Authentication of the premises of a governmental laboratory will be carried out on the basis of its governmental status.
 - v) Documents authenticating the premises of overseas laboratory: Any document from local authority/ Government, authenticating laboratory premises as per law of the country.

- c) Certificates of accreditation for IS/ISO/IEC 17025 and scope of accreditation covering all the test parameters as per the Indian Standard/s for which recognition is sought

- d) List of Indian Standards (clearly mentioning the latest versions & amendments) with product name for which recognition is sought (BIS/ LRS/ F-02). In case an Indian Standard is having no. of parts/sections than each of such part/section is to be separately listed out.

Note: In case the document(s) of address proof and legal identity is (are) in the local language, then their authenticated English Translation may preferably also be provided.

Note: The above list shall not include any Indian Standards or other international standards on methods of tests which may have been cross referred in the product standards.

- e) Organization chart of the laboratory, clearly indicating the names and designations of various functionaries engaged in laboratory activities.
- f) List of Technical & Managerial personnel of the laboratory with their name, designation, qualification, experience, training details, etc. on the prescribed proforma (BIS/ LRS/ F-03).
- g) Layout Plan of the Laboratory clearly indicating key facilities, sample receipt, remnant store etc. and including floor plans covering all areas under the address.
- h) Declaration regarding requirement-wise details of test facilities available for each of the Indian Standard for which recognition is sought shall be submitted on the prescribed proforma (BIS/ LRS/ F-04) separately for each Indian Standard. In case an Indian Standard provides for option of more than one test method for any requirement, then the laboratory shall declare the actual test method it follows with the facilities available for the same. In case an Indian Standard provides option to use 'any instrumental method' then the laboratory shall declare the test actual method it follows which should be as per any national or international standard method.
- i) Details of reference materials required and used for testing and calibration with details of traceability to national/international standards and validity.
- j) Declaration of IS-wise Testing Capacity per month for each of the standard with testing time on the prescribed proforma (BIS/ LRS/ F-02) and testing charges in the prescribed proforma (BIS/ LRS/ F-05).
- k) Copies of such documents of the laboratory which cover the requirements specific to this scheme which *inter alia* include, but not limited to the following:
 - i) Handling of Samples for BIS Conformity Schemes - covering aspects related to safe-handling of samples, access control, confidentiality, recoding, decoding, review of test request, testing of samples as per the test method prescribed in the relevant Indian Standard, methodology followed / proposed to be followed for addressing queries / disputes related to samples or test requests, if any.
 - ii) Handling of Remnants of Tested Samples - covering retention period of remnants, methodology for safe-keeping and return / disposal of samples, responsibility, etc.
 - iii) Maintaining Confidentiality - including access control to testing area.
 - iv) Handling of Complaints - including provision for retesting / witnessing of testing.
- l) Undertaking to abide by the Terms and Conditions of this scheme on continuous basis on the prescribed proforma, to be submitted on laboratory's letter head in the proforma (BIS/ LRS/ F-07)
- m) Undertaking with regards to maintenance of impartiality as per clause 4.1.5 of this scheme.
- n) Documents as referred in the application form but not covered above.
- o) Any other document considered relevant by the laboratory

4.3.1 The application, form duly filled-in, shall be signed by its owner/top management i.e. Proprietor, Partner, Director, Chief Executive Officer (CEO) or Head as the case may be or any other person so authorized for the purpose by the management. The name and designation of the person signing the application shall be recorded legibly in the space for the purpose in the application form. In case application is signed by authorized signatory, a certificate from the top management of the laboratory on its official letter head, bearing seal of the laboratory and clearly attesting the signature of the authorized signatory, shall also be required to be submitted with the application.

4.3.2 The application form along with the required documents and the covering check-list (BIS/LRS/F/06) shall be submitted to the BIS laboratory under the jurisdiction of which the laboratory is located as given below:

BIS Lab	Jurisdiction	Address of BIS Laboratory	Email Id
Bengaluru	Karnataka, Kerala and Lakshadweep	Bangalore Laboratory Bureau of Indian Standards Peenya Industrial Area, 1 st Stage, Bangalore -Tumkur Road, Bangalore-560 058, Karnataka	<u>bnbol@bis.gov.in</u>
Central	Delhi-NCR, Rajasthan and Madhya Pradesh	Central Laboratory Bureau of Indian Standards Plot No. 20/9, Site IV, Sahibabad Industrial Area, Sahibabad - 201 010, Uttar Pradesh	<u>cl@bis.gov.in</u>
Eastern	Arunachal Pradesh, Assam, Bihar, Jharkhand, Chhattisgarh, Manipur, Meghalaya, Mizoram, Nagaland, Odisha, Sikkim, Tripura and West Bengal	Eastern Regional Laboratory Bureau of Indian Standards P-230, C.I.T. Scheme VII M, Block-W, Kankurgachi, Kolkata – 700054, West Bengal	<u>erol@bis.gov.in</u>
Northern	Jammu & Kashmir, Punjab, Haryana, Himachal Pradesh, Chandigarh (UT), Uttarakhand and Uttar Pradesh	Northern Regional Laboratory Bureau of Indian Standards B-69, Phase VII, Industrial Focal Point, SAS Nagar, Mohali – 160051, Punjab	<u>nrol@bis.gov.in</u>
Southern	Tamil Nadu, Puducherry, Telangana, Andhra Pradesh and A & N Islands	Southern Regional Laboratory Bureau of Indian Standards C.I.T Campus, IV Cross Road, Chennai - 600 113, Tamil Nadu	<u>srol@bis.gov.in</u>
Western	Gujarat, Goa, Daman & Diu, Dadra & Nagar Haveli and Maharashtra	Western Regional Laboratory Bureau of Indian Standards Manakalaya, E-9, M.I.D.C., Behind Marol Telephone Exchange, Andheri (East), Mumbai - 400 093, Maharashtra	<u>wrrol@bis.gov.in</u>

4.4 Receipt of Application: Applications submitted by the laboratory shall be verified by BIS for its completeness. The verification will be done only w.r.t. availability of the documents. Depending upon the outcome of verification, the following actions could be taken:

a) Application found complete w.r.t. the requisite fees and required documents would be accepted for further processing.

