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

Director, 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.

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

India has about five lakh laboratories, consisting of three lakhs medical laboratories and more than two lakhs test and calibration laboratories. Though laboratory accreditation activities started in 1989 by NCTCF in the Department of Science and Technology, which later became NABL in 1992, but in spite of its best NABL could accredit about eight thousand laboratories. And for a country that aspires to become a five trillion economy, there have to be more means to accelerate the pace of accreditation.

Keeping the overall picture of laboratory accreditation accomplished and the need of the country in mind a group of Indian laboratories, with their financial support, decided to launch FDAS as a tool to serve the Indian economy and as a non-profit making mode, and achieve self-reliance over a period of time. FDAS aims to achieve MRA signatory status of Asia Pacific Accreditation Cooperation (APAC), and now an Associate member of APAC.

2.0 Mode of Service

FDAS, the NGO registered under the "Registration and Regulation of Societies Act, 2012 of Haryana Government", aims to serve the community as a charitable organization and as a non-profit making body and by maintaining financial sustainability.

3.0 Professional commitment of FDAS:

FDAS is committed to being 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, and to incorporating their views to the extent possible. FDAS has the complaints & Appeals redressal system, also when resolved complaints are not to the satisfaction of CABs/laboratories, they are free to make an appeal against the decision of FDAS, which are considered by the Jury, which is not involved in the decision making & is independent to consider such appeals and to pronounce its judgment, which is a binding to the parties concerned. The jury would have more than one expert.

4.0 FDAS Policy on grant of accreditation and Impartiality/Confidentiality:

FDAS is open to granting accreditation to all willing laboratories (CABs), irrespective of ownership, size, or affiliations, and from all sectors of the economy and committed to maintaining impartiality in its functioning from the test, calibration, and medical laboratories. As a policy, its management, staff, committee members, assessors, and experts involved in the process of accreditation are required to pledge to maintain impartiality and confidentiality. FDAS has a website (www.fdasindia.org) and it gives the details of scope of accreditation of laboratories along with the certificate. FDAS accreditation is an acknowledgement for the competence of the applicant for the scope of testing/calibration parameters identified by FDAS and is not to certify a product.

5.0 Accreditation Requirements:

FDAS grants accreditation to the applicant CABs (test, calibration, and medical laboratories) for the defined scope subject to the demonstration of competence and compliance to the following applicable norms.

5.1 General requirement for the competence of testing and calibration laboratories ISO/IEC 17025: 2017.
5.2 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 applicable for different accreditation schemes.

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

6.0 Scope of FDAS (Test laboratory)

FDAS is open to granting accreditation to test laboratories in from following fields.

6.1 Biological
6.2 Chemical
6.3 Electrical
6.4 Electronic
6.5 Fluid Flow
6.6 Mechanical
6.7 Non-Destructive (NDT)
6.8 Optical and Photometry
6.9 Radiological
6.10 Thermal

7.0 Sub-division of Fields in groups for Testing Laboratories:

(It is to facilitate applicants to define the scope of accreditation.)

7.1 Groups in Biological field

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
Ayush products
Cosmetics

7.2 Groups in Chemical field

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
Ayush products
Toys & Children's products
Trace element analysis (like in food containers)
Cosmetics

7.3 Groups in Electrical field

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

7.4 Electronic

Any electronic products

7.5 Groups in Fluid Flow field

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

7.6 Groups in Mechanical field

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
Leather and Leather Products

7.7 Groups in Non - Destructive Testing field

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

7.8 Groups in Optical & photometry field

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

7.9 Groups in Radiological field

Radiation monitors
Radiation sources
Radiological equipment & nucleonic equipment

7.10 Groups in Thermal field

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

8.0 FDAS Scope for Calibration laboratories.

(FDAS grants accreditation in following fields to Calibration laboratories).

8.1 Chemical
8.2 Electro-technical
8.3 Fluid Flow
8.4 Mechanical
8.5 Optical & Photometry
8.6 Radiological
8.7 Thermal

9.0 FDAS scope for medical laboratories:

(FDAS grants accreditation in following fields to medical laboratories).

9.1 Clinical Biochemistry
9.2 Clinical Pathology
9.3 Hematology and Immunohematology
9.4 Microbiology and Serology
9.5 Histopathology
9.6 Cytopathology
9.7 Genetics
9.8 Nuclear Medicine (in-vitro tests only)

10.0 Guide to make application for accreditation.

10.1 Applicants are advised to submit a hard copy of its application, lab's Management System Manual, and FDAS Check list-1 (FDAS 111/ FDAS112), with submission of soft version of the same.

