EIC LABORATORY APPROVAL SCHEME- 2010

0. INTRODUCTION

0.1 The Export Inspection Council (EIC) is the official export inspection and certification body of India set up under the Export (Quality Control & Inspection) Act, 1963 to ensure sound development of India's export trade through quality control and inspection. It operates through its field organizations, Export Inspection Agencies (EIAs), set up under Section 7 of the Act, headquartered at Chennai, Delhi, Kochi, Kolkata and Mumbai, and a network of 34 sub offices including laboratories in important ports and industrial centers in India to carry out its functions.

0.2 Accordingly, EIC is operating export inspection and certification schemes for various notified commodities. Product testing is integral to the export inspection and certification services being rendered by EIC/EIAs and therefore, EIAs have established a network of laboratories of therefore own to cater to the inflow of samples generated during the operation of its export inspection and certification systems. However, the need for independent testing facilities may arise from time to time to supplement its own laboratory network due either to shortage of capacity or absence of specific testing capability as per standards for export which are normally international standards or regulatory standards prescribed by the importing countries.

0.3 Keeping this in view, EIC has modified its laboratory approval scheme (of 2002) for approval of laboratories that are technically competent, implement quality management systems as per national & international standards and perform tests as per the guidelines/ procedures stipulated in the relevant standards of various export products.

0.4 The conformity assessment under EIC Laboratory Approval Scheme is based on changing international requirements from time to time, in addition to conformity/ accreditation to ISO/IEC 17025 'General requirements for the competence of Testing and Calibration laboratories' with their scope covering the products of interest to EIC.

0.5 This modified Scheme shall come into force with immediate effect (January 2010).

1. SCOPE

1.1 This document lays down the guidelines for applicants, general as well as the technical criteria for approval, terms and conditions of approval, and financial aspects for according approval / renewal of approval to independent labs for the purpose of making available the testing facility to trade in order to meet the international specifications based on assessment of need by EIC.

1.2 The approval scheme shall apply to laboratories, which shall be functioning independently irrespective of being an in-house lab or linked directly or indirectly to any of the manufacturing/ processing unit to the satisfaction of EIC for demonstrating no conflict of interest.

1.3 Approval under the Scheme shall be accorded to a laboratory for single premises only where actual testing is carried out. If the laboratory carries out testing activities in more than one premise, separate approval for each premise will have to be obtained with a clear demarcation of scope of approval.

2. CRITERIA FOR APPROVAL

The laboratories seeking approval shall comply with ISO / IEC 17025 'General requirements for the competence of Testing and Calibration laboratories'. The applicant lab shall have testing experience of export products as per international standards (of quality and safety parameters) for a minimum period of three years. In addition, they will be assessed for capability & competence for the scope of interest to EIC as per internationally accepted methods for the purpose based on international requirements and notifications issued for various commodities from time to time.

3. PROCEDURE FOR OBTAINING APPROVAL

3.1 APPLICATION

3.1.1 Laboratories interested in obtaining approval under the Scheme should apply to the concerned regional EIA office in the prescribed proforma in duplicate along with two copies of its Laboratory Quality Manual and application fee as prescribed from time to time. The application fee is non- refundable. The Schedule of Fee is given in Clause 9. Lab seeking approval for any of the EIC's Residue Monitoring Plan (RMP) can obtain information on relevant test parameters by making a written request to EIC, alternatively information can be downloaded from EIC website*. Separate Annexure(s) to be attached with the application for assessment of facilities available to carry out RMP sample testing.

3.1.2 The application shall be signed by the proprietor, partner or the Chief Executive Officer (CEO) of the laboratory or any other person duly authorized for the purpose. The name and designation of the person signing the application must be recorded legibly in a space set apart for the purpose in the application form.

3.1.3 On receipt of application, along with fee, concerned EIA office shall deposit the fee and forward the details to EIC along with one copy of application.

3.1.4 On receipt of the application, laboratory quality manual along with the fee details, EIC shall scrutinize it for completeness as well as adequacy of facilities with regard to list of equipments and details of personnel to meet the basic requirements, with the scope of approval applied for, to be of interest to EIC.

*** Note: - Approval for RMP sample testing shall be subject to lab having complete test facilities for all parameters listed under the specified RMP of different commodities as per EIC's requirements that shall be assessed during audit.**

3.1.5 If necessary, EIC shall seek further information from the applicant in order to facilitate processing of the application.

3.1.6 The application for approval shall be considered based on the testing requirements, which EIC is looking for. EIC reserves the right to reject an application for one or more of the following reasons:

i) The lab is seeking approval for products / parameters for which there is no need as assessed by EIC;
ii) The lab does not have adequate facilities for the products / parameters applied for as given in its application;
iii) Application fee has not been submitted;
iv) Application form is not completely filled in;
v) Quality Manual has not been submitted along with the application;
vi) Any other reasons as deemed fit by EIC

The reason for rejection of the application shall be duly communicated to the applicant by EIC.

3.1.7 EIC shall acknowledge the receipt of each application accepted after scrutiny and give it an 'Application Number' to be referred to in all future correspondence.

3.2 ADEQUACY AUDIT/ DESK ASSESSMENT

After the application has been accepted by EIC as complete, the Quality Manual shall be examined by Assessor/ any other person deemed fit by EIC, for verifying its adequacy and conformity to the Criteria for Approval given in Clause2. Any deficiencies observed in the Manual shall be duly communicated by EIC to the applicant for taking suitable corrective actions and resubmission of the revised Manual for re-examination. EIC shall process the application further for assessment only after the Manual is adjudged to be adequate.

3.3 ASSESSMENT

3.3.1 Once the inadequacies observed in the quality manual is addressed and application accepted-satisfying all above aspects, EIC shall organize an assessment of the lab by deputing a team of at least two assessors to ascertain compliance to the documented quality system, facilities/ infrastructure and technical competence.