- b) Application found incomplete w.r.t. the requisite fees and/or the required documents mentioned shall be returned to the laboratory, along with the original financial instrument through which the fees was paid, if any with the advice for re-submission of the application complete in all respect.
- c) In case the laboratory had submitted the fees through electronic means but the application is incomplete, then the application and the documents as received would be returned with the advice for re-submission of the application complete in respect of all documents. The application so submitted if found complete, would be accepted for further processing.
- d) In case the laboratory had submitted the fees through electronic means but the initial or the re-submitted application is incomplete and if the applicant laboratory desires to get the fees back then the fees would be returned by BIS excluding any tax component.

4.4.1 A laboratory will not be permitted to apply for recognition during the currency of the cooling-off period, imposed if any, at the time of Withdrawal of recognition of the laboratory's previous recognition and any such application, if received, shall be returned.

4.5 Recording of Application: Application found complete w.r.t. documents and submission of fees and accepted for further processing shall be processed further as per details given below:

- a) Application would be recorded and assigned unique serial no called the 'Application Number'. All future correspondence between the laboratory and BIS shall be made referring this application no.
- b) Evaluation of Documents – Details given in the application form and the attached documents would be assessed against the criteria for recognition and other provisions of Laboratory Recognitions Scheme as per Cl 4.2.2.
- c) Deficiencies observed during evaluation of documents would be conveyed to the laboratory for providing clarification/corrective action/re-submission of the document as required within 10 days.
- d) On receipt of the required clarification/corrective action/re-submitted document and found satisfactory on further evaluation, the application would be processed further.
- e) In case the laboratory does not provide the required clarification/corrective action/re-submitted document within the prescribed time limit, or if the details/documents provided are not found satisfactory to meet the criteria and other provisions of this scheme , then actions would be taken as per Clause 4.6.
- f) Once application is recorded, the application fee shall not be refunded or adjusted against any future application.

4.6 Rejection of Application - Application for recognition shall be liable for rejection for any or more of the following reasons:

If the laboratory

- a) does not pay any of the prescribed fees or charges.
- b) does not take corrective action(s) on deficiencies observed during evaluation of documents within 15 days.
- c) does not confirm readiness for initial audit within 15 days from the receipt of communication of the audit team from BIS.
- d) does not submit clarification/corrective actions for non-conformities observed during the Initial and verification audit within time frame as agreed between the laboratory and the audit team (time period for submission of corrective action will not exceed 45 days in any case).
- e) is found to have made any false declaration in the application form and/or attached documents with respect to infrastructure, testing facilities, calibration /CRM/SRM, competence of testing personnel, etc.

- f) violates provisions of the BIS Act, 2016 and the Rules & Regulations framed there under.
- g) Risk to impartiality is found to have been compromised as prescribed in clause 4.1.5, or otherwise.
- h) is not able to maintain its accreditation as per IS/ISO/IEC 17025 during the processing of application.

4.6.1 Procedure for Rejection of Application

- a) A notice for rejection of application stating the reason(s) thereof, will be served to the applicant, giving 14 days' time to respond and providing justification for the delay as well as for submitting the required clarification/corrective action/re-submission of the documents.
- b) While issuing notice for rejection, an opportunity for personnel hearing would be provided, if so requested by laboratory.
- c) In case no reply is received within the stipulated time, to the notice of rejection or no request is received for personal hearing, then the application shall be rejected and decision conveyed to the laboratory.
- d) If reply given by the laboratory to the notice and/or the justifications submitted during the personal hearing are found unsatisfactory and/or unacceptable, the application shall be rejected.

4.7 Initial audit: On satisfactory evaluation of documents after recording of the application as at clause 4.5 above, an initial audit of the laboratory shall be carried out for on-site assessment of the laboratory's compliance to the procedures and the activities described in the documented management system and relevant management system standard. The audit shall, *inter alia*, cover assessment of the applicant laboratory's competence to do testing as per the relevant Indian Standard(s), availability of adequate infra-structure, competence of testing personnel, etc. The various stages and actions for the initial audit are as given below:

- a) **Audit team-** BIS shall constitute an audit team comprising of adequate number of auditors (with experts as required) depending upon the ISS in the scope of recognition sought by the laboratory as per Annexure D.
- b) The names and contact details of the audit team members shall be communicated to the laboratory for confirmation within 7 days . The Audit team shall interact with the laboratory for carrying out the audit at a mutually convenient date which shall normally be within 15 days of receipt of confirmation.
- c) **Audit fees-** The laboratory shall be required to pay the prescribed audit fees in advance, the details of which shall be communicated to the laboratory along with the intimation regarding the audit team.
- d) **Travel and stay arrangements-** The laboratory shall arrange for travel and stay arrangement for audit team members as per the entitlements of the auditors.
- e) **Obligations of the laboratory** - The laboratory shall ensure availability of all concerned personnel whose competence is to be assessed during the audit. The laboratory shall provide all necessary assistance to the audit team for smooth conduct of the audit and shall provide all necessary document/information as required by the audit team. The laboratory shall also arrange for availability of samples of the product as per the relevant Indian Standards, for which recognition is sought.

