

Food Testing Laboratory Accreditation Procedure

- Compliance with ISO/IEC-17025, General requirements for the competence of testing and calibration laboratory are pre requisite for obtaining accreditation for food testing.
- In India, National Accreditation Board for Calibration and Testing Laboratories (NABL) provides accreditation to the testing laboratories in accordance with ISO/IEC-17025, General requirements for the competence of testing and calibration laboratories, ISO/IEC-17043, General requirements for proficiency testing, ISO-17034, General requirements for competence of reference material producers and ISO-15189, Medical laboratories-requirements for quality and competence.
- NABL has signed Mutual Recognition Arrangements (MRA) with International Laboratory Accreditation Cooperation (ILAC) as well as Asia Pacific Accreditation Cooperation (APAC) for accreditation of Testing and Calibration Laboratories (ISO/IEC 17025), Medical Testing Laboratories (ISO 15189), Proficiency Testing Providers (PTP) (ISO/IEC 17043) and Reference materials producers (RMP).
- The test result issued by ISO-17025 accredited laboratory is valid throughout the globe.
- The food testing laboratories can began their operation for the disciplines such as (a) chemical (b) microbiological and (c) molecular biology which includes GMO testing in food products specifically for export testing.
- ISO-17025 accreditation can be obtained for a single discipline, product and analytical parameter by the laboratories; however, the cost effectiveness would be subject to comprehensive accreditation covering all disciplines and parameters.
- Initial accreditation of laboratories is generally for three years with annual/biannual surveillance based on performance and associated risk.
- The food testing laboratories seeking ISO-17025 accreditation as well as approval for export testing for products looked after by APEDA, EIC, IOPEPC, FSSAI, etc. are audited jointly by NABL in an integrated manner from the year 2018-2019 onwards. Laboratories can apply online to NABL.
- The laboratories complying with the requirements are recommended to respective organisation by NABL for carrying out sampling and analysis.
- The existing/new/upcoming food testing laboratories have to maintain calibrated testing equipment's corresponding to the scope of analysis, laboratory management procedures as per ISO-17025 requirements, validated analytical methods and quality control, proper record of raw and final data.

- The quality manual, operating procedures, work instructions, formats and checklists and all reporting procedures must comply with the ISO-17025 requirements.
- The quality manager or any other representative of the laboratory such as management representative should be trained and competent on interpretation and application of ISO-17025 requirements.
- The food testing laboratories are free to obtain standalone ISO-17025 accreditation from NABL and approach to respective organisation for approval or apply for integrated assessment, both the options are available.
- In case of APEDA approval, ISO-17025 accreditation is mandatory covering products such as: Fresh Fruits Vegetables and their Products, Meat and Meat Products, Poultry and Poultry Products, Dairy Products, Confectionery, Biscuits and Bakery Products, Honey, Jaggery and Sugar Products, Cocoa and its products, Chocolates of all kinds, Alcoholic and Non-Alcoholic Beverages, Cereal and Cereal Products including Rice, Groundnuts, Peanuts and Walnuts, Pickles, Papads and Chutneys, Guar Gum, Seeds, Floriculture and Floriculture Products, Herbal and Medicinal Plants, Organic and natural products and Cashew nuts.
- Although APEDA handles more than 50% food products exports, it does not charge fee for laboratory approval. The requirements for food testing laboratories to obtain approval of respective organizations are given in NABL website. The specific/additional requirements of APEDA approval are prescribed in NABL-127 as summarized follows:
 - ❖ The approved laboratories shall cater to APEDA scheduled products and all organic products for sampling, analysis; procedure for exports, residue monitoring for exports as per the laid down procedures by APEDA from time to time.
 - ❖ The assessment shall be conducted covering areas of the relevance to the scope of approval of the laboratory. 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 laboratory personnel in conducting laboratory analysis/testing, performance in witness tests, documentary evidence of participation in PT programme organized by APEDA, NRL as well as International proficiency testing programs.
 - ❖ The testing under the scope shall be in compliance to the analytical methods of validation as per the requirements of the importing countries.
 - ❖ The Laboratory shall be audited for internationally accepted harmonized methods of sampling, sample preparation and analysis purpose.
 - ❖ Sampling and analysis charges for each product shall also be submitted together with application by the applicant laboratory, whenever, prescribed by APEDA.