3.3.2 The assessment will be in line with EIC requirements / international norms and with special reference to the following:

a) Opening Meeting - This meeting will be conducted by the assessment team leader in which the Chief Executive Officer of the lab, the management representative and the technical heads of all the divisions being audited are expected to be present. During this meeting, the team leader will explain the scope and extent of the assessment as well as the proposed plan for assessment. Permission to take copy of documents relevant to substantiate the audit findings shall be complied with by the lab.

b) Conduct of Assessment - The assessment shall be conducted as per the assessment plan agreed to during the opening meeting, and shall cover areas of the relevance to the scope of approval of the lab. Evaluation shall include verification of test facilities, accommodation and environment, examination of documents and records, including in-house INTERNATIONALLY ACCEPTED METHOD VALIDATION* documents in place that shall be matrix specific for the scope applied for approval, assessment of competence of lab personnel in conducting lab analysis/ testing, performance in witness tests, documentary evidence of participation in International Proficiency testing programs for relevant analytes and matrices and compliance to its Annual Plan for participation in such programs. A lab official, conversant with the activities of the division(s) being audited, should accompany each assessor. The non-conformances (NC's) identified by the assessment team shall be briefed to the lab at the end of **the** day for necessary corrective action.

*Performance criteria approach shall be adopted as per EC directive 2002/657/EC or its equivalent, any other as deemed fit by EIC for the purpose.

c) Closing meeting - The assessment shall conclude with a closing meeting during which the assessment team shall present its findings to the lab. All the members present in the opening meeting should preferably be present in the closing meeting. The non-conformance reports will be acknowledged by Management Representative or authorized signatory, as a token of acceptance and time frame for the corrective action(s) will be agreed to. In case the lab has taken any corrective action for the closure of NC's, the same shall be reviewed.

3.3.3 Before assessment is undertaken, the applicant lab shall have conducted at least one internal quality system audit, one technical audit covering all areas under scope applied for and also one management review to ensure the implementation of the documented quality system. The related documents of the same shall be presented to assessment team before the commencement of audit.

3.4 ASSESSMENT FEE

The applicant lab shall pay in advance an assessment fee, as estimated by EIC, depending upon the number of assessors and man-days required, based on the scope applied for as also the anticipated expenses for travel/stay etc. as per the Schedule of Fee given in Clause 9.

3.5 RESPONSIBILITIES OF APPLICANT DURING THE ASSESSMENT

The lab is expected to provide the following assistance to the assessment team during the visit:

a) Arrangements for stay, local guidance and travel etc.
b) A suitable room where members of the team can meet and discuss during the day and at the end of the day to exchange their notes and findings.
c) Secretarial and other office assistance like photocopying etc.
d) Free accessibility to the records, test facilities as is deemed relevant by the assessors

3.6 FOLLOW UP ON ASSESSMENT

The laboratory shall take necessary time – bound corrective actions, for the NC's brought on record by the assessment team which may have to be verified by EIC before grant of approval to the lab under the scheme. This may even call for a follow up visit, for full or partial assessment, as the case may be. Necessary fee for the same shall be applicable as per clause 9.

3.7 GRANT OF APPROVAL

3.7.1 Based on the findings of the assessment team and its satisfactory recommendation the case for granting approval shall be processed for approval of Director, EIC. The decision of the Director, EIC for granting the approval or otherwise shall be final.

3.7.2 The approval granted shall be valid for a period of two years from the date of approval and it shall be renewable for two years at a time. It shall be binding on the lab approved under this scheme to comply with the directions/any modification in the scheme, issued by EIC from time to time.

3.8 CONSIDERATION FOR ACCREDITATION

Labs having NABL accreditation or having implemented ISO/IEC 17025 standard for its operation and or having been assessed for compliance to ISO/IEC 17025 standard and also the scope applied for, under this approval scheme will have due weightage. The adequacy audit of Quality manual may in such cases be waived off; however lab shall undergo initial assessment as well as annual surveillance to ensure the technical competence of the laboratory.

4. SURVEILLANCE

4.1 All approved labs shall be subjected to surveillance audits at least once in a year by EIC as per decision of the Director EIC to verify the continued compliance and maintenance of competence as also the implementation of quality system established by the lab and or for complaints received or any other reasons.

4.2 During the validity of approval, if the laboratory is found violating the terms and conditions of Approval, its approval is liable to be suspended and may call for special visits, which the lab is liable to pay special visit charges, as set out in Schedule of Fee given in Clause 9.

4.3 If complaint is received against a consignment for presence of any hazards either microbiological or other contaminants like heavy metals, pesticide or antibiotic residues, the laboratory in which the sample has been tested and or drawn prior to export, shall be subjected to audit trail by an assessor or an officer nominated by the Director EIC with instructions to the concerned EIA for follow up. The laboratory shall be audited for the following parameters;

a. Availability of trained manpower for conducting the tests
b. Internal quality control systems
c. Verification of related records
d. Relevant Equipment status and its records
e. Method of Proficiency testing or Inter laboratory comparison
f. Witness of retesting of retained, remnant and or corresponding sample.
g. Any other as deemed fit of merit

5. EXTENSION OF SCOPE

Any approved laboratory can request EIC for extension of its scope of approval to cover additional products and test parameters as of interest to EIC by making a written request to regional EIA, containing information on the relevant methods and standards and or the additional facilities set up for the same along with the fee prescribed in clause 9.0. In case changes are to be made to the Quality Manual, the revised Manual shall also be submitted for scrutiny. The request shall be examined by EIC to assess whether a visit is required for verification or not. In case a visit is to be made, assessment fee shall be payable as given in Clause 3.4 above. However, no application fee shall be payable for extension of scope.

6. RENEWAL OF APPROVAL

6.1 Any approval granted automatically expires at the end of the period of its approval. The approved laboratory shall apply to EIA with a copy to EIC at least four months before the date of expiry of their approval.

6.2 The laboratory shall submit the renewal application along with the prescribed application fee as at clause 9. A renewal assessment, similar to the initial assessment, shall be carried out for considering further renewal.

6.3 If any non-conformity is found during the renewal assessment, the laboratory shall take necessary corrective actions, which may need to be verified by EIC, before the approval is renewed.

6.4 It shall be ensured during renewal assessment that the terms and conditions for approval were not breached during the validity of approval.

6.5 Incase there is a impediment in renewal of approval, the lab shall undertake to maintain the integrity of already received samples by providing appropriate storage conditions and

not issue test reports of such samples until approval is renewed. Further the lab shall restrict itself from accepting any samples pending the renewal of approval for the applied scope from EIC.