4.8 Decisions for Recognition - On the basis of the audit findings, closure of all non-conformities observed if any, and confirmation on record that criteria for recognition is met and the laboratory has submitted to abide by the Terms & Conditions of this scheme, the application shall be processed for grant of recognition through the following:

- a) Finalizing the scope, in terms of Indian Standard, for which recognition is granted.
- b) Specifying restrictions regarding varieties/grades/sizes/designations etc. in particular standards depending upon the test facilities as available.
- c) Exclusion of test(s) permitted, if any under particular standard(s).
- d) Recognition shall be for a period of three years subject to payment of applicable recognition fee.
- e) The laboratory shall pay the recognition fees within 14 days from date of receipt of communication in this regard.
- f) In case, the laboratory does not pay the prescribed fee within the stipulated 14 days, BIS may process the application for rejection following due process.
- g) Recognition shall be effective from the date of realization of the recognition fee.
- h) A unique Recognition No. shall be allotted to each recognized laboratory.
- i) Decision of grant of recognition shall be communicated to laboratory, enclosing therewith instructions for use of software for receipt of samples and issue of test reports.

5. Terms and Conditions of Laboratory Recognition Scheme

Every laboratory recognized by BIS shall abide by the following terms and conditions:

- a) The laboratory shall inform BIS about major changes made, if any, to the Laboratory Quality Management System which formed the basis for the grant of the recognition.
- b) The laboratory shall ensure that infrastructure, test facility and manpower required as per the relevant Indian standard are met and maintained on continuous basis. Any change in status i.e., either upgradation or disruption of facilities shall be promptly informed to BIS.
- c) In case changes in the infrastructure, test facility and manpower which adversely affects the laboratories capability to test any requirement(s) as per the Indian standard(s), then the testing should be suspended under intimation to BIS and so maintained till such time the issue is addressed satisfactorily. BIS may, at its discretion, decide to impose condition for verification of corrective actions through special audit before permitting normal operation under the Scheme.
- d) The laboratory shall inform BIS as and when it plans for shifting of its laboratory premises to an address other than that declared and verified at the stage of grant of recognition. The laboratory shall not accept samples for the testing at the new premises without prior permission of BIS.
- e) The laboratory shall inform BIS as and when there is any change in testing capacity in terms of number of samples for any IS which can be tested in a month. The fresh declaration in this regard shall be submitted on the prescribed proforma (BIS/LRS/F-02)
- f) The laboratory shall inform BIS as and when there is any change in status e.g., expiry, withdrawal, extension date of validity date of accreditation for IS/ISO/IEC 17025 .
- g) The testing charges for outside recognized laboratory during the tenure of the recognition shall be declared and fixed at the time of its recognition for two years. There shall be no upward revision in the testing charges during the period of two years except when the standard is revised/amendment issued. The laboratory shall follow the policies of BIS regarding the testing charges as amended from time to time.
- h) The laboratory shall issue the Test Report containing information as per IS/ISO/IEC 17025 including information related to sample, code, dates of commencement and completion of testing, clause reference of the tests performed, relevant standard, amendment, and its specified values as per relevant IS. The laboratory shall issue test report in the formats prescribed by BIS, wherever applicable.
- i) The laboratory shall issue the test report within 7 days of completion of testing. Under no circumstances the issuance of test reports shall be withheld by the laboratory for any reason.
- j) The laboratory shall facilitate and permit access to BIS for all audits and investigations which BIS may carry out, with or without prior announcement to the laboratory and provide the required information as sought.
- k) The laboratory shall give minimum 30 days' notice while surrendering recognition and shall

comply with the instructions given by BIS for handling and disposal of samples/remnants pending with it. The laboratory shall not claim refund of the recognition fee for the unutilized period of recognition.

l) The laboratory shall retain remnants of the samples for a minimum period of **3 months** from date of issuance of test report or till the shelf life of the product whichever is earlier. The laboratory shall maintain proper record of disposal of remnants and produce the same as and when required.

m) The laboratory shall pay such fees for application, recognition, renewal and enhancement of scope of recognition, audits and other services as applicable and pay such additional fees on account of revision of any standard from time to time.

n) The application for renewal of recognition, if desired by the laboratory shall be submitted along with the requisite fees (Renewal and Accreditation fees) and the required documents at least **6 months** prior to the expiry of recognition.

o) The laboratory shall not accept any BIS sample for testing during application stage or after the validity of recognition is over except in the situation covered under clause 8.1.4. of this scheme.

p) The laboratory shall not accept any BIS samples during the period of suspension of recognition and shall inform the details of the sample pending with it at the time of suspension. The laboratory shall abide by the directions of BIS for handling of BIS samples and issuance of reports for the samples pending with it at the time of suspension.

q) The laboratory shall maintain records of all complaints received by it for the BIS samples and test reports issued for the same and shall document the actions taken for the complaints so received. Laboratory shall give full details of actions taken in response to complaints or discrepancy in test results and allow access to all relevant records and documents for the purpose of any investigations and provide certified copies thereof.

