FEDERATION FOR DEVELOPMENT OF ACCREDITATION SERVICES

Information Brochure

FEDERATION FOR DEVELOPMENT OF ACCREDITATION SERVICES
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FDAS POLICY

FDAS is committed to provide accreditation services, in a non-discriminatory manner to applicant CABs operating as Test Laboratories, Calibration Laboratories and Medical Laboratories, in a timely manner, irrespective of the size and ownership and to operate its documented management system in compliance with ISO/IEC 17011:2017 and applicable ILAC/APAC norms.

DEVI SARAN TEWARI

PRESIDENT, FDAS

1.0 Introduction

Federation for Development of Accreditation Services (FDAS), India is a program to grant accreditation to CABs/Laboratories, as a non-government organization and in non-profit mode, under section 9(1) of the Haryana Registration and Regulation of Societies Act, Department of Industries & Commerce, Haryana, vide registration number HR/018/2019/03652, on 27th March 2019, by The Registrar of Societies, Govt of Haryana, India.

FDAS operates accreditation system by complying to ISO/IEC 17011: 2017, and applicable norms to grant accreditation to Test, Calibration and Medical laboratories, as per international norms. FDAS is committed to abide by the norms from international institutions like ISO, IEC, ILAC, APAC etc., so that its accredited CABs/Labs are having demonstrated global equivalence.

The idea to conceive FDAS is from a group of Indian laboratories, to serve the constituents of Indian economy, as a non-profit making body, and by making it financially sustainable through reasonable fee structure for grant of accreditation.

2.0 Mode of Service

FDAS, the NGO registered under "Registration and Regulation of Societies Act, 2012 of Haryana Government", aims to serve the community as the charitable and non-profit making body, by charging nominal accreditation fee, enough to financially sustain, to meet its own financial obligations with its earnings.

3.0 Professional commitment of FDAS.

FDAS is committed to be professional in its approach with laboratories in general and specifically with its accredited CABs/laboratories, by keeping them informed with justification before making a change in its management system that may affect CABs/laboratories functioning. FDAS has set up complaint redressal system, also when resolved complaints are not to the satisfaction of a CABs/laboratories, they are free to make an appeal against the decision of FDAS, which are considered by the Jury, which is independent to consider such appeals and to pronounce its judgement, which is a binding to the parties concerned. Jury would have more than one expert.

4.0 Accreditation Criteria

FDAS grants accreditation to the applicant test, calibration, and medical laboratories for the defined scope for which it has demonstrated its competence and compliance to the following applicable norms.

i. General requirement for the competence of testing and calibration laboratories ISO/IEC 17025: 2017.
ii. Medical laboratories – requirements for quality and competence, ISO 15189: 2012

Besides, accredited laboratories are required to abide by the:

i. Terms and conditions of FDAS to maintain accreditation (FDAS 131).
ii. Terms and conditions for use of FDAS symbol by laboratories (FDAS 132)
iii. FDAS supplementary criteria for accreditation in different accreditation scheme.

FDAS has adopted ILAC documents from P & G series, where available, and can be downloaded from: ***www.ilac.org***

5.0 Scope of accreditation (field wise)

For defining the scope of accreditation, FDAS has classified Test, Calibration and Medical laboratories in accordance, to the fields they cover in their operations and as follows:

5.1 Fields & groups of Testing Laboratories:

5.1.1 Biological

Bio-chemical
Bio-efficiency
Biological assay
Drugs & Pharmaceutical
Environmental biology
Food and agricultural products
Forensic analysis
Genetic activity
Industrial culture
Inhalation toxicology
Microbiological tests
Mycotoxins
Pharmacology tests
Shelf life of canned & processed food
Specialized instrumental analysis
Sterility test(s) for drugs
Toxicology tests
Virus (molecular technologies, Antiviral agents, Viral load, viral sequence data, surveillance)
ELISA tests

5.1.2 **Chemica**l

Air Gas and Atmosphere
Alcohol and Allied chemicals
Building materials
Coal, Coke and other solid fuels
Dyes and intermediates
Disinfectants
Drugs & Pharmaceuticals, cosmetics
Explosives
Fertilizers
Food and agricultural products
Forensic analysis
Inks
Industrial and fine chemicals
Lac & lac products
Ores and minerals
Metals and alloys
Paints, pigments and related tests
Paper and pulp
Photographic chemicals
Petroleum products
Plastics and resins
Pesticides

