

**CAMS/D-01**




**CONFORMITY ACCREDITATION  
MANAGEMENT SYSTEM**

**Organization information and General  
Information Brochure' under CAMS**


**Issue No: 01  
Issue Date: 01:02:2018**

**Amendment No: 00  
Amendment: Nil**

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AMENDMENT INFORMATION

Sl no	Page No.	Specific reference no	Date of Amendment	Amendment made	Reasons of Amendment	Signature QM/MR	Signature Director
01							
02							
03							
04							

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### **Policy of CAMS towards Conformity Assessment**

International Standard ISO/IEC 17000 defines Conformity Assessment as a “Demonstration that specified requirements related to a product, process, system, person or body are fulfilled. Conformity Assessment procedures, such as testing and/or calibration, offers assurance that when products and services adhered in true spirit by CABs comply with specified or declared requirement of standard and practices.

Each organization or CAB must decide which type of conformity assessment is necessary for which purpose. This decision should be based on an assessment of the risk involved with a particular product or process, and on an understanding of the impact the associated costs and benefits will have on achievable development.

Successive reviews of the WTO/TBT agreement have established the usefulness of ISO/IEC conformity assessment standards and guide in harmonizing the conformity assessment practice and as benchmarks for the technical competence of assessment bodies, which ensures credibility and confidence in their results and associated activity.

Accreditation is the third party endorsement related to a conformity assessment body conveying the formal demonstration of its competence to carry out specific conformity assessment task.

CAMS as an authoritative body shall give formal recognition of technical competence for specific tests/measurements, based on third party assessment and prevailing best practices in line with Standard ISO/IEC 17025-2017 and ISO 15189:2012.

Inbuilt confidence in accreditation is obtained by a transparent system of control and adherence of unbiased practices over the accredited CABs. As such CAMS accredited CABs fulfils reasonably the accreditation criteria, and provides assurance to all stake holders including uses, purchaser, regulator, government, organized sector and the public.


### **About CAMS**

Dr. Sambhu Chakraborty is the pioneer in Laboratory Quality Accreditation system beginning from 1990. His Organization “IAQM” - Institute of Applied Quality Management witnessed the Laboratory quality Accreditation evolution from ISO Guide 25 to ISO/IEC 17025 and ISO 15189 in industrial and medical fields, and gained tremendous experiences while working in association with more than 500 laboratories in the country and globally.

CAMS-Conformity Accreditation Management System is introduced by the India’s’ oldest and most reputed Quality Accreditation Training Institute under the banner of Institute of Applied Quality Management.

CAMS Accreditation Board is impartial, transparent and performs accreditation and allied activities as established in its accreditation system in accordance with **ISO/ IEC 17011** “Conformity Assessment – General requirements for Accreditation bodies accrediting conformity assessment bodies”.

CAMS is providing accreditation based on ISO/ IEC 17025: 2017 ‘General Requirements for the Competence of Testing and Calibration Laboratories’ and ISO 15189: 2012 ‘Medical laboratories – Requirements for quality and competence’

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CAMS has entered agreement with International Organization for Laboratories (IOL)- An ILAC stakeholder for promotion of Laboratory quality Accreditation. IOL has given the commitment to provide financial subsidy to IOL member laboratory organization for Accreditation by CAMS only.

### **Origination Structure of CAMS**

Organization structure of CAMS has been design to meet the requirement often effective, efficient and workable accreditation system.

Organization chart of CAMS is appended below.

The chart shows the different positions of the organization, interpersonal relationship, internal and external support services, having directly or indirectly linkage with accreditation procedure and smooth functioning of the organization. Some positions are on pay role while others may be under honorary category. Dual function, may also be done by certain position without affecting the policy or integrity aspects.

CAMS operates its accreditation process through internal resources, if available and/or through Lead Assessors and Technical Assessors covering all fields and disciplines as specified in the scope of CAMS. All Lead Assessor and Technical Assessors are personnel having considerable experience in CAB activities empanelled through contractual agreements.

Such empanelment to be reviewed time to time to monitor the functioning of assessors, restricted deployment of assessors or inclusion of new assessor. Assessors are qualified and experienced. They are trained as assessors by CAMS or other accreditation bodies of national or international.

Recommendations of Accreditation Committee form the basis of accreditation decisions. Membership of accreditation committees is drawn from different bodies, experienced assessors, academic institutions, professional bodies, regulatory agencies etc. The members of the Accreditation Committee are selected on the basis of their technical knowledge, scientific experiences and familiarity with accreditation process.

For acceptance of test/ calibration data across the World, CAMS operates and commits to update its accreditation system as per international norms and through demonstration of compliance in accordance with current version of ISO/ IEC 17011.


