



Report on Need of Laboratory Accreditation System for CEMS in India



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Abbreviations

ACIME-Association for the Certification of Measuring Instruments for the Environment
AETB- Air Emissions Testing Bodies
AMS- Automated Measuring Systems
ANAB- American Association for Laboratory Accreditation
ANSI- American National Standards Institute
APLAC- Asia Pacific Laboratory Accreditation Cooperation Inc
ASCLD/LAB- American Society of Crime Laboratory Directors / Laboratory Accreditation Board
AST- Annual Surveillance Test
ASTM- American Society for Testing and Materials
CAB-Conformity Assessment Body
CAIR- Clean Air Interstate Rule
CAMD- Clean Air Markets Division
CE- Conformité Européenne
CEMS- Continuous Emission Monitoring Systems
CEN- European Committee for Normalization
CFR- Code of