- ❖ The laboratory shall be subjected to verification audit (informed in advance/ unannounced depending upon the nature of complaint) in case of any complaints in sampling, testing and test reports or any other reasons.
- ❖ Based on the finding of the verification assessment, NABL along with APEDA shall take appropriate action including suspension/withdrawal of approval of the laboratory as per NABL 216 document.
- ❖ The applicant laboratories seeking approval and accreditation as per integrated assessment process shall have complete range of Chemical, Microbiological and GMO analysis before applying to NABL for approval/Accreditation.
- ❖ The applicant laboratories would be accorded approval for:
 - Chemical, Microbiological and GMO analysis for the products specified by APEDA.
 - Premises only where actual analysis is being carried out shall be approved. In case analysis is carried out at more than one premise, approval of all these facilities shall have to be obtained.
- ❖ The laboratories shall comply with the following before applying to APEDA for approval and NABL for accreditation.
 - Availability of high precision equipment's such as GC-MS/MS, HPLC-MS/MS, ICP-MS, etc. with appropriate back-up, supporting equipment's as well as accessories so as to ensure prescribed turn-around time.
 - 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. However, if the laboratory establishes field/satellite laboratories for preliminary/screening tests near/at the place of the primary production of the food and feed of animal or plant origin, the facilities can be considered as part of the central/main laboratory of the establishment, with additional scope, where conformity tests can be carried out for the presence of the particular substance(s), provided such arrangements are addressed in the Quality Manual/Management system document of the laboratory.
 - Sensitize personnel for drawing the sample, preparation of samples for analysis as well as analysis of control sample, retention and storage in controlled temperature of appropriate capacity.
 - Method validation for sampling and residual analysis, participation in PT programs, organized by APEDA NRL, estimation of uncertainty, traceability, etc.

- ❖ The laboratories seeking GMO analysis approval shall also comply with the following in addition to the above. The laboratories shall submit list of experts, method of sampling and list of equipment's as well as any other relevant information that would be appropriate for analysis of GMO in agro products. The following basic criteria shall be met by the applicant laboratories:
 - a) The laboratories shall have equipment's like RT-PCR, DNA sequence, etc. with appropriate back-up equipment's.
 - b) The laboratories shall have validated method of sampling and analysis for GMO.
 - c) The laboratories shall have relevant expertise to analyze GMO products in terms of technically qualified personnel.
- ❖ Copies of SOPs on methods of sampling and analysis as well as evidence to sensitized team for drawl of product samples, retention facility in controlled temperature shall be submitted by the applicant laboratory.
- ❖ Details of Sampling and analysis charges for each product shall also be submitted together with application by the applicant laboratory.
- ❖ Each application received for approval shall be considered based on the need of a laboratory in the region/area for scheduling an assessment of the laboratory.
- ❖ The applicant/approved laboratory shall participate in PT programs organized by APEDA National Referral Laboratory (NRL) at NRC Grapes, Pune from time-to-time for the purposes of following harmonized methods of sampling and analysis.
- ❖ The successful laboratory shall be part of the monitoring programs implemented by APEDA or any other agencies nominated by APEDA for the products specified by it from time to time and abide by the procedures to be complied therewith such as uploading of data, chromatograms, etc. as announced by APEDA or the NRL.
- ❖ The laboratory shall be audited for following harmonized methods of sampling, sample preparation and analysis purposes.
- ❖ Whenever required, the approved laboratory shall draw samples only by its own trained, authorized and approved samplers. The approved samplers shall have the minimum qualification of graduation along with minimum sampling experience with training imparted by NRL, NIPHM, DMI or any other government institution on application of methods of sampling.
- ❖ Approval to successful laboratories would be granted for analysis for the products and parameters found to be in order based on the assessment outcome for Chemical, Microbiological and GMO analysis. Evaluation of samplers for authorization of

sampling to assess the technical competence in a specific area shall also be conducted during the assessment.