10.2 Laboratories (test & calibration) operating in more than one field of testing are required to submit single application by giving the details of the scope of testing, personnel and equipment sequentially for each field.

10.3 Testing laboratories/CABs involved in product testing are mostly inter-disciplinary laboratories and are required to apply for each field they operate in the same application. As an example.

- Textile & Leather laboratories to apply for Chemical and Physical (Mechanical) testing.
- Metallurgical laboratories to apply for Chemical, Mechanical & NDT testing.
- Plastic laboratories to apply for Chemical, Mechanical, Optical, NDTtesting etc.
- Building/Construction material laboratories to apply for Chemical, MechanicalNDT testing etc.
- Environment, Pollution, Forensic, Environmental testing laboratories to apply for each fieldin which they operate.

10.4 Applicant laboratories are advised to seek accreditation for only those parameters for which resources and competence are available.

10.5 Calibration laboratories, when operating in more than one field of calibration, are to apply field wise, by defining scope of calibration.

10.6 Medical laboratories to apply for the field(s) they operate and defining scope of test.

Note: In case laboratory is not responding after application, within three months by providing the required information or not able to confirm assessment dates, the application would be considered closed and application fee paid would be adjusted.

11.0 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. First time applicants are subjected to Initial assessment by an assessment team.

Determining laboratory's competence involves an assessment by a team lead by Lead assessors and relevant expert assessors which completes its assessment by examining documented management system of the laboratory, for its compliance to ISO/IEC 17025/ ISO 15189 and adequacy, examination of laboratory records to ensure its implementation, witnessing the tests/calibrations, interviewing the laboratory personnel, besides examination of laboratory's technical records from applied scope etc.

Where non-conformities are found, laboratory is given time (not more than 3-months) to take the required corrective action, and submission of the documentary evidence on corrective action taken to the relevant member of the assessment team, he would take the decision to close the non-conformity and inform FDAS. Thereafter Director FDAS takes the decision for grant of accreditation based on assessment findings.

Initial accreditation is granted for two years, and accredited laboratories/CABs are subjected to onsite surveillance around the middle of the accreditation cycle of two years to verify their continued compliance with FDAS requirements and laboratories/CABs are advised to apply for re-assessment for next cycle of accreditation to ensure accreditation continuity, two months before accreditation period ends. Reassessed CABs/laboratories are subjected to desktop surveillance around the middle of the accreditation period of two years.

To ensure continuity in accreditation, CABs/Laboratories are advised to apply for re-assessment two

months before the expiry of accreditation (The accreditation cycle is 2 years).

As per FDAS norms accreditation status would remain valid, till 2 months after the expiry of validity period of accreditation.

12.0 PT/ILC requirement:

The minimum requirements for proficiency testing are 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.

13.0 Useful information to Laboratories:

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

13.1 Initial Assessment

The term Initial assessment is used for first time applicant.

13.2 Reassessment

Already accredited laboratories are required to apply for reassessment.

13.3 Validity of accreditation

Accreditation given is valid for a period of two years.

13.4 Expansion in scope of accreditation:

i. When the Application for expansion of the scope of accreditation is from same field/group, FDAS seeks the evidence on resources and competence, to determine, if the site visit is required. If the documentary evidence found to be enough, the accreditation is possible without organizing lab visit.

   Example: A mass, pressure, temperature 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 co-terminus, with main accreditation.

13.5 Rights and duties of FDAS

13.5.1 Duties of FDAS:

- attend to labs need for permitting its operations from new premises, subject to the compliance of its norms.
- to accept complains from laboratories/CABs and public and communicate the decision in time.
- to accept appeals from laboratories/CABs and communicate the decision in time.
- give enough time when new criteria/change in criteria is to be implemented.
- take feedback from stakeholders when criteria is intended to be revised.
- provide accreditation services with discrimination.
- to protect confidentiality
- to maintain MRA with APAC/ ILAC.

13.5.2 Rights of FDAS

- Terminate, withdraw, suspend accreditation granted to laboratories/CABs, on violation of terms and conditions.
- Revise the norms of accreditation fee and other related financial aspects from time to time.