7. TERMS AND CONDITIONS OF APPROVAL

7.1 The approval shall be granted for a period of two years, which shall be renewable for maximum of two years at a time, before expiry of earlier approval, subject to satisfactory performance based on periodic review/ surveillance of the laboratory by EIC.

7.2 The testing charges for products/parameters as per relevant methods, for which the laboratory is approved, shall be valid for the period of approval and any subsequent revision shall be with prior concurrence of EIC.

7.3 The approved laboratory shall normally perform the testing of the samples sent to it by EIC/EIAs on its own. Any subcontracting of testing in any circumstances shall only be done with the due concurrence of EIC.

7.3.1 The sub-contracted work shall be placed only with another EIC-approved laboratory for the same scope.

7.3.2 In case of sub-contracting, EIC/EIAs shall not enter into any correspondence with the laboratory to whom sample is sub-contracted by the approved laboratory and EIC/EIAs shall pay testing charges as approved for the approved laboratory.

7.4 The approved lab shall not make any change in the Quality System which forms the basis for the grant of the recognition and which prevents its compliance to the Scheme without prior approval of EIC. It shall document all changes made to the Quality System and make records of such changes available to EIC within a period of 10days with a copy to the concerned EIA.

7.4.1 Any change in key personnel in relation to quality assurance, key technical functions or senior management shall be duly intimated to EIC within a period of 10days with a copy to the concerned EIA.

7.4.2 The approved laboratory shall inform EIC immediately about the major changes/breakdown of equipment/ subcontracting with reasons thereof etc. effecting testing of the relevant products/compliance to this Lab scheme for Approval with a copy to the concerned EIA.

7.4.3 The approved laboratory shall inform EIC immediately about the suspension/ withdrawal of accreditation from NABL with a copy to the concerned EIA.

7.5 The following instructions for testing samples sent by EIC/EIAs shall be followed by all approved labs:

7.5.1 Samples for testing in independent laboratories approved by EIC shall always be accompanied by a test request. Samples shall not be accepted by them if they are not accompanied by such test requests.

7.5.2 The approved laboratories shall be allowed to draw samples by employing trained and authorized samplers on behalf of EIC/EIAs for parameters, wherever the lab is authorized to do so.

7.5.2.1 The sampler shall draw sample from only complete Assortment/ Batch/ shipment/ consignment/ Lot as the case may be and strictly adhere to the sampling procedure and provide sampling details as per EIC requirements.

7.5.2.2 The sampler shall also ensure drawl of true representative sample of complete Assortment/ Batch/ shipment/ consignment/ Lot as the case may be and cover maximum lots of productions.

7.5.2.3 The sampler shall endorse the relevant records complete Assortment/ Batch/ shipment/ consignment/ Lot as the case may be on site.

7.5.3 The laboratory shall ensure that the seal is intact with the details of the sealing indicated in the test request while accepting the samples /sample containers sealed by EIA officers/authorized representatives of lab. A statement/record to this effect shall be made on receipt of sample and in the test report by the concerned laboratory.

7.5.4 The laboratories are liable to maintain confidentiality of samples and information thereof.

7.5.5 The laboratory shall carry out the tests as per the conditions stipulated in the relevant standard method approved by EIC, which has been satisfactorily validated in-house **"as fit for the purpose",** with duly calibrated equipments and use of only valid reference materials/standards.

7.5.6 The test report shall be sent to the EIA office who requested the testing duly sealed in confidential cover unless the report is sought by any other means in the format as per the requirements of EIC (specimen format for Test Report at **Annexure 9**).

7.5.7 The laboratory shall keep the remnants of the sample after testing for a minimum period of three months in stipulated storage conditions before they are disposed of or returned to the customer**.** The mode of disposal of sample after test shall be recorded and indicated in the test request as well.

7.5.8 The test report shall be treated as strictly confidential between the testing laboratory and EIA. No information regarding the sample or its results shall be divulged to any person including the manufacturer/ processor who may deliver the sample on behalf of EIA for testing.

7.5.9 The manufacturer/processor shall not be allowed to witness the test or to come in contact with the testing personnel without prior approval of concerned EIA. Any assistance or intervention from the manufacturer required for testing the sample shall be duly indicated by EIA in the test request and shall be reported in the test report.

7.5.10 The laboratory shall issue the test reports within a maximum period of 7 days, excluding the time period required for testing by the relevant specification.

7.5.11 The Test report/Certificate shall include information as per the details given in EIC-approved proforma (Annexure-7), alternately the approved laboratory shall issue reports ISO/IEC 17025,

7.5.12 The laboratory shall maintain the record of observations and a copy of the test report for a minimum period of three years.

7.5.13 In case of withdrawal/cancellation of approval, the laboratory shall give and undertaking to make available of records of EIC/EIA related testing of three years.

7.5.14 The payment towards testing charges for the samples tested shall be made by the concerned EIA office, who has sent the samples and therefore, the concerned laboratory shall forward the bill, in duplicate, to them along with the test reports.

7.6 The approved laboratories shall participate in Proficiency Testing / Inter-Laboratory Test Comparison programs organized by national and international bodies of repute/ as recommended by EIC/EIAs for demonstrating their technical competence of the laboratory personnel at their own cost.

7.7 The approved lab shall permit access to EIC/EIA officer(s)/team(s) deputed for the purposes of assessment, surveillance or investigation. It shall give access to all relevant records, documents and equipments etc. for the purpose of verifying any details.

7.8 An approved testing laboratory shall not use its approval in such a manner as to bring EIC into disrepute/dispute and shall not make any statement relevant to its recognition, which EIC may consider to be misleading.

7.8.1 The approved lab may make a public claim regarding its approval. However, such claim shall be strictly based on the scope of its approval. It shall discontinue claiming EIC approval and withdraw all promotional and advertising material upon expiry/ suspension or cancellation of its approval.

7.8.2 The approved lab enjoying the privilege of approval under this scheme shall furnish within 15 days of grant of approval, either a performance bank guarantee of Rs One Lakh or the payment of Rs One Lakh (refundable) by way of Demand Draft/ Pay order drawn in favor of Export Inspection Agency- DELHI/ MUMBAI/ KOLKATA/ CHENNAI/ KOCHI, to the concerned regional EIA. This guarantee/ payment made can be invoked only with the due approval of the Director EIC by his nominated official for breach of any of the undertakings given.