Pollution and environment
Rubber and rubber products
Leather and leather products
Specialized instrumental analysis
Textile and wool
Water
Wood and wood products

5.1.3 Electrical

Battery Testing
Distribution Equipment testing
Domestic equipment testing
Environmental testing
Explosion proof testing
Illuminated testing
IP cubicle testing
Relay testing

Switching duty test (HV)
Switching duty test (LV)
Short-time current test
Short circuit withstand test
Rated make/break test
Electrical endurance test
Temperature rise test
Locked rotor tests on Motors
Load loss & No load loss test

Corona inception/extinction
Front of wave impulse flashover
High voltage dc
Impulse flashover
Impulse withstand
Pollution performance
Porosity test
Power frequency flashover voltage
Power frequency sparkover
Power frequency voltage withstand
Puncture withstand voltage
Radio interference voltage
Switching impulse voltage
Temperature cycle
Visible discharge
Voltage distribution

Ageing tests on insulation
Arc resistance
Cable testing
Capacitor testing
Chemical tests on electrical insulating metals
Comparative tracking index

Dielectric constant
Dielectric strength
Electric conductivity
Fire resistance testing
Heat cycle
IDE measurement
Inductance measurement
Insulation resistance
Leakage current
Load cycle
Mechanical tests on electrical Insulating materials
Overload run test on capacitors
Physical tests on electrical insulating materials
Partial discharge tests
Resistance measurement
Self-healing test on capacitors
Stability test on capacitors
Surface resistivity
Thermal resistivity
Transient over voltage on capacitors
Verification of insulating properties
Volume resistance
Volume resistivity
Wrapping tests on cables

Combustion testing
Insulating oil testing
Metallurgical testing
Refractory material testing
Thermal testing of materials

Analogue simulation
Grounding system testing
Meter testing

Line material testing
Tower testing
Vibration testing

5.1.4 Electronic

Any electronic products

5.1.5 Fluid Flow

Air/gas delivery system
Wind velocity and direction
Compressed gas/steam
Flue gases emission
Liquid
Slurry

5.1.6 Mechanical

Mechanical properties of materials
Properties of powder metallurgical products
Plastics and rubber
Building materials
Metallographic tests
Performance/endurance test
Simulated tests
Creep test
Textile and allied material

5.1.7 Non-Destructive Testing

Eddy current testing
Magnetic particle testing
Leak test
Penetrant testing
Ultrasonic testing
Radiological testing
Acoustic & others

5.1.8 Optical & photometry

Colorimetry
Fiber Optics
General Tests on Optical instruments
Lasers
Micro-metrology
Ophthalmic lenses
Optical components & systems
Optical materials
Photometry
Photosensitive films, plates and detectors
Polarimetry
Radiometry
Thin film optics

5.1.9 Radiological

Radiation monitors
Radiation sources
Radiological equipment & nucleonic equipment

5.1.10 Thermal

Calorific values
Combustion properties
Heat flux
Latent heat
Radiation properties
Specific heat
Thermal conductivity
Thermal diffusivity
Thermo-mechanical properties

Others

5.2 Fields of Calibration laboratories:

5.2.1 Chemical
5.2.2 Electro-technical
5.2.3 Fluid Flow
5.2.4 Mechanical
5.2.5 Optical & photometry
5.2.6 Thermal
5.2.7 Radiological

5.3 Fields of Medical testing laboratories:

5.3.1 Clinical Biochemistry
5.3.2 Clinical Pathology
5.3.3 Hematology and immunohematology
5.3.4 Microbiology and serology
5.3.5 Histopathology
5.3.6 Cytopathology
5.3.7 Genetics
5.3.8 Nuclear Medicine (in-vitro tests only)

6.0 Who can apply for accreditation.

FDAS is open to grant accreditation without any discrimination, small or big, irrespective of ownership to test, calibration and medical laboratories.

Testing laboratories involved in product testing, are mostly inter-disciplinary laboratories, and are required to apply for each field of testing in which it may be operating in the same application. As an example;

Textile laboratories are required to apply for Chemical and Physical (mechanical) testing.

Metallurgical labs are required to apply for Chemical, mechanical & NDT.