- ❖ The laboratory shall be audited periodically to check utilization of harmonized methods of sampling, sample preparation and analysis. The laboratory shall also be audited by Directorate of Marketing and Inspection for the purpose of approval for issue of Agmark Grading Certificates.
- ❖ Issue of approval may be refused or, if issued, may be cancelled or suspended:
 - a) If the laboratory does not conform or fail to perform as per requirements.
 - b) If there are adverse reports from the financial institutions/banks against any of the owner/directors/partners/trustees.
 - c) If skilled/semi-skilled personnel are not available to manage the laboratory.
 - d) If there are adverse reports from the exporters, importers, etc.
 - e) Any other complaints made to APEDA by any other entity.
 - f) On expiry of the approval date specified in the Approval Certificate.
- ❖ Applicant laboratory will submit information in the prescribed formats with application in NABL-154 form.
- ❖ When physical checks are to be undertaken, sampling plans for exported products should take into account the level of risk, the presentation and type of commodity to be sampled, the reliability of controls of the importing country and of those responsible for handling the product in the importing country.
- ❖ Inspection services should draw up control programs based on precise objectives and appropriate risk analysis. Accreditation certificate shall be attached with technical annex. There shall be documented validation reports, proficiency tests results, analytical spectrum and methods, standard operating procedures for analytical method, resources and training etc.
- ❖ Control Programs shall be designed with consensus of APEDA. Every effort should be made to apply risk analysis based on internationally accepted methodology, where available. The elements of the control program should be formally documented including methods and techniques.
- ❖ In the drawing and analysis of samples, adequate sampling and appropriately validated analytical methods should be established to ensure that the results are representative and reliable in relation to the specific objectives and during export rejections our results shall stand robust and traceable in international market.
- ❖ Non-conformities/ Export Rejections: Where an exported product is found not to be in conformity, the resulting measures should take into account the following criteria to

ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers:

- a) Repeated non-conformity in the same importing country or in the same product or in the same category of products
- b) History of non-conformity of those responsible for handling the products;
- c) Reliability of checks.
- d) In respect of the product not in conformity, control programmes to ensure problems do not re-occur.
- e) Analytical report of non-compliant samples shall be documented and retained in records.

❖ Authenticity and Validity of Certificates

- a) Certification procedures should include procedures to ensure the authenticity and validity of certificates at all the relevant stages and to prevent fraudulent certification.

- b) In particular, personnel:

- Should not certify matters without their personal knowledge or which cannot be ascertained by them;
- Should not sign blank or incomplete certificates, or certificates for products which have not been produced under appropriate control programmes.
- Where a certificate is signed on the basis of another supporting document, the person signing the certificate should be in possession of that document;
- Should have no direct commercial interest in the products/exporters being certified.

- ❖ During the visit of international delegations, the laboratory shall ensure the availability of inspectors/samplers/auditors who had conducted the onsite inspections/sampling for a specific audit/sampling.

- ❖ The application for approval shall be considered based on the testing requirements of APEDA. NABL/APEDA reserves the right to reject an application for one or more of the following reasons:

- a) The Laboratory is seeking approval for the scope, which is not the need of APEDA at that time.
- b) The Laboratory does not have adequate facilities for the scope for approval and adequacy audit fee, as applicable has not been submitted.
- c) The laboratory is subcontracting any test under the scope for approval.
- d) Any other reason as deemed fit by NABL/APEDA.

- ❖ The scope covered shall not include any test by sub-contracting.
- ❖ The approved laboratory can request NABL for approval of additional personnel responsible for authorizing the results. In such cases an onsite assessment shall be conducted for the additional authorized signatories as per the procedure.
- ❖ In case of authorizing additional sampler, based on documentary compliances, virtual interview of the sampler may be considered depending upon the requirements.
- ❖ If complaint is received from importing country (e.g. RASFF-Rapid Alert System on Food and Feed, rejection, noncompliance, etc.) against a consignment, for presence of any hazards either microbiological or other contaminants like heavy metals, aflatoxin, pesticide, antibiotic residues, the laboratory in which the sample has been tested and or drawn prior to export, shall be subjected to audit trail (verification audit-informed in advance/uninformed depending upon the nature of complaint) by a joint assessment team comprising of officer/assessors from APEDA and NABL immediately. The expenditure incurring for the verification assessment shall be borne by the laboratory. Such verification assessment shall also be conducted in case of any other complaints in testing and test reports or any other reasons.
- ❖ The approved laboratory shall not make any change in the Quality Management System, which forms the basis for the grant of the recognition and which prevents its compliance to the Scheme without prior approval of APEDA/NABL.
- ❖ Any change in key personnel in relation to quality assurance, key technical functions (including personnel responsible for authorizing the results and samplers) or senior management shall be duly intimated to APEDA/NABL within a period of 15 days.
- ❖ The approved laboratory shall inform NABL/APEDA, immediately about the major changes/breakdown of equipment with reasons thereof etc. affecting testing of the relevant products/compliance to this laboratory scheme. The laboratory shall not carry out sampling or accept any sample for testing, when there is breakdown of the equipment to be required for performing the test(s). The laboratory shall not carry out sampling or accept any sample for testing, without prior approval of APEDA, when there is major change in the Management System, which may affect performance of the testing.
- ❖ Sample shall always be accompanied by a test request specifying the parameter, specification and purpose. Samples shall not be accepted by them if they are not accompanied by such test requests. The samplers shall strictly adhere to the sampling procedure of the lab based on instructions issued by APEDA for various food products from time to time/EC regulations/importing country requirements, and provide sampling details as per APEDA requirements. The sample shall be drawn only from the complete Assortment/Batch/Shipment/Consignment/Lot as the case may be