7.8.3 The lab shall be show caused and reasons furnished thereof shall be adjudged by the nominated official of EIC before any action for invocation of its bank guarantee/ payment is initiated.

7.9 A laboratory may relinquish approval by giving three month's notice in writing to EIC. It shall however either complete testing of all EIA samples pending with it or return the samples pending along with the test requests. It shall not be entitled to any refund of approval fee.

7.10 EIC may, at its discretion cancel or suspend approval, reduce its scope or direct reassessment due to changes in personnel/equipment, break-down of equipment, and/or if a complaint or any other information is received which indicates that the technical competence and integrity/ confidentiality of the laboratory is not satisfactory.

7.11 The laboratory shall not use the approval certificate/letter after its validity period is over or in case of cancellation of approval.

7.12 The approved laboratory shall submit to EIC a statement as per schedule given below containing the following particulars namely:

(i) Number of samples received for testing; --- once in six months
(ii) Number of samples tested; --- once in six months
(iii) Number of samples declared pass/compliant; ---- once in six months
(iv) Number of samples declared failing/non compliant; --- monthly
(v) Number of samples pending testing ------ monthly
(vi) Delay in issuance of test reports, if any & the reason thereof --- monthly

In case of failures, as and when observed, a report with complete details as per **Annexure 8** shall be sent to EIC with a copy to regional EIAs immediately.

7.13 The approved lab shall not handle any sample of the client for laboratory testing when the laboratory fails to demonstrate satisfactorily to EIC that its direct/indirect trade association has no consequence/ bearance on its test results.

8. EXPIRY/ SUSPENSION AND CANCELLATION OF APPROVAL

8.1 The approval of laboratories shall automatically expire at the end of their validity, unless renewal is sought timely by the laboratories concerned along with the prescribed fees.

8.2 The approval of laboratories shall also expire if the renewal is not agreed to by EIC.

8.3 The approval of laboratories may also be suspended/ cancelled any time during the approval period for any and or the reasons given below:

8.3.1 If EIC feels that no useful purpose is being served by the continuation of the approval of the laboratory;

8.3.2 If the laboratory is found violating the terms & conditions of approval; and

8.3.3 If the laboratory is unable to maintain the Criteria for Approval.

8.4 EIC shall issue a show cause notice in case it intends to suspend/ cancel approval of a lab, as per clause 8.3.2 & 8.3.3 after due investigation, if required. The concerned laboratory shall be given an opportunity to explain its view point before any action is taken against the lab.

8.5 The laboratory, whose approval has been cancelled, can apply for fresh approval but not earlier than one year from the date of cancellation of approval.

8.6 The laboratory, whose approval has been cancelled, shall return their pending samples in appropriate conditions to EIAs for onward transmission to another approved laboratory and undertake to retain records as per requirements of Clause 7.5.13.

9. SCHEDULE OF FEE

9.1 The following shall be the fee payable by applicant / recognized labs.

a) Application Fee: (Approval/ renewal of approval)	Rs.5000.00
b) Adequacy/ Desk audit of Quality Manual	Rs. 2500.00
c) Assessment / Surveillance Fee / Special visit charges (as referred above)	Rs.4000.00 per man-day plus expenses for travel and stay of assessors chargeable at cost
Approval Fee (to be paid in advance biannually)	Rs.50, 000.00
Enhancement of Scope per commodity	Rs. 5000.00
d) Change in Name of Laboratory	Rs. 2,000.00 (copy of legal document reflecting the change of name shall be submitted

9.2 The laboratory shall make these payments in the form of Demand Draft / Pay Order drawn in favor of the 'EXPORT INSPECTION AGENCY-DELHI / MUMBAI / KOLKATA / CHENNAI / KOCHI, depending upon the location of the Laboratory.

10. RELAXATION IN CRITERIA

10.1 In case of need for specialized labs, the compliance to Criteria for Approval vide Clause 2 may be relaxed at the discretion of Director EIC and labs approved based on technical competence only.

10.2 Anything not covered under this approval scheme shall be dealt on case to case basis under the provisions of EIC rules & regulations in force.

APPLICATION FOR APPROVAL/RENEWAL OF APPROVAL UNDER EIC LABORATORY APPROVAL SCHEME, 2010

1. Name of the Laboratory/Applicant

1.1 Address of location for
Which approval is sought

1.2 Phone, Fax and e- mail

1.3 Address of Head office (if different from 1.1)

1.3.1 Name of Chief Executive

1.3.2 Phone, Fax and e- mail

2. Scope of approval applied for (Name Products/ Parameters and corresponding standards) (Please attach as **Annex 1** in the format given)

2.1 Date of validity of Approval (in case of renewal of approval)

3. Legal status and date of establishment (Please give registration number and name of the authority who granted the registration with all documentary proof).

4. Is the laboratory operating on a commercial basis?

5. Has the lab implemented Quality System as per guidelines of ISO/IEC 17025: latest version?

6. Whether accredited/ recognized by NABL as per ISO/IEC 17025 or any other body?

6.1 If, yes, Scope of accreditation/recognition (please also attach the certificate along with comparison of accredited scope with LOD and applied scope for EIC approval on separate sheet).

6.2 Whether major changes in Quality Manual carried out? If yes, enclose the copy of same (applicable for renewal of approval)

7. List of equipment with laboratory (Please attach as **Annex 2** in the format given)

7.1 List of Standard/ Certified reference materials (SRM/CRM) available for use: (Please attach as **Annex 3** in the format given)

8. Internal Audit and Management Review:

- Date of last Internal Audit, its findings and corrective action taken :
- Whether all requirements of ISO/ IEC 17025: 2005 covering all activities of laboratory have been audited at least once in last one year:
- Date of last Management review:

9. Manpower details:

9.1 Name and designation of the person responsible for technical operation/ Technical Manager(s).

9.2 Name and designation of the person responsible for Quality Management Systems/ Quality Manager.

9.3 No. of personnel

- Senior management
- Testing personnel
- Authorized signatories for issuance of test reports
- Authorized samplers

9.4 Details of professionally qualified staff with qualification (Please attach as **Annex 4 & 5** in the format given)

10. Details of subcontracting, if any

11. Proficiency Testing: Participation in International PT programme**:** (Please attach as **Annex 6** in the format given)

12. Total Turnover (in terms of Test reports issued for last 3 years Product / Product group wise);

12.1 For domestic purposes

12.2 For exports

13. Name of exporters for whom products tested in the areas applied for over last one year.

14. Any complaints/disputes in last three years pertaining to lab testing activities (Please attach as **Annex 7** in the format given).