Plastic labs are required to apply for Chemical, mechanical, optical, NDT etc.

Building/construction material labs to apply for Chemical, mechanical, NDT etc.

An electrical product testing lab to apply for electrical, mechanical, chemical field.

Likewise, labs involved in conducting the tests with respect to Environment, Pollution, Forensic etc., are required to apply for each field in which these are operating.

FDAS application format requires to define the scope of test for each field, as accreditation to the laboratory is given for defined scope.

The accreditation program of FDAS, is an acknowledgement of competence and the capacity of testing of the parameters to be tested for a product and is not to certify a product.

Applicant laboratory may seek accreditation for the select parameters as per their resources and competence, out of the required parameters to be tested.

Calibration laboratories, when operating in more than one field of calibration, are required to apply for each field, by defining their scope of calibration.

Medical laboratories are required to apply for the field(s), by defining the scope of test.

7.0 Evaluation of competence

Steps Involved in evaluation of the competence of a laboratory.

- **i.** On receipt of application for accreditation, it is acknowledged & applicants are asked for information not furnished, if any.
- **ii.** On request, FDAS organizes on-site pre-assessment to determine the preparedness of laboratory, otherwise Pre-assessment is accomplished by remote assessment by the lead assessor, to examine documented management system.
- **iii.** Thereafter final assessment is conducted by an assessment team, with the expertise for the scope for which the laboratory has applied for accreditation.

FDAS grants accreditation for two years, and accredited laboratories are subjected to onsite surveillance around middle of the accreditation period of two years to verify their continued compliance to FDAS requirements and are required to re-apply for next cycle of accreditation to maintain continuity in accreditation. Reassessed CABs/laboratories are subjected to desktop surveillance around middle of the accreditation period of two years.

Accreditation status would remain valid till 2 months after its expiry and would cease if not applied for re-assessment before the expiry.

8.0 PT/ILC requirement:

The minimum amount of appropriate proficiency testing required per laboratory is given below:

- One PT/ILC activity from each applied field prior to gaining accreditation.
- One PT/ILC activity relating to each group of laboratory's scope of accreditation at least every four years.

9.0 Useful information to Laboratories:

9.1 Accredited laboratories/CABs are entitled to use FDAS symbol subject to compliance of the "Terms and conditions for use of FDAS symbol" and FDAS symbol can be obtained from FDAS by the accredited CABs/Labs.

9.2 Assessment

Initial assessment for grant of accreditation is called assessment.

9.3 Reassessment

Already accredited laboratories are required to apply for reassessment.

9.4 Validity of accreditation

Accreditation given is valid for a period of two years.

9.5 Expansion in scope of accreditation:

i. Application for expansion of the scope of accreditation, from same field/group, is possible without onsite assessment, on furnishing the documentary evidence on resources and applicable competence, along with application of expansion in scope to FDAS. Example: A mass calibration lab can expand its range, by procuring required resources.

ii. Expansion of scope of accreditation from new field/ group would require on site assessment, as such expansion has no relevance with the existing expertise and experience.
iii. All midterm accreditations would be co-terminus, with main accreditation.

9.6 ISO/IEC 17025:2017

clauses 6.4.2:

When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

Applicability of the above clause:

Lab's own equipment has gone out of order, in the middle of testing and customer's need must be met, lab can use equipment outside its permanent centre, subject to compliance of ISO/IEC 17025: 2017, Example: weighing balance.

9.7 Inhouse trainings: FDAS gives due recognition to inhouse trainings.

9.8 Complaints

Labs / stakeholders are free to lodge a complaint to FDAS on any of their concern, FDAS would process the complaint as per its procedure.

9.9 Appeals

Appeals against the decision of FDAS are processed as per FDAS procedure for handling appeals.

10.0 Steps Involved in getting Accreditation:

Stage I: Preparing the laboratory for Accreditation

1.0 Laboratory management to nominate a person to coordinate activities related to accreditation including the following.

1.1 Determines the gaps in the existing documented management system against the requirement of ISO/IEC 17025 or ISO 15189, using applicable checklist - 1, (available at www.fdasindia.org) & bridge the gaps if any.
1.2 It is mandatory to have documented management system as per the requirement of ISO/IEC 17025/ISO 15189, which can be documented by the laboratory in its manual (Quality manual or Laboratory manual), procedures, Instructions, log-sheets etc.