having uniform characteristic in the form of source/production conditions/processing conditions.

- ❖ The samplers shall also ensure drawl of true representative sample of complete Assortment/ Batch/Shipment/ Consignment/Lot/Source wise/Pond wise (if applicable) as the case may be.
- ❖ The laboratory shall ensure the integrity and chain of custody of sample during transportation. Further, 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 regulatory authority/authorized representative of laboratory/processor / exporter. A statement/report to this effect is made receipt of sample and in the test report by the concerned laboratory.
- ❖ The laboratory shall carry out the tests as per the conditions stipulated in the relevant standard method approved by APEDA, which has been satisfactorily validated “as fit for the purpose”, with duly calibrated equipment's and use of only valid certified reference materials and/or internal standards.
- ❖ The laboratory shall keep the remnants of the sample after testing for a minimum period of one month and reference sample for a period of three months or as prescribed in the relevant procedures in stipulated storage conditions before they are disposed off or returned to the customer. In case of samples tested for Biological parameters the sample shall be retained for reasonable period as per lab's policy based on APEDA/ importing country's requirement. The mode of disposal of sample after test shall be recorded and indicated in the test request as well.
- ❖ The laboratory shall maintain the record of observations, a copy of the test report and purchase documents for a minimum period of three years. In case of chemicals/media etc, the laboratory shall maintain purchase documents till the validity of chemical/media etc. Original data/records to establish audit trail/data integrity shall be maintained in the lab pertaining to each activity which affects the quality of test results.
- ❖ The laboratory shall issue the test reports immediately after completion of the tests and not later than a maximum period of 7 days, excluding the time period for testing by the relevant specification.
- ❖ The laboratory shall only utilize the service of authorized signatory and authorized samplers complying with the following requirements of NABL/APEDA.
- ❖ In case of withdrawal/cancellation of approval, the laboratory shall give an undertaking to make available of the records of APEDA related testing of three years.
- ❖ The approved laboratories generating pre-shipment test reports with digital signatures shall issue test reports directly to APEDA which will issue the Health Certificate and

shall not provide any copy of above test report directly to the exporter/processor. Such laboratories shall submit an undertaking in ₹ 100/- Non-Judicial stamp signed by the CEO of the laboratory with respect to above.

- ❖ The approved laboratory shall participate in Proficiency Testing/Inter-Laboratory Test Comparison programmes organized by national and international bodies of repute for demonstrating technical competence of the laboratory personnel. The Annual proposed plan for participation in Proficiency testing programs pertaining to approved scope for the forthcoming year shall be submitted to APEDA/NABL before 31st December of each year. The laboratory shall cover all the critical parameters in the relevant matrix within a period of 4 years. In case of, unsatisfactory result (Quantitative score $Z > \pm 2$) is scored, the same shall be informed to APEDA/NABL immediately with appropriate root cause analysis.
- ❖ The approved laboratory shall permit access to APEDA officer(s)/team(s) deputed for the purpose of any assessment, surveillance or investigation. It shall give access to all relevant records, documents and equipment's etc. for the purpose of verifying any details.
- ❖ An approved testing laboratory shall not use its approval in such a manner as to bring APEDA/NABL/Government of India into disrepute/dispute and shall not make any statement relevant to its approval, which APEDA may consider to be misleading.
- ❖ Laboratory may relinquish approval by giving three months' notice in writing to NABL/APEDA. It shall however wither complete testing of all samples pending with it or return the samples pending along with the test requests. NABL/APEDA may, at its discretion cancel or suspend approval, reduce its scope or direct re assessment due to change in personnel/equipment, breakdown 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.
- ❖ An approved testing laboratory 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 APEDA approval and withdraw all promotional and advertising materials upon expiry/suspension or cancellation of its approval. Further, the approved laboratory shall not issue any export worthy certificate/Health certificate for the commodities under the purview of APEDA without written instructions issued by APEDA in this respect to the laboratory.
- ❖ The approved laboratory shall submit periodic statements to APEDA containing the particulars, as per the schedule given below in prescribed format:

i.	Number of samples declared failing/non compliant	Monthly for the entire month by first working day of the next month
ii.	Number of samples pending	- do -

	testing	
iii.	Delay in issuance of test reports, if any & the reason thereof	- do -
iv.	Number of samples received for testing	once in six months for the period between 1st April to 30th September and 1 st October to 31st March of every financial year
v.	Number of samples tested	- do -
vi.	Number of samples declared pass/compliant	- do -
vii.	Number of samples failed specifying the parameter/test and other details	- do -

- ❖ The laboratory shall return the pending samples(s) in appropriate conditions to the customer for onward transmission to another laboratory and undertake to retain records as per requirements stated above on cancellation/withdrawal/non renewal/ expiry of approval.
- ❖ The testing charges for the products and parameters shall be applicable as fixed by APEDA from time to time. However, in case the testing charges are not fixed by APEDA, then mutually agreed charges shall be applied. No testing charges shall be applicable for the samples submitted by APEDA for the purpose of ILC (Inter laboratory comparison), proficiency testing, reference sample testing verification due to complaints, if any, etc.
- ❖ For qualification and experience requirements for personnel responsible for authorizing the results.

Format for information on Sampling and Analysis Charges:

No.	Parameter/Matrix	Analysis charge	Sampling charge
1.			
2.			
3.			

Format for List of products presently being analyzed by laboratory:

No.	Products	Tick, as applicable
1.	Fresh fruits and vegetables	
2.	Processed fruit and vegetable	
3.	Cereals (rice, wheat, maize) and products	
4.	Meat, poultry, dairy products and honey	
5.	Nuts and Oil seeds (walnuts, ground nuts) and products	

6.	Guar Gum	
7.	Pulses	
8.	Other processed foods	
9.	GMO & DNA analysis	
10.	Organic Foods	

Format for Products interested for recognition of sampling and analysis:

No.	Products	Tick, as applicable
1.	Fresh fruits and vegetables	
2.	Processes fruit and vegetable	
3.	Cereals (rice, wheat, maize) and products	
4.	Meat, poultry, dairy products and honey	
5.	Nuts and Oil seeds (walnuts, ground nuts) and products	
6.	Guar Gum	
7.	Pulses	
8.	Other processed foods	
9.	GMO & DNA analysis	
10.	Organic Foods	

Format for annual proposed plan for proficiency testing:

Sl.	Analytes	Matrix	Proficiency test (Program ID Number/ Round Robin No.)	Start date of proficiency test
1.				
2.				

- APEDA also provides financial assistance to its approved laboratories for upgradation in terms of high precision equipments upto Rs. 1.0 crores or 50% of the total cost whichever is less.
- Apart from APEDA, Ministry of Food Processing Industries (MOFPI) also provides financial assistance for setting up/upgradation of food testing laboratories. The applicant laboratories may apply against Letter of Interest issued by MOFPI from time to time in this respect. The scale of assistance is 50% and the upper ceiling is based on requirement of the laboratory setting up/upgradation.
- To facilitate the users, copy of ISO-17025 standard, generic template of Quality Manual as per ISO-17025 requirements and scheme guidelines for financial assistance of APEDA are attached. The users may subscribe to ISO/IEC-17025 standard with its update.

Document Source: ISO-17025, FAS guidelines of APEDA, NABL-127

Link: www.apeda.gov.in, <https://nabl-india.org/>