r) The laboratory shall have the relevant Indian standards including cross-referred standards (National or International) required for testing of products covered under scope of recognition.

s) As and when any standard for which recognition is granted or their cross-referred standard is revised or any amendment is issued to it, the laboratory shall review and update its test facilities to implement such revision/amendment and inform BIS accordingly.

t) The laboratory shall neither entertain nor contact BIS licensees/applicants for samples received from BIS. For any clarification which may be required for the sample the laboratory shall interact only with the BIS office/laboratory from where the sample is received. This clause shall not be applicable for samples sent directly by the manufacturers under the various conformity assessment schemes of BIS.

u) Upon Withdrawal of recognition or expiry of the recognition, the laboratory shall discontinue claiming BIS recognition and withdraw all publicity material (both in print and electronic media) which may contain reference thereto.

v) The laboratory shall submit a statement of samples received and test reports issued for BIS samples in the prescribed format twice a month (on every 1st and 16th of the month) as per the instructions provided by BIS.

w) The laboratory would be required to work through available BIS portal as per the instructions provided by BIS for receiving, accepting, forwarding and uploading of test reports etc.

x) The Laboratory will also maintain impartiality as per the requirements of clause 4.1.5 of this scheme. In addition, neither members of management of the laboratory nor any employee of the laboratory shall, in any way, act as authorized Indian representative for any foreign manufacturer under the Foreign Manufacturers' Certification Scheme and / or Compulsory Registration Scheme/ any other conformity assessment scheme of the Bureau; and

Also if any of the family members of management of the laboratory or sister units of the laboratory are acting as authorized Indian representative for any foreign manufacturer under the Foreign Manufacturers' Certification Scheme and / or Compulsory Registration Scheme/ any other conformity assessment scheme of the Bureau; the name of such manufacturers shall be declared to BIS. In such a situation, lab shall not be permitted to test samples of these manufacturers in their laboratory.

- y) In case exclusion for some test has been permitted to the laboratory by BIS, the laboratory shall inform the same to prospective BIS applicants before accepting the samples from them.
- z) The laboratories recognized for testing of products covered under various conformity assessment schemes of BIS shall adhere to scheme specific guidelines issued by BIS from time to time.

6 Operation of Laboratory Recognition Scheme after Grant of Recognition.

6.1 Witnessing of Testing – The laboratory shall agree and facilitate witnessing of its testing of any sample as decided by BIS.

6.2 Surveillance Audits – BIS shall carry Surveillance Audits as under:

- a) Frequency of surveillance audit would generally be once in a year.
- b) All surveillance audits shall be surprise audits.
- c) Surveillance audits may be carried out by the audit team nominated by BIS and involve man days as per Annexure D
- d) Laboratory would not be required to pay any audit charges or the travel & stay expenses of the auditors & experts.
- e) Non-conformities, observed if any, shall be dealt with in the same manner as in the initial audit.
- f) Laboratory shall be required to pay audit charges and arrange for the travel & stay of the auditors for verification (follow-up) audit, if required to be carried out for verifying the corrective actions taken for the non-conformities.

6.3 Supervisory Visits – Supervisory visits may be carried out by senior BIS officers not below rank of Head Lab at the laboratory to assess implementation of this scheme. No expenses for such visits will be charged from recognized laboratories.

6.4 Extension & Deletion from the Scope of Recognition

6.4.1 Extension of Scope of Recognition shall be dealt as follow:

- a) The laboratory shall make formal request for extension of scope for addition of Indian Standard to its scope along with the prescribed fee and Declaration regarding the test facilities for the additional standard on proforma BIS/LRS/F-02, 03, 04, 05 along with undertaking in Annex-C.
- b) Laboratories shall also submit documentary evidence of the IS (whose inclusion is being sought) being already covered under their scope of accreditation as per IS/ISO/IEC 17025 with the test method and accuracy as per the requirement of the Indian Standard for which inclusion is sought (i.e. Scope of accreditation as per IS/ISO/IEC 17025 covering the IS along with the test method and accuracy as per the requirement of the Indian Standard).
- c) On satisfactory assessment of the documents mentioned at Sl. No. a) and b) above, the extension of scope for the additional standard may be permitted on desktop audit basis , based on the undertaking submitted with the application for inclusion and agreeing to all the terms and conditions of this scheme.
- d) The test facilities for the IS included in the scope of recognition would be verified during the next surveillance audit .

e) In case deviation are observed in the scope and declaration vis a vis the test facilities as actually verified during the BIS audit, the recognition of the laboratory would be suspended for the IS included in the scope and processed for deletion of the ISs included.

6.4.2. In case of revision/amendment to the standard if the recognized OSL provides the documentary evidence and conformation for the changes in test facilities (if any required) as per the amendment/revised version of the IS , the same shall be included in the scope of the lab on desktop audit basis. The verification of the test facilities shall be carried out during the next surveillance/renewal audit.

6.4.3 In case the request for inclusion by the lab consists of IS which are similar to ISs already included in the scope of the laboratory and no additional testing facility is required for the new ISs proposed for inclusion, the inclusion may be permitted by BIS on desktop basis. The verification of testing facilities for the included ISs may be carried out during the next surveillance/renewal audit.

6.4.5 Reduction in Scope of Recognition –

Any Indian Standard (IS) may be deleted from the scope of recognition for any of the following reasons:

- (i) Supersession/withdrawal of the IS.
- (ii) Lab is assessed incompetent for any particular product.
- (iii) Lab requests for deletion of any IS (s).