15. **DETAILS OF APPLICATION FEE**

15.1 The following shall be the fee payable by applicant / recognized labs.

- Application Fee/ Renewal Application Fee: Rs.5000.00

15.2 Demand Draft / Pay Order no……dated…….Amount……Drawn on……payable to Export Inspection Agency- Bombay/Calcutta/ Cochin/ Delhi /Chennai (As applicable depending upon location of the laboratory)

16. **DECLARATION BY THE LABORATORY:**

I / We declare that

a) We have read & understood the terms and conditions of the EIC Laboratory Approval Scheme and are willing to abide by them

b) We agree to comply fully with ISO/IEC 17025: 2005 for the approval of testing laboratory.

c) We agree to comply with approval procedures, pay all costs for assessment, verification visit (if any), surveillance and reassessment irrespective of the result.

d) We agree to co-operate with the assessment team appointed by EIC for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of approval.

e) We satisfy all national, regional and local regulatory requirements for operating a laboratory.

f) Incase of breach of any of the terms and conditions of EIC Laboratory approval scheme, the decision to invoke action/ Bank guarantee/ payment made, by the Director (I&Q/C) EIC, is final and binding on us.

g) All information provided in this application is true to the best of our knowledge.

Date: Signature of Authorized Signatory

Place: Name

Designation

Stamp

Application (one copy) with fee and quality manual is to be submitted to the concerned EIA as per address given below:

Export Inspection Agency-Mumbai,
Aman Chambers-4th Floor, 113, Maharshi Karve Road
Mumbai-400 004
Phone: 91-22-23630311/23630312 Fax: 91-22-2368 3927
E mail: eiabombay@eicindia.org

Export Inspection Agency-Kolkata,
World Trade Centre,
14/1B, Ezra Street
Kolkata-700 001
Phone: 91-33-22355004/22352651/22352652 Fax: 91-33-22354562.
E mail: eiacalcutta@eicindia.org

Export Inspection Agency-Kochi,
27/1767A, Shipyard Quarters Road,
Panampilly Nagar (South),
Kochi-682 036
Phone: 91-484-2314645/2316946/ 2316949 Fax: 91-484-2316948
E mail: eiacochin@eicindia.org

Export Inspection Agency-Delhi,
Thakkar Bapa Smarak Sadan, 2nd Floor,
Dr. Ambedakar Marg, (Link Road)
(Behind Jhandewalan Metro Station)
New Delhi – 110 055
Phone: 91-11-23626320/21/22/23/24/25/26/27 Fax: 91-11-23626328
E mail: eiadelhi@eicindia.org

Export Inspection Agency-Chennai,
6th Floor, CDMA Tower – II,
No. 1, Gandhi Irwin Road, Egmore,
Chennai-600 008
Phone: 91-44-28552841/28552842 Fax: 91-44-28552840
E mail: eiamadras@eicindia.org

One copy of application along with laboratory quality manual without fee to be submitted to:
Director
EXPORT INSPECTION COUNCIL OF INDIA,
(Ministry of Commerce & Industry, Government of India),
3rd Floor, ND YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi- 110001.
Tele No.011-23365540, 23748188, 23748189
Fax: 011-23748024
e-mail: eic@eicindia.org

Annex 1
FORMAT FOR SCOPE OF APPROVAL APPLIED FOR
(Item 2 of Application)

S. No	Group of Products, materials or items tested (separate annexure for each commodity/product)	Specific tests or types of tests performed	Specification, standard/test method against which product tested	In-house method validation * in place. State which criteria	Equipment & technique used	Range of testing/ LOD/ Decision limit (alternately CCα)	Detection capability/ LOQ (alternatively CCβ)	Accuracy at Detection capability	Measurement of Uncertainty (±) / Claimed accuracy	Accreditation status

** refer page 3of EIC laboratory approval scheme footnote* (Page x of y)

Note: - Separate Annexure to be enclosed for approval of testing facilities for products covered under Residue Monitoring Plan (RMP). However, Approval may be limited to the scope of interest of EIC based on its need to use lab facilities.

Annex 2
FORMAT FOR LIST OF EQUIPMENT
(Item7 of Application)

S. No.	Name of equipment and date	Model/Type/year of make	Receipt date & date placed in service	Range and accuracy	Maintenance (In house/ outside)	Date of last calibration	Due date of next calibration	Traceability	Calibrated by whom (Incase in-house, whether personnel trained/ authorized for the purpose)

(Page x of y)

Annex 3
FORMAT FOR LIST OF REFERENCE MATERIALS AVAILABLE
(Item7.1 of Application)

S.No	Name of reference Material/strain/ culture/CRM	Source	Date of expiry/validity	Traceability

(Page x of y)

Annex 4
FORMAT FOR MANPOWER AVAILABLE
(Item9.4 of Application)

Sr. No.	Name of the official with designation (Date of Joining the Lab)	Academic and professional qualification	Relevant experience including training	Area of specialization in testing

(Page x of y)

Annex 5
FORMAT FOR AUTHORISED SAMPLER/SIGNATORIES FOR ISSUE OF TEST CERTIFICATES AND REPORTS

(Item9.4 of Application)

S. no	Laboratory/ Department/ Section	Name & Designation of Sampler/Signatory	Qualification with Specialization	Experience in years related to present work	Relevant Training	Authorized for which specific area of sampling/testing	Specimen Signature

(Page x of y)

Annex 6

FORMAT FOR PROFICIENCY TESTING:

(Item 11 of Application)

Sr. No.	Product/ Matrix	Details of Test(s)	Date of Testing	Nodal Laboratory (Accreditation body/ Country)	Performance in terms of Z score	Corrective action taken

(Page x of y)

Annex 7

FORMAT FOR COMPLAINTS/DISPUTES IN LAST THREE YEARS

(Item 14 of Application)