### **Scope of CAMS Accreditation**

#### Industrial testing Laboratories

	Chemical		Mechanical		Electrical		Biological
	Non-Destructive		Electronic		Fluid-Flow		Forensic Science
	Photometry		Radiological		Others		

#### Medical testing Laboratories

	Clinical Biochemistry		Clinical Pathology		Haematology and Immunohaematology		Microbiology and Serology
	Histopathology		Cytopathology		Genetics		Nuclear medicine ( <i>in-vitro</i> tests only)

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**Accreditation Procedure**

Application for Accreditation in duly filled in relevant form CAMS/D-05 or CAMS/D-06 along with signed CAMS/D-01 and relevant fees and CAMS/D-10 or CAMS/D-11 to be submitted.

**Acknowledgement and Registration of Application**

Immediately on receipt of application form along with associate documents and fees CAMS to acknowledge the CAB and keep a record to that effect. On scrutiny of applications for its completeness or getting same rectified in all respects by correspondence, a unique number is allocated to each application of the CAB, and same used for all correspondences in future.

CAMS secretariat either through internal resources or through appropriate empanelled assessor evaluate the technical inputs and technical content as submitted in tool kit CAMS/D-10 or CAMS/D-11. In case inadequacy persists the same to be communicated to CABs for further rectification.

Based on rectification of deficiencies by CABs, completeness of criteria, and readiness for assessment CAMS would plan for assessment for which all imputes and evidences to be obtained from CABs and forwarded to assessment team members along with form CAMS/D-15.

Appointed lead Assessor/ Assessor to be briefed about any special issues or aspects to be emphasized during the course of assessment.

**Assessment**

The date(s) and time of assessment to be agreed by CABs and assessment team. A formal letter of appointment to be sent to each member of assessment team endorsing its copy to CABs for acceptance and extending cooperation.

In case CAB has any reservation against assessment team member(s), it may take up the issue with CAMS for replacement along with justification for so. CAMS will examine the issue and may consider the request if found appropriate for the sake of transparency.

CAB has to arrange for outstation and local travel and extend facility for comfortable stay at station.

If necessary Expert(s) may be appointed for assessment or be part of assessment team.

CAMS may nominate its staff member or trainee assessor to join the assessment team as an Observer.

The facility available for assessment team to be extended for Expert(s) and may be considered for observer by CAB.

Assessment team to submit report in form CAMS/D-15 or CAMS/D-16, along with appropriate evidences at the earliest, not later than 7 days, from date of completion of assessment. Specific observation to be made with regards to competence of CAB for management and technical operational aspects, suitability of technical personnel, maintenance of records including risk identification, preventive action, and decision.

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Non conformance(s) raised, if any by the team members need to be attended by CABs expeditiously and corrective action(s) to be sent to CAMS Secretariat with in a period not later than **45 days**, endorsing its copy to concern Lead Assessor/ Assessor(s)/ Expert.

Observer will submit report to CAMS with regards to his/her findings and experience gained without raising NC or endorsing its copy to CAB.

Based on recommendation of closure by concern Lead Assessor/ Assessor(s)/ Expert, CAMS will treat those as closed. Incompleteness or deficiencies if any need to be conveyed by CAMS to CABs for obtaining additional clarification, evidences or modification for acceptance by concern Lead Assessor/ Assessor(s)/ Expert and finally CAMS officials namely Managers accreditation services treats NC(s) as closed.

Assessment team in its reports shall indicate recommendation towards grant of accreditation with or without conditions. Such condition could be verification (physical or documentary) of specific deficiencies or NC(s) within a spelt out time frame not later than **45 days**. Partial acceptance of scope offered or complete denial of accreditation may also be recommended.

After satisfactory corrective action by the CAB as scrutinized and accepted by CAMS, the concern application would be taken up to Accreditation Committee by Manager Accreditation Services. Accreditation officer will present the summary during the formal meeting highlighting significant aspect for taking a clear view about the assessment before the accreditation committee for deliberation and recommendation for grant of accreditation or otherwise.

Deficiency if any, desired clarification or additional impute are sought from appropriate quarters such as CAMS secretariat CAB and or assessment team members.


Subject to satisfaction of accreditation committee and formal recommendation for so duly signed CAMS place the same to Chairman Accreditation Services (Director Accreditation Services in absence) for final acceptance or otherwise.

**Issue of Accreditation Certificate**

When the recommendation results in the grant of accreditation, CAMS issues an accreditation certificate which has a unique number and CAMS logo, discipline, date of validity along with the scope of accreditation.