Stage II: Submission of application to FDAS

1.0 When documented management system complies to the requirement (ISO/IEC 17025 or ISO 15189)**,** submit application for accreditation along with:

1.1 Applicable fee
1.2 Checklist – 1- FDAS 111/Checklist (medical lab) – FDAS 112
1.3 FDAS – 131 (Terms & conditions of FDAS to maintain accreditation)
1.4 FDAS – 132 (Terms & conditions for use of logo)

Stage III: Assessment

1.0 First time applicant laboratories are subjected to pre-assessment, for examination of its management system documentation by L.A. & without visiting lab unless requested. On successful outcome of pre-assessment, final assessment is organized.

1.1 On agreed date final assessment is organized by Dealing Officer by constituting a team consisting of lead assessor and technical assessor(s).

1.2 Assessment team lead by LA, conducts the assessment which involves examination of documents, work records, witnessing the test/calibration, interviewing of personnel etc. Lab is informed about the corrective action required (CAR) to be taken by the laboratory and within agreed time schedule.

1.3 LA sends team's recommendation to concerned dealing officer, as per the assessment format of FDAS, pending the completion of corrective action required, if any.

1.4 On receipt of the details of the corrective action taken by laboratory along with documentary evidence, the concerned assessor/LA, would forward to dealing officer stating that required corrective action (CAR) has been taken and NC(s) is/are being removed/withdrawn.

1.5 After examination of the assessment report, and action taken by the lab for corrective action required, dealing officer submits his recommendation for grant of accreditation to Director.

1.6 Director asks QM to examine the compliance to the procedures involved, And based on the report from QM, Director takes appropriate action for grant of accreditation to the applicant laboratory, which in turn is communicated to the laboratory through accreditation certificate with recommended scope of accreditation.

Note - 1: Assessors are not empowered to change the applied scope of accreditation while on site except on technical matters.

Note-2 Assessors are empowered to give time of one month for required corrective action, beyond which dealing officer is to be contacted.

Note-3: Laboratories are free to appeal against the findings of assessment.

Stage IV: Reassessment

To ensure continuity in accreditation, applicants are advised to apply for re-assessment two months before the expiry of accreditation (The accreditation cycle is 2 years).

11.0 Financial obligations on the part of CABs

11.1 Application Fees: (to be paid along with application)	Rs.20000.00/ Field + applicable GST
11.2 Annual Accreditation Fees: (to be paid after grant of accreditation)	Rs.10000.00/Field + applicable GST
11.3 Assessment Charges:	a. Actual expenditure incurred by assessment team on account of their travel, boarding and lodging b. The honorarium @ Rs.5000.00 per day for Lead Assessor (LA) & Rs.4000.00 per day to each Assessor/ Technical assessor (TA) + applicable GST.

	c. For first time applicant, pre-assessment is a home-based activity for LA for one day.
11.4 Midterm, Application Fees for expansion of scope:	Rs. 20,000.00/Field + applicable GST
11.5 Surveillance Fees:	No surveillance fees/charges will be levied. However, the expenditure for FDAS team's visits to CAB/lab when required as stated above, under a) & b) of 13.3 to be borne by CABs.

N.B

Note: 1. Assessment team to be provided single seated air-conditioned room in a hotel/ guest house.
Note: 2. Laboratories are advised to provide return air ticket, local travel and hospitality.
Note: 3. Where direct air connectivity in not available, provide 2nd AC return-rail ticket.
Note: 4. Invoice for assessor's honorarium would be raised/sent after completion of assessment.
Note: 5. Accreditation certificate will be issued only after clearance of all dues.
Note: 6 Payments in the form of Crossed Cheque (Core banking only)/Demand Draft are to be made in favour of **"Federation for Development of Accreditation Services" payable at Gurgaon.**

OR

NEFT/RTGS to the following A/C

Name of the A/C	Federation for Development of Accreditation Services
Name of the Bank & Address	Union Bank of India, G/ 6 A, Bestech Square, Sector 56 Gurgaon (Haryana) 122002
A/C No.	579201010050690
Type of A/C	Current
IFSC Code	UBIN0557927
MICR Code	110026093

12.0 Contact Details:

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FAMILIARIZATION WITH ACCREDITATION PROCESS