Sr. No.	Name of the client	Nature of complaint/dispute	Whether resolved in favor of Laboratory/Client	Brief of the action taken for resolving the complaint	Latest status (if not resolved yet)

(Page x of y)

Annex 8

FORMAT FOR COMMUNICATION OF FAILURES/ MONTHLY STATEMENTS OBSERVED DURING TESTING

(Clause 7.12 of EIC Laboratory Approval Scheme)

S. No.	Sample Code /Sample No.	Date of receipt	Date of completion of test	Name of the exporter	Type of product	Test Certificate No.	Invoice No./Purchase order No. (if sample covered under pre export testing) *	Reasons for analysis if other than pre export*	Parameters tested	Reported Results (concentrations in ppm/ppb, inclusive of correction factor/recovery factor) [failures to be reported in bold]	Method of Analysis	Results communicated to EIA

* where ever applicable

(Page x of y)

'Specimen' FORMAT OF TEST REPORT

(Clause 7.5.6 of EIC Laboratory Approval Scheme)

(On letter head of Laboratory with complete details of location where tests carried out)

Test Report No.: (to be mentioned on every page for identification purpose with date)

Name & address of Processor/Exporter:

Invoice order/purchase order no.:

Date of sampling:

Condition of Sample (at the time of receipt):

Details of sample: Type & Nature of Product:
Type of Packing
No. of M/Cs
(serial no. if any)
Code covered in the consignment.
No. of Cases:
Sampled Cases Seal No.
(if any):
**Sampled by:

Result of Analysis

Date of start of analysis: Date of completion of analysis:

Test results

1	2	3	4	5	6	7	8
SL. No.	**Parameter tested for**	***Results * (inclusive of column 4 of this table)***	***Correction Factor/ Recovery correction***	***Decision limit* / CCα (ppb/ ppm) ***	***Uncertainty at declared MRL/MRPL/ Detection Capability (as the case may be)***	**MRL/ MRPL (ppb/ ppm)***	**Method & equipment used for Testing**

*** Specify the unit of measurement as µg/Kg or mg/Kg to avoid any confusion and use the same unit of measurement in all parameters.**

*mandatory (reported results are inclusive of recovery correction/correction factor for the batch assay)
**mandatory Sampling is carried out by the authorized sampler only

In case of RMP sample(s) tested, whether sample confirms/does not confirm to the MRL/ MRPL based on the requirements. (Test formats applicable as per respective RMP schemes)

Remarks, if any

Appendix 1

Glossary

1. **Accuracy:** Closeness of agreement between a test result and the true, or the accepted reference value. When applied to a set of test results, it involves a combination of random error (estimated as precision) and a common systematic error (trueness or bias) (ISO 5725-1).

2. **Analyze:** The chemical species of which the concentration (or mass) is to be determined. For the purposes of these guidelines: a Veterinary medicinal Product/ pesticide or a metabolite, breakdown product or derivative/ element etc.

3. **Analytical sample:** Sometimes referred to as a "test portion", or "test sample". A sample prepared from the laboratory sample and from which "test portions" or "analytical portions" are taken (ISO 78/2, 1982). See also Directive 2002/63/EC.

4. **Analytical portion:** Sometimes referred to as "test portion". The quantity of material (usually homogenized) taken from the analytical sample, and on which the analysis/test is performed (ISO 78/2, 1982,). See also Directive 2002/63/EC.

5. **AQC:** Analytical quality control. Measurement and recording requirements intended to demonstrate the performance of the analytical method in routine practice. The data supplement those generated at method validation. AQC data may be used to validate the extension of methods to new analytes, new matrices and new levels. Synonymous with the terms internal quality control (IQC) and performance verification. Concurrent AQC data are those generated during analysis of the batch in which the particular sample is included.

6. **Batch** (analysis): For extraction, clean-up and similar processes, a batch is a series of samples dealt with by an analyst (or team of analysts) in parallel, usually in one day, and should incorporate at least one recovery determination. For the determination system, a batch is a series undertaken without a significant time break and which incorporates all relevant calibration determinations (also referred to as an "analysis sequence", a "chromatography sequence", etc.). With formats such as 96-well plates, a plate or group of plates may form a batch. A determination batch may incorporate more than one extraction batch. This document does not refer to "batch" in the IUPAC or Codex sense, which relates to manufacturing or agricultural production batches.

7. **Bias:** Also referred to as "accuracy" .The difference between the mean measured value and the true value, i.e. the total systematic error.

8. **Blank:**
   (i) Material (a sample, or a portion or extract of a sample) known not to contain detectable levels of the analyte(s) sought. Also known as a matrix blank
   (ii) A complete analysis conducted using the solvents and reagents only; in the absence of any sample (water may be substituted for the sample, to make the analysis realistic). Also known as a reagent blank or procedural blank

9. **Bracketing calibration:** Organisation of a batch of determinations such that the detection system is calibrated immediately before and after the analysis of the samples, for example, calibrant 1, calibrant 2, sample 1.....sample *n*, calibrant 1, calibrant 2.

10. **Calibration:** Determination of the relationship between the observed signal (response produced by the detection system) from the target analyte in the sample extract and known quantities of the analyte prepared as standard solutions. In the present document, calibration does not refer to calibration of weighing and volumetric equipment, mass calibration of mass spectrometers, and so on.

11. **Calibration standard:** A solution (or other dilution) of the analyte (and internal standard, if used) used for calibration of the determination system. May be prepared from a working standard and may be matrix-matched.

12. **Certified reference material:** (CRM)-See reference material

13. **Comminuting:** The process of reducing a solid sample to small fragments

14. **Confirmation:** The process of generating sufficient evidence to ensure that a result for a specific sample is valid. Analytes must be identified correctly in order to be quantified. The identity and quantity of residues should be confirmed. It is impossible to confirm the complete absence of residues. Adoption of a "reporting limit" at the LCL avoids the unjustifiably high cost of confirming the presence, or absence, of residues at unnecessarily low levels. The nature and extent of confirmation required for a positive result depends upon importance of the result and the frequency with which similar residues are found. Assays based on colorimetric, ELISA, TLC or ECD tend to demand confirmation, because of their lack of specificity. Mass spectrometric techniques are often the most practical and least equivocal approach to confirmation. AQC procedures for confirmation should be rigorous.