13.6 FDAS Norms for the reproduction of its symbol:

It is not mandatory for accredited laboratories to use FDAS symbol, but laboratories using FDAS symbol must comply to FDAS 132 Terms and conditions for use of symbols by laboratories.

14.0 Conditions to be met by CABs when shifting of the location of CAB is involved

14.1 The laboratory should inform FDAS well in advance, before shifting the location of CAB with following information.

- Date(s) of shifting
- new location's address with documentary evidence of possession

14.2 After shifting to new location, Laboratory should

- Ensure re-calibration is completed where it is likely to be disturbed, either by going for calibration or by verification through CRMs/BNDs*
- Ensure that environmental conditions are met as per requirement

Note: Normally documentary evidence should suffice (including Documentary evidence to display right to use the new premises), but in certain cases a visit by FDAS may be required. In view of this,interested CAB should remain in touch with FDAS, so that FDAS can take action in time.

14.3 Laboratory should refrain from using FDAS accreditation during this shifting period and is allowedto use it only after the approval from FDAS.

After approval, FDAS issues revised certificate and scope to the laboratory to reflect the change of address, after receiving applicable fee.

15.0 ISO/IEC 17025:2017 & Interpretation of following clauses:

15.1: Personnel Competence

clauses 6.2.2:

"The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience".

Explanation: Since FDAS is not defining competence norms it is for the laboratory to define the competence requirements for each level of function in terms of education, qualification, training, technical knowledge, skills, and experience.

It for FDAS to determine the adequacy and compliance to the requirement of clause 6.2.2

15.2: Training

Clause (6.2.5 c) "Training of Personnel"

FDAS gives due recognition to inhouse trainings by competent laboratory personnel.

15.3 Equipment

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:

In those situations, where 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 center, subject to compliance of ISO/IEC 17025: 2017, Example: weighing balance.

15.4 Validity of Results:

Clause 7.7.1:

Laboratories must comply with requirement of ensuring validity of results from the listed option a) to k), but it is not necessary to comply to all. i.e., a) to k).

16.0 Complaints

Laboratories & its stakeholders are free to lodge a complaint to FDAS on any of their concern, FDAS would process the complaint as per its procedure. Procedure for Complaints is available on website of FDAS. Complainants are advised to address their complaint to Quality Manager, FDAS.

17.0 Appeals

Appeals against the decision of FDAS are processed as per FDAS procedure for handling appeals, which is available on FDAS website. Appellants are advised to send their appeals to Quality Manager, FDAS.

18.0 Steps Involved in getting Accreditation:

Stage I: Preparing the laboratory for Accreditation

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

- 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.
- 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

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

- Applicable fee
- Checklist – 1(ISO/IEC 17025)- FDAS 111/Checklist-1 (ISO-15189) – FDAS 112
- Management System Manual
- FDAS – 131 (Terms & conditions of FDAS to maintain accreditation)
- FDAS – 132 (Terms & conditions for use of logo by accredited CABs)
- FDAS – 138 (Legally enforceable agreement between FDAS and its accredited laboratories)

Stage III: Initial Assessment

First time applicants are subjected to initial assessment, however if applicant request for preliminary visit, FDAS is open to it, to determine the preparedness of the laboratory, through LA, & as non-consultant activity.

i. On agreed dates initial assessment is organized by Dealing Officer by constituting a team consisting of lead assessor and technical assessor(s).

ii. 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 in agreed time.

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

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

v. 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.

vi. 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 the 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 a time of one month for required corrective action, beyond which the dealing officer is to be contacted.

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

19.0 Financial obligations on the part of CABs

19.1 Application Fees: (to be paid along with application)	Rs.20000.00/ Field + applicable GST
19.2 Expansion of Scope Fee: (to be paid along with application)	Rs.20000.00/ + applicable GST when assessment isrequired. Rs. 10000.00/ + applicable GST when expansion request is from the same group in which laboratories are accredited.
19.3 Annual Accreditation Fees: (to be paid after grant of accreditation)	Rs.10000.00/Field + applicable GST

19.4 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.
19.5 Midterm, Application Fees for expansion of scope:	Rs. 20,000.00/Field + applicable GST
19.6 Fees for shifting of location of CAB	Rs. 5,000 + applicable GST.

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

20.0 Contact Details:

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FAMILIARIZATION WITH ACCREDITATION PROCESS