Scope of accreditation to indicate range of testing/ limit of detection /specification /standard, technique used wherever applicable along with and MU / CV%.

For site laboratory, tests performed at site are clearly identified in the scope of accreditation while issuing the certificate.

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### **Continuing Accreditation**

It is obligatory on part of accredited laboratory to sustain status of accreditation by ensuring conforming to requirement of ISO/ IEC 17025: 2017 or ISO 15189: 2012 as relevant.

The accredited CABs shall be required to comply at all times with the terms and conditions of CAMS as contained in Clause 16 of CAMS/D-5/ CAMS/D-6. On the event of change in key functionary including person under whose signature test results are issued, scope( test method, range, enlargement etc.), the matter has to be intimated to CAMS within 10 days for record and subsequent appropriate actions. Similarly in case where accreditation criteria are modified the CAB will be informed about the same and advised to align this operation within 6 months time.

### **Surveillance and Re-assessment**

The CAMS accreditation certificate is valid for a period of 2 years. CAMS conducts annual Surveillance aimed at evaluating continued compliance with relevant international standerds (ISO/ IEC 17025: 2017and ISO 15189: 2012 ) and fulfilment continued terms and condition of CAMS.

#### **Surveillance**

The desktop surveillance consists of confirmation of complience of all requirment as per relevant standards by CABs along with evidences for so in toolkits no. CAMS/D- 10 or D-11 On obtaining complite information with supportive doucument evaluation to be made by CAMS.

#### **Following sitiutions and consequent procedure may arise.**

On the eve of satisfactory information, the CAB will be allowed to continue acreditation, with or without any conditions as deemed fit. Formal communication to be made to CAB accordingly.

In case some conditions are imposed or additional information sought for establishment of competency and adherence of implementation of standards,the claratfication provided by CABs to be evaluated for appropriateness and actions as under may arise.


- a) Acceptance of clarification and allowing continued accreditation,
- b) Arranging verification through on site visit by one or more assessor with respect to specific issues.
- c) When unsatisfactory, thorough on site assessment by one or more assessor(s).
- d) Based on final status appropriate decisions to be taken by CAMS which may lead continued accreditations with or without condition or denial of accreditation.

#### **Reassessment**

The accredited CAB is subjected to on site re-assessment every 1 year. The CAB has to apply 3 months before the expiry of accreditation in appropriate form no CAMS/D-05 or CAMS/D-06 along with acceptance of terms and condition, toolkit no CAMS/D-10 or CAMS/D-11 and applibable fees as content in document CAMS/D-01, so that the continuity of the accreditation status is maintained.

The entire procedure for procesing reassessment application is in line with processing of applications ( initial) and as spelt out in this brochure.



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**Appeals against Adverse decision**