7 Suspension of Recognition - Recognition of the laboratory would be liable to be suspended as and when non-compliance to fulfilment of the recognition criteria and/or violation of terms and conditions of this scheme are observed or reported. The causes which may lead to suspension of recognition are as below :

- (a) Lab fails to observe terms & conditions and undertaking of the Lab Recognition Scheme.
- (b) Break down of system as observed during audits or otherwise.
- (c) Non intimation of significant changes in lab management (as per signed undertaking submitted).
- (d) Lack of cooperation to BIS in conduct of audits or in resolving various related issues.
- (e) Prima-facie evidence suggests that the test results reported by the lab are not genuine/ valid and/or the laboratory does not carry out the test(s) properly as per the requirement of relevant ISs.
- (f) Failure to take corrective actions on NCs reported during audits within stipulated timeframe.
- (g) Shifting of laboratory premises.
- (h) Prolonged closure of laboratory due to any reason whatsoever.
- (i) Repeated occurrence of similar NCs.
- (j) Accreditation body withdraws accreditation as per IS/ISO/IEC 17025 during its validity period.
- (k) Occurrence of any natural calamity that affects the operations of the laboratory.
- (l) Lab continues testing and issuing of test reports for product(s) related to BIS conformity assessment schemes which is beyond scope of recognition, without seeking formal inclusion of the product(s) in their scope of recognition.
- (m) Complaint is established.

(n) Impartiality of laboratory as required under clause 4.1.5 of this scheme is found to be compromised.

7.1 Maximum period of suspension/partial suspension The period of Suspension shall not exceed three months. It may be extended beyond three months in special case with valid reason(s) by the BIS and shall not exceed six months. The recognition of the laboratory shall be withdrawn after this period.

7.2 Revocation of suspension/partial suspension When necessary corrective actions are confirmed by the lab, BIS may consider revocation of suspension based on satisfactory assessment including on-site verification, if necessary.

7.3 Recognition fee is payable even during period of suspension.

7.4 Partial Suspension - During the operation of the scheme, recognition of lab may be suspended partially for a product/ a group of products/ product field due to any of the following reasons:

- a) Inability of laboratory to demonstrate capability of testing of a product or a group of products.
- b) Failure to take corrective actions on NC reported during audit within stipulated timeframe.
- c) Repeated occurrence of similar NCs pertaining to a product or a group of products or product field(s).
- d) Accreditation body withdraws accreditation as per IS/ISO/IEC 17025 for the particular product(s)

7.5 During the period of suspension/partial suspension, the lab shall not accept and test any sample forwarded by BIS or by BIS licensees/applicants for tests to be carried out as per SIT under the various conformity assessment schemes of BIS . However, in case of partial suspension, the lab shall not accept and test any sample of the product/a group of products/product field(s) for which the lab was placed under partial suspension.

7.6 Samples pending with the lab at the time of suspension/ partial suspension shall not be tested without prior approval of the BIS. Lab shall furnish to BIS the details of samples pending for testing or under test at the time of suspension/partial suspension within two days from the date of receipt of intimation of suspension/partial suspension in the prescribed format (Annexure- E). The BIS will take a decision on testing or otherwise of samples already under test/pending for testing depending upon ground(s) of suspension and communicate the same to the lab. If statement is not received, BIS will not consider test reports of such samples.

7.7 Maximum period of partial suspension: The period of partial suspension shall not exceed three months. It may be extended beyond three months in special case with valid reason(s) by the BIS and shall not exceed six months. The ISs for which the recognition of the laboratory has been suspended will be processed for deletion from the scope of the laboratory.

7.8 Revocation of partial suspension: When necessary corrective actions are confirmed by the lab, BIS may consider revocation of suspension based on satisfactory assessment including on-site verification, if necessary for which the laboratory will be required to pay the necessary audit charges.

7.9 Recognition fee is payable even during period of suspension

8 Renewal, Deferment cum Expiry and Withdrawal of recognition.

8.1 Renewal

8.1.1 For renewal of recognition the lab shall apply to BIS on application form as prescribed(BIS/LRS/F-01) **at least six months before** validity date of the recognition along with

requisite fees as prescribed and related documents. A renewal notice may be sent to the lab well in advance. However, non-receipt of such notice from BIS cannot be considered as ground for not applying for renewal in time.

8.1.2 A renewal audit may be carried out before considering further renewal. The lab shall pay in advance the renewal audit fees as prescribed. BIS may also take decision regarding renewal of recognition without carrying out any renewal audit on desktop basis if past performance during surveillance audits has been satisfactory.

8.1.3 Renewal application fees and renewal audit fees (for the audits already carried out) are non-refundable. However in case renewal has been done without carrying out renewal audit, the renewal audit fees will be refunded.

8.1.4 If renewal of recognition is pending with BIS due to any reason which cannot be assigned to the Lab, though renewal application along with requisite fees ,dues have been received before the expiry date of recognition, the Lab shall be allowed to function as a recognized lab till a decision on the renewal application is taken by BIS.

8.1.5 In case lab is under partial suspension, then renewal for ISs under suspension may be considered only if the action taken were found satisfactory for the aspects for which partial suspension was imposed.

8.2 Deferment/Expiry of Renewal

8.2.1 Reasons for deferment of renewal - Renewal of recognition may be deferred for a maximum period of six months due to any of the following reasons:-

- (a) Recognition may be deferred if the lab is under suspension at the end of validity period.
- (b) Any complaint against the lab is under investigation or decision on some related issues is pending at the end of validity period.
- (c) If the renewal process is delayed due to any of the following reasons on the part of the lab :
 - i) Non-compliance by the lab to the requirements necessary to process renewal.
 - ii) The lab is not ready for renewal audit/ follow up audit.
 - iii) Performance is not satisfactory as assessed during renewal audit.

The laboratory will be intimated about its recognition being put under deferment due to above reasons .In case the laboratory does not take corrective action during the period of deferment, a deferment-cum-expiry notice (14 days prior to the deferment period being over) with the option of personal hearing will be sent to the laboratory giving 14 days time to reply. If no reply is received within the stipulated period or reply is found unsatisfactory, or if the plea(s) extended at the time of personal hearing are not acceptable to the BIS, the recognition shall be allowed to expire.

8.2.2 If renewal is not sought by the laboratory along with requisite fees before the validity period is over, a Deferment-cum-expiry notice with the option of personal hearing will be sent to the laboratory soon after the validity period is over by giving 14 days time to reply. If no reply is received within the stipulated period or reply is found unsatisfactory, or if the plea(s) extended at the time of personal hearing are not acceptable to the BIS, the recognition shall be allowed to expire.

8.2.3 Samples pending with the lab at the time of deferment/expiry of recognition shall not be tested without prior approval of the BIS. Lab shall furnish to BIS the details of samples pending for testing or under test at the time of deferment within two days from the date of receipt of intimation of deferment in the prescribed format. The BIS will take a decision on testing or otherwise of samples already under test/pending for testing depending upon ground(s) of deferment and communicate the same to the lab. If statement is not received, BIS will not consider test reports of such samples

8.2.4 The period of deferment of renewal may be extended beyond six months in exceptional situation with approval of the BIS.

8.2.5 The renewal of deferred recognition may be considered on satisfactory compliance of the requirement for which renewal was deferred.

8.2.6 Recognition fee is payable even during period of deferment.

8.3 Withdrawal of recognition

8.3.1 The recognition of the laboratory may be withdrawn any time during the recognition period by the BIS for any of the following reasons:

- (a) If the laboratory surrenders recognition
- (b) If continuation of the recognition of the laboratory would not be of any assistance to the conformity assessment schemes of BIS.
- (c) If the laboratory does not maintain adequate secrecy pertaining to the sample(s) under test and test results;
- (d) If the lab acts/works directly or indirectly against the interest of BIS in any form or in any manner;
- (e) If the laboratory is found indulging in unethical practices as detailed below :
 - i) Laboratory tries to influence BIS through unethical means for procuring more business.
 - ii) Laboratory has approached/allows BIS applicants or licensees to approach them or their representative before or after issuing test report for BIS samples (this clause shall not be applicable for samples sent directly by the manufacturers as per the various conformity assessment schemes of BIS).
- (f) If the laboratory after the imposition of suspension does not take corrective actions by the stipulated period or the corrective actions taken are found not satisfactory.

(g) If the partial suspension/ suspension continues beyond the permissible period for reasons for which the lab is responsible.

(h) Impartiality of testing by laboratory as required under clause 4.1.5 of this scheme is found to be compromised.

8.3.2 For the reasons mentioned above, the recognition of the lab shall be suspended with immediate effect (if not already under suspension). Process for Withdrawal of recognition will be initiated by issuing a notice for Withdrawal of recognition to the lab with provision of personal hearing to explain as to why such proposed action may not be taken against the lab. If no reply is received within 14 days or if the reply is found unsatisfactory or if the plea(s) extended at the time of personal hearing are not acceptable to the BIS, the recognition of the laboratory shall be withdrawn.

The cooling period for any lab whose recognition is withdrawn shall be minimum 6 months and maximum shall be one year. The cooling off period and notice shall not be applicable in case of surrender of recognition by the laboratory, however BIS may confirm the request for surrender of recognition.

9. Special Audits and Visits

9.1 Special Audit - In addition to the initial audit and surveillance audits, all other audits carried out at the request of the laboratory such as verification (follow-up), extension of scope, verification of corrective actions, revocation of suspension, verification of satisfactory working of equipment after breakdown, change of new premises etc. would be termed as special audits. The laboratory shall be required to pay the prescribed audit charges and also arranged for travel and stay for the auditors/experts, as applicable.

9.2 Special Visits – BIS may, at its discretion, carry out Supervisory visits, visits for investigation for complaints as per its requirement and these will not be treated as special audit.

10. Changes in management/structure of laboratory

10.1 During the operation of recognition, a number of special situations arise on account of changes in the management/structure of the lab. The situations may be of the following type:

- a) Change in address of the laboratory premises;
- b) Change in the name of laboratory without change of ownership and management;
- c) Change in the ownership of the laboratory, with or without change in the name;
- d) Division of the laboratory into two or more units with one of them retaining the original name;
- e) Division of the laboratory into two or more units none retaining the original name;
- f) Merging of two or more laboratories into one entity with change in name or retaining one of the original names.

10.2 In case of **10.1(a)**, the lab is required to intimate the Bureau in advance about shifting of the laboratory and stop testing at the old premises. On receipt of this information, the recognition will be suspended by the BIS. On completion of shifting the lab will intimate this fact to BIS along with the following documents:

(i) Any legal document authenticating the new premises as per clause 4.2.2(b).

.ii) Certificate of Accreditation of the laboratory for the new premises as per IS/ISO/IEC 17025 or ISO/IEC 17025.