15. **Contamination:** Unintended introduction of the analyte into a sample, extract, internal standard solution etc., by any route and at any stage during sampling or analysis.

16. **Determination/detection system:** any system used to detect and determine the concentration or mass of the analyte. For example, GC-FPD, LCMS/ MS, LC with post-column derivatisation, ELISA, TLC with bioassay.

17. **False negative:** A result wrongly indicating that the analyte concentration does not exceed a specified value.

18. **False positive:** A result wrongly indicating that the analyte concentration exceeds a specified value.

19. **Interference:** A positive or negative response produced by a compound(s) other than the analyte, contributing to the response measured for the analyte, or making integration of the analyte response less certain or accurate. Interference is also loosely referred to as "chemical noise" (as distinct from electronic noise, "flame noise", etc.). Matrix effects are a subtle form of interference. Some forms of interference may be minimized by greater selectivity of the detector. If interference cannot be eliminated or compensated, its effects may be acceptable if there is no significant impact on accuracy (bias) or precision.

20. **Internal quality control:** (IQC)-see AQC

21. **Internal reproducibility:** see reproducibility

22. **Internal standard:** A chemical added, in known quantity, at a specified stage in analysis to facilitate determination of the identity and/or quantity of the analyte. The analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard should have similar physico-chemical characteristics to those of the analyte. Isotopic ally labeled analytes form ideal internal standards, where available. For all other types of internal standard, the relative responses must be calibrated for each batch of analyses. Standard addition could be regarded as a special form of ideal internal standardization.

23. **Laboratory sample:** The sample sent to and received by the laboratory.

24. **LCL:** Lowest calibrated level. The lowest concentration (or mass) of analyte with which the determination system is successfully calibrated, throughout the analysis batch. See also "reporting limit".

25. **Level:** In this document, refers to concentration (e.g. mg/kg, μg/ml) or quantity (e.g. ng, pg).

26. **Limit of detection:** The minimum concentration or mass of the analyte that can be detected with acceptable certainty, though not quantifiable with acceptable precision. Various definitions are used but, for convenience, it is often the quantity of analyte that generates a response 3 times greater than the noise level of the detection system. Definitions based on standard deviation of blank values can be difficult to apply in chromatographic analysis. With most methods and determination systems, the limit of detection has no fixed value. The term is usually restricted to

the response of the detection system but, in principle, it should be applied to the complete analytical method.

27. **LOD:** Limit of determination (see LOQ below).

28. **LOQ:** Limit of quantitation (quantification) (also known as limit of determination, LOD). The minimum concentration or mass of the analyte that can be quantified with acceptable accuracy and precision. Should apply to the complete analytical method. Variously defined but must be a value greater than the limit of detection. With most methods and determination systems, the LOQ has no fixed value. LOQ is preferable to LOD because it avoids possible confusion with "limit of detection". However, in legislation MRLs that are set at the limit of quantification/ determination are referred to as "LOD MRLs", not "LOQ MRLs".

29. **Matrix blank:** See blank.

30. **Matrix effect:** An influence of one or more undetected components from the sample on the measurement of the analyte concentration or mass. The response of some determination systems (e.g. GC, LC-MS, ELISA) to certain analytes may be affected by the presence of co-extractives from the sample (matrix). Partition in headspace analyses and SPME is also frequently affected by components present in the samples. These matrix effects derive from various physical and chemical processes and may be difficult or impossible to eliminate. They may be observed as increased or decreased detector responses, compared with those produced by simple solvent solutions of the analyte. The presence, or absence, of such effects may be demonstrated by comparing the response produced from the analyte in a simple solvent solution with that obtained from the same quantity of analyte in the presence of the sample or sample extract. Matrix effects tend to be variable and unpredictable in occurrence, although certain techniques and systems (e.g. HPLC-UV, isotope dilution) are inherently less likely to be influenced. More reliable calibration may be obtained with matrix-matched calibration when it is necessary to use techniques or equipment that is potentially prone to the effects.

31. **Matrix-matched calibration:** may compensate for matrix effects but does not eliminate the underlying cause. Because the underlying cause remains, the intensity of effect may differ from one matrix or sample to another, and also according to the "concentration" of matrix. Isotope dilution or standard addition may be used where matrix effects are sample dependent. Matrix-matched calibration intended to compensate for matrix effects and acceptable interference, if present. The matrix blank (see "blank") should be prepared as for analysis of samples. In practice, the pesticide is added to a blank extract (or a blank sample for headspace analysis) of a matrix similar to that analyzed. The blank matrix used may differ from that of the samples if it is shown to compensate for the effects. However, for determination of residues approaching or exceeding the MRL, the same matrix (or standard addition) should be used.

32. **Method:** A sequence of analytical procedures, from receipt of a sample through to the calculation of results.

33. **Method development:** The process of design and preliminary assessment of the characteristics of a method, including ruggedness.

34. **Method validation:** The process of characterizing the performance to be expected of a method in terms of its scope, specificity, accuracy (bias), sensitivity, repeatability and reproducibility. Some information on all characteristics, except reproducibility, should be established prior to the analysis of samples, whereas data on reproducibility and extensions of scope may be produced from AQC, during the analysis of samples. Wherever possible, the assessment of accuracy (bias) should involve analysis of certified reference materials, participation in proficiency tests, or other interlaboratory comparisons.

35. **MRL:** Maximum residue level. In the Directives that list MRLs for pesticide/commodity combinations, an asterisk indicates that the MRL* is set at or about the LOQ.

36. **MS/MS:** Tandem mass spectrometry, here taken to include MSn. An MS procedure in which ions of a selected mass to charge ratio (*m/z*) from the primary ionization process are isolated, fragmented usually by collision, and the product ions separated (MS/MS or MS_2). In ion-trap

mass spectrometers, the procedure may be carried out repetitively on a sequence of product ions (MS_n), although this is not usually practical with low-level residues.

37. **Performance verification:** see analytical quality control (AQC)

38. **Procedural blank:** See blank.

39. **Procedural standard:** A calibration standard of a derivative, degradation product, etc., of the analyte which is generated from a precursor, as part of the analytical method. Procedural standards are often employed in cases where the derivative, degradation product, etc., is not available as a "pure" standard. The term is not applied to transient species generated in the detector, e.g. fragments in mass spectrometry. However, it is applicable to the products of post-column reactions generated prior to detection in HPLC.