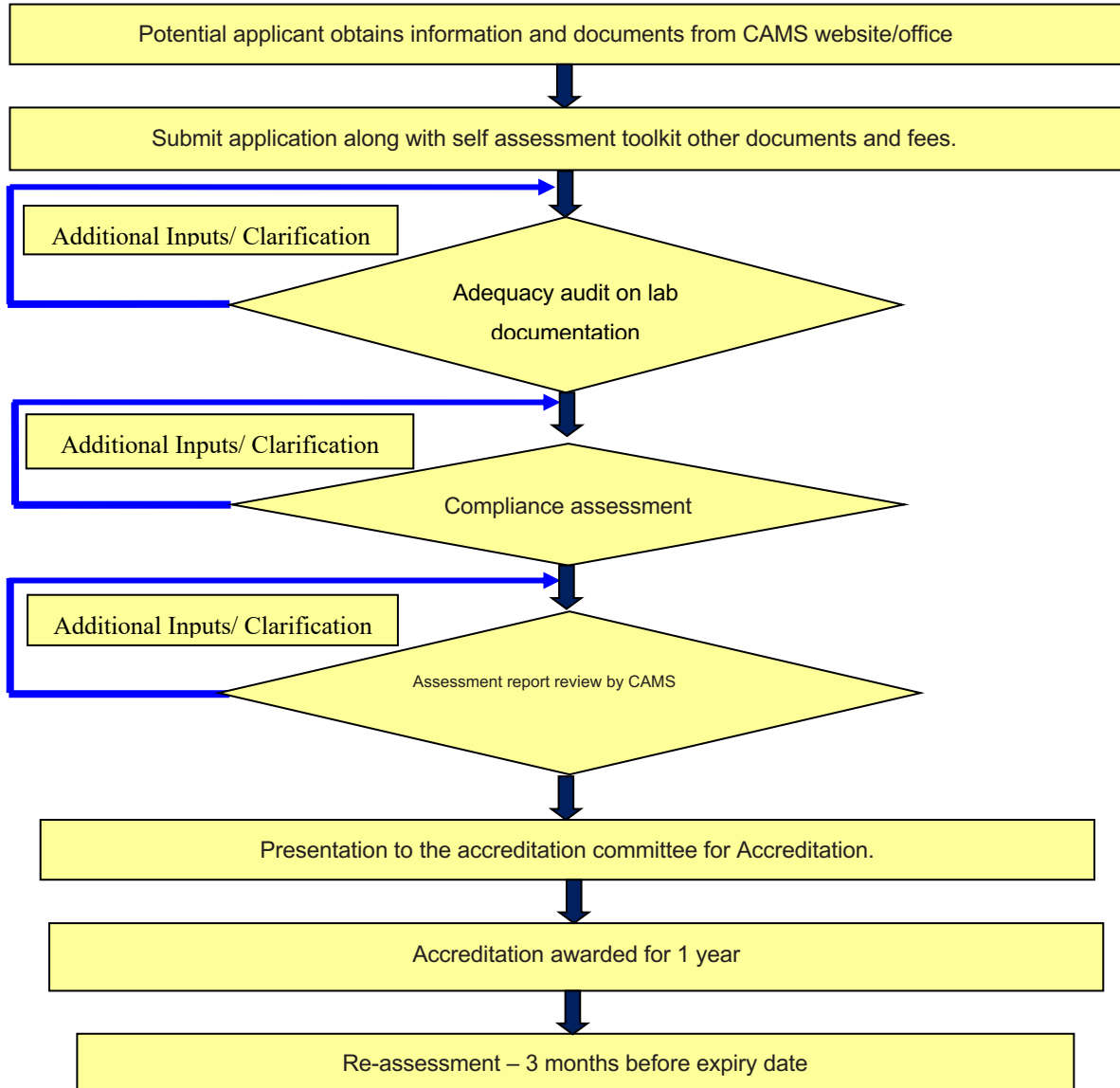
CABs have been provided with natural justices to provision of making appeal at any stage of processing as applicants or during enjoying accreditation status against adverse decision taken by CAMS.

A transparent methodology with defined authority has been designed and documented for dealings such appeals under reference (CAMS/D-13).


**Complaints**

CAMS is open to receiving complaints from individual or organisation in regards to the activities performed by its officials, assessors, functionaries associated with CAMS or in regards to accredited CABs. Primarily General Secretary will be responsible for receiving and maintaining records in accordance with documented procedure for dealing of complaints. (CAMS/D-13).

**ACCREDITATION FLOW CHART**



<b>FEES STRUCTURE</b>			
<b>SL. NO.</b>	<b>FIELD</b>	<b>APPLICATION FEES</b>	<b>ACREDITATION FEES (per year)</b>
<b>A.</b>	<b>Medical Laboratories</b>		
1.	Small Laboratories (Up to 100 patients/ day/location)	₹15,000	₹16,000
2.	Medium Laboratories (101-400 patients/ day/location)	₹35,000	₹38,000
3.	Large Laboratories (401-1000 patients/ day/location)	₹88,000	₹95,000
4.	Very Large Laboratories (above 1000 patients/ day/location)	₹1,75,000	₹1,90,000
<b>B.</b>	<b>Charges For Collection Centers attached to the laboratory</b>		
1.	For one Sample collection centre	₹200	₹800
<b>C.</b>	<b>Testing Laboratories (Per discipline)</b>	₹8,500	₹19,000
<b>D.</b>	<b>Assessment Fees ( per Assessment Visit)</b>	₹10,000	
<b>E.</b>	<b>Assessor charge</b>		
1.	Lead Assessor ( Per Day)	₹5,000	
2.	Technical Assessor ( Per Assessor /Per day )	₹5,000	
<b>F.</b>	<b>Additional/Special Assessment Fees as per requirement, per assessment visit including assessor fee.</b>	₹12,000	
Assessor travel & allied expenditure (lodging and boarding, local transport ) Actual charges, cost of to & fro journeys (flights Economy class or by 2nd AC Class train or AC Bus and decent accommodation to be arranged/borne by CAB. No cash transaction be effected			
All payments shall be made by at par cheque / Demand draft / NEFT payable in favor of CAMS at Kolkata. In addition to the above-mentioned fee, GST @ 18.0 % (Existing) or as applicable to be paid along with said charges / fees.			
Corporate/ Govt. Laboratory may request to submit the quotation. No of Auditors deployment and day(s) of assessment will depend on the location and scope of Accreditation involved.			

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