BIS in turn would arrange for verification audit at both locations and shall consider revocation of suspension of recognition subject to satisfactory audit.

10.3 In case of **10.1(b)**, any of the legal documents as specified in clause 4.2.2 (a) shall be resubmitted along with a fresh undertaking in part B of the application form and BIS/LRS/F-07 in the new name of the lab.

10.4 In case of **10.1(c)**, any of the legal documents as specified in clause 4.2.2 (a) shall be resubmitted, along with a fresh undertaking in part B of the application form and BIS/LRS/F-07 by the new owner/management.

10.5 In case of **10.1(d)**, the lab is required to intimate BIS immediately and stop testing at all the units. The lab will also not issue any test report from any of the units. On receipt of this information, the recognition will be suspended by the BIS. The BIS shall consider revocation of suspension of recognition subject to satisfactory audit of the recognized lab retaining the original name and on submission of the following documents by the lab:

(i) No objection Certificate from the other unit(s) and/ or any other suitable legal document.

(ii) Fresh undertaking in part B of the application form and BIS/LRS/F-07 from the lab.

(iii) Any of the documents authenticating the premises as specified in clause 4.2.2 (b).

10.6 In case of **10.1(e)**, the units will be treated as new entities and they may apply for recognition afresh.

10.7 In case of merger of two or more labs into one entity (**10.1 (f)**) with or without change of name, the recognition of the lab shall stand withdrawn. The merged entity shall be treated as new entity & it may apply for recognition afresh.

10.8 The procedure to deal with special situation in case of labs located overseas will be same as detailed in above.

10.9 Lock out, Winding Up, Liquidation, Dissolution and Closure etc. of the lab. The lab will inform any such situation with exact status of its functioning to the BIS immediately. On receipt of information, the BIS will decide suspension/ Withdrawal of recognition of the lab depending upon the situation. In case of winding up, liquidation etc, full details regarding the authorized owner of the company or the liquidator shall be provided by the lab to enable BIS to lodge a claim for recovery, if any.

11. Appeal - Laboratory aggrieved by the order of Withdrawal of recognition may file an appeal to

the Director General, BIS within a period of 60 days from the date of the order of Withdrawal of recognition.

12 Recognition of Foreign Laboratories

Criteria for recognition of Foreign Laboratories shall be same as that for Indian Laboratories described in this Scheme with the additional requirement as given below:

- a) The foreign laboratories shall set up a liaison/branch office located in India with the required permissions, which shall meet all liabilities with respect to BIS Act, Rules and Regulations for the purpose of BIS recognition. The requirement to set up an office in India shall not apply, if BIS enters in to an MoU with respective Foreign Government for implementation of BIS Act, Rules and Regulations including the punitive provisions, or if the foreign laboratory nominates an Authorized representative located in India who declares his consent to be responsible for compliance to provisions of BIS Act 2016, Rules and Regulations on behalf of the laboratory as per Terms & Conditions of the Agreement signed between BIS and the foreign laboratory. The Authorized Representative may either be in-charge or a senior officer of the Indian office or a legally appointed agent of the foreign laboratory in India.
- b) Travelling and stay expenses of the auditors shall be borne by the auditee laboratory as per entitlement of the auditors. The per diem allowances to the auditors as applicable shall be paid by the auditee lab to BIS as per BIS Rules as amended from time to time.
- c) The test certificate issued by the laboratory shall have reference to its accreditation as per IS/ISO/IEC 17025 status/logo of Accreditation Body and also reference to its ILAC/APLAC membership.
- d) The recognition of foreign laboratories will be subject to acceptance of all other terms and conditions of this scheme and as per the decision of BIS in this regards. The foreign laboratories applying for BIS recognition shall be required to sign agreement with BIS in the format to be prescribed by BIS.

12.1 Schedule of Fees and charges for Foreign Laboratories

Schedule of fees and charges for foreign laboratories shall be same as for domestic laboratories and is given in Annex B.

13 Complaint/Feedback against the Laboratory- Any complaint/feedback received against a laboratory from any source will be examined/ investigated by BIS and action as deemed fit by BIS will be taken.

14 Testing charges: The testing charges for outside recognized laboratory during the tenure of the recognition shall be declared and fixed at the time of its recognition for two years. There shall be no upward revision in the testing charges during the period of two years except when the standard is revised/amendment issued. The laboratory shall follow the policies of BIS regarding the testing charges as amended from time to time.

15 Government laboratories empanelled by BIS (Group 2 Labs) :

As per the BIS conformity assessment regulations 2018, the following laboratories are covered under the definition of third party laboratory:

“third party laboratory” means a laboratory established, maintained or recognised by the Bureau or Government laboratories empanelled by the Bureau or any other laboratory decided by the Executive Committee of the Bureau.”

BIS is utilizing test facilities of Lab of national repute and eminence for products for which testing facilities are not available with BIS or BIS recognized labs or limited testing facilities are available. These laboratories are included under Group 2 labs and are not BIS recognized laboratories since a formal and detailed procedure for recognition as mentioned in BIS LRS is not applicable to these laboratories. BIS is not carrying out audits of these laboratories and the testing charges of these laboratories are also not regulated by BIS. The inclusion of a laboratory in the list of Government empanelled laboratory of BIS will be as per the requirement and decision of BIS.

16 General :Any situation not covered under this Scheme, will be considered by the BIS and decision of BIS shall be final.

Annexure A

Delegation of Powers in relation to Laboratory Recognition Scheme

Sl. No.	LRS Activity	Responsibility
1.	Formulation of Operational Procedure & Guidelines and their Interpretation	DDGL
2.	Empanelment of Auditors and Experts (Internal/External)	DDGL
3.	Recording of application	OIC (LRS)
4.	Nomination of Audit team for all types of audits {Initial, Surveillance, Verification (Follow-up), Special etc.}	Head (Lab)
5.	Rejection of application including summary rejection.	Head (Lab)
6.	Grant and Renewal of Recognition	Head (Lab)
7.	Extension and Reduction of scope of recognition	Head (Lab)
8.	Expiry, Deferment of Renewal and Extension of validity of Recognition	Head (Lab)
9.	Suspension/ Partial Suspension/ Revocation of Suspension	Head (Lab)
10.	Withdrawal of recognition	DDGL
11.	Operation of recognition of Overseas(Foreign Labs)	DDGL
12.	Decision for exclusions of certain tests as per IS	Head (Lab)
13.	Closure of Complaints against the Recognized laboratory	Head (Lab)
14.	Appellate Authority for decisions taken under LRS	DG

Annexure B
Schedule of Fees for LRS

Sl. No.	Item	Fees/Charges (Rs.)
1	Application Fee for initial recognition and renewal of recognition for upto 10 IS.	40,000
2	Application Fee for initial recognition and renewal of recognition for additional 20 IS (each)	10,000
3	Recognition Fee for up to 10 IS for 3 years	1,00,000
4.	Recognition Fee for 11-100 IS for 3 years	2,00,000
5.	Recognition Fee for more than 100 IS for 3 years	3,00,000
6.	Application Fee for Extension of scope.	10,000 for upto 10 IS 20,000 for more than 10 IS
7.	Processing Fee for extension of scope of recognition	Audit Fee for required Man days
8.	Initial / Renewal assessment audit fee	Audit Fee for required Man days
9.	Surveillance Audit Fee	Nil
10	Audit Fee per man day	5,000

Recognition fee shall be payable at the time of grant of recognition or renewal of recognition upfront for all the three years.

@ Plus the actual expenses on travel and stay of the audit team, if required.

Plus taxes, as applicable.

* Schedule of fees and charges are subject to revision from time to time.

In case of foreign laboratories:

1. All payments are to be made in equivalent USD by Laboratories situated in Non-SAARC Countries.
2. All payments can be made either in Indian Rupees with GST (as applicable) or in equivalent USD by Laboratories situated in SAARC Countries.
3. The cost of travel ,ticket, visa, insurance and stay of the auditors etc. shall be payable as per BIS norm.
4. The amount indicated above are excluding bank commissions and transfer charges. Ensure that bank commission and/or transfer charges, if any, are deposited in addition to the above-mentioned amount and

fluctuation in the foreign exchange rate is also taken care of so that the above mentioned net fee/charges (in INR) are credited to BIS Account.

5. The payment for foreign laboratories may only be deposited with BIS through RTGS/NEFT/SWIFT transfer. Our Bank account details are as follows:

Name of the Bank: Syndicate Bank

Address of the Bank: BIS Branch, Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi

BIS Account No.: 90842180024625

Swift Code: SYNBINBB126 (For transfer in US Dollars)

IFSC Code: SYNB0009084 (For transfer in INR)

* Schedule of fees and charges are subject to revision from time to time.

ANNEX C
UNDERTAKING FOR INCLUSION

We, M/s _____ located
at _____
_____ ,

are applying for inclusion under BIS LRS. We undertake that :

1. Complete test facilities for the ISs for which application has been made for inclusion under BIS LRS are available with our laboratory. The scope of accreditation as per IS/ISO/IEC 17025 and clause wise details of test facilities are attached.
2. The test facilities available for the ISs for which application has been made are as per the range and accuracy as mentioned in the Indian Standard.
3. In case of inclusion on the basis of this procedure and non availability of test facilities/non availabilities of test facilities of required range and accuracy as per the requirements of IS detected in subsequent BIS audit, recognition of our laboratory will be suspended for the IS included and processed for deletion of these IS from the scope of the lab.

Note : Any test parameters for which test facilities are not available are also to be mentioned in the application and decision on inclusion of such IS will be taken by BIS.

Date

Place

Signature
(Owner / Partner / Director of the laboratory / Authorized Signatory*)
Name
Designation
Seal

* In case of authorized signatory, a letter from Owner / Director / Partner of the lab certifying the signature of authorized signatory to be submitted with the application.

Annexure D
Allotment of Audit Man-days

1. Surveillance audit

S. No.	ISS covered in the scope for which recognition is sought	Audit Man days*
1.	Up to 10	2
2.	More than 10 and less than 100	4
3.	More than 100	8

1. For Renewal/Initial audit

S. No.	ISS covered in the scope for which recognition is sought	Audit Man days*
1.	Up to 10	4
2.	11-50 ISs	6
3.	51-100 ISs	8
4.	More than 100	10

*The above table is for guidance purpose. However the man days may be decided by Heads of BIS Labs depending upon the type and number of IS in the scope of OSL.

ANNEX E

Status of BIS samples pending for testing/under test

Name of the Lab:

OSL code:

Sl. No.	Description of sample	IS no.	BIS sample code no.	Name of RO/BO from where sample is received	Date of receipt of sample	Sample as applicable			Remarks
						Pending for Testing	Under test		
							Testing started	Testing expected to complete on	

Date:

Sign:.....

Name:.....

Designation:.....

Seal of the Lab:.....