40. **Reagent blank:** See blank.

41. **Recovery:** (of analyte through an analytical method) the proportion of analyte remaining at the point of the Final determination, following its addition (usually to a blank sample) immediately prior to extraction. Usually expressed as a percentage. Routine recovery refers to the determination(s) performed with the analysis of each batch of samples.

42. **Reference material:** Material characterized with respect to its notionally homogeneous content of analyte. Certified reference materials (CRMs) are normally characterized in a number of laboratories, for concentration and homogeneity of distribution of analyte. In-house reference materials are characterized in the owner's laboratory and the measurement accuracy (bias) may be unknown.

43. **"Pure": S**tandard A relatively pure sample of the solid/liquid analyte (or internal standard), of known purity. Usually >90% purity, except for certain technical pesticides.

44. **Repeatability:** The precision (standard deviation) of measurement of an analyte (usually obtained from recovery or analysis of reference materials), obtained using the same method on the same sample(s) in a single laboratory over a short period of time, during which differences in the materials and equipment used and/or the analysts involved will not occur. May also be defined as the value below which the absolute difference between two single test results on identical material, obtained under the above conditions, may be Expected to lie with a specified probability (e.g. 95%).

45. **Reporting limit or reporting level:** The lowest level at which residues will be reported as absolute numbers. It may represent the practical LOQ, or it may be above that level to limit costs. It must not be lower than the corresponding LCL. For EU monitoring purposes where samples for surveys are analyzed over a 12-month period, the same reporting limit should be achievable throughout the whole year.

46. **Representative Analyte:** An analyte used to assess probable analytical performance in respect of other analytes notionally sought in the analysis. Acceptable data for a representative analyte are assumed to show that performance is satisfactory for the represented analytes. Representative Analytes must include those for which the worst performance is expected.

47. **Representative matrix:** Sample material or an extract of a commodity used as an indicator of method performance, or for matrix-matched calibration, in the analysis of broadly similar commodities. Similarity is usually determined according to the content of water, acids, sugars, lipids, secondary plant metabolites, etc., physical characteristics, or matrix effects. Represented analyte Analytes notionally sought but for which no concurrent quality control data are generated. Quality control data obtained from representative analytes are assumed to show whether or not analytical performance is acceptable for these analytes. Relative responses must be reasonably consistent to ensure that calibration is meaningful. Accuracy (recovery bias) is assumed to be no worse than that of the worst-case representative analyte(s). Represented matrix Sample material or an extract of a commodity sufficiently similar to the representative matrix that analytical quality control data (or matrix-matched calibration) generated from the latter can be considered

valid for the former. Where potentially unacceptable residues are detected, method performance data should be generated from the represented matrix.

48. **Reproducibility:** The precision (standard deviation) of measurement of an analyte (usually by means of recovery or analysis of reference materials), obtained using the same method in a number of laboratories, by different analysts, or over a period in which differences in the materials and equipment will occur. Internal reproducibility is that produced in a single laboratory under these conditions. May also be defined as the value below which the absolute difference between two single test results on identical material, obtained under the above conditions, may be expected to lie with a specified probability (e.g. 95%).

49. **Response:** The absolute or relative signal output from the detector when presented with the analyte.

50. **RSD:** Relative standard deviation (coefficient of variation).

51. **Sample:** A general term with many meanings but, in these guidelines, refers to laboratory sample, test sample, test portion, or an aliquot of extract.

52. **Sample preparation:** The first of two processes which may be required to convert the laboratory sample into the test sample. The removal of parts that are not to be analyzed, if required.

53. **Sample processing:** The second of two processes which may be required to convert the laboratory sample into a test sample. The process of homogenization, comminuting, mixing, etc., if required.

54. **SD:** Standard deviation.

55. **Selectivity:** The ability of the extraction, the clean-up, the derivatisation, the separation system and (especially) the detector to discriminate between the analyte and other compounds. GC-ECD is a selective determination system providing no specificity.

56. **S/N:** Signal-to-noise ratio.

57. **Specificity:** The ability of the detector (supported by the selectivity of the extraction, clean-up, derivatisation or separation, if necessary) to provide signals that effectively identify the analyte. GC-MS with EI is a fairly non-selective determination system capable of high specificity. High resolution mass MS and MS_n can be both highly selective and highly specific.

58. **Spike or spiking:** Addition of analyte for the purposes of recovery determination or standard addition.

59. **Standard:** A general term which may refer to a “pure” standard, stock standard, working standard, or calibration standard.

60. **Stock standard:** The most concentrated solution (or solid dilution, etc.) of the “pure” standard or internal standard, from which aliquots are used to prepare working standards or calibration standards.

61. **Test portion:** Also referred to as the “analytical portion”. A representative sub-sample of the test sample, i.e. the portion which is to be analyzed.

62. **Test sample:** Also referred to as the “analytical sample”. The laboratory sample after removal of any parts that are not to be analyzed, e.g. bones, adhering soil. It may or may not be comminuted and mixed before withdrawing test portions. See also Directive 2002/63/EC.

63. **Trueness:** The measure of trueness is normally expressed as ‘biases. The closeness of agreement between the average value obtained from a series of test results (i.e. the mean recovery) an accepted reference or true value (ISO 5725-1).

64. **Uncertainty:** (of measurement) A range around the reported result within which the true value can be expected to lie with a specified probability (confidence level, usually 95%). Uncertainty data should encompass trueness (bias) and reproducibility.

65. **Unit:** (sample) a single fruit, vegetable, animal, cereal grain, can, etc. For example, an apple, a T-bone steak, a grain of wheat, a can of tomato soup.

66. **Validation:** sees method validation

67. **Violative residue:** A residue which exceeds the MRL or is unlawful for any other reason.

68. **Working standard:** A general term used to describe dilutions produced from the stock standard, which are used, for example, to spike for recovery determination or to prepare calibration standards.

Reference Document for Definition: - METHOD VALIDATION AND QUALITY CONTROL PROCEDURES FOR PESTICIDE RESIDUES ANALYSIS IN FOOD AND FEED Document No. SANCO/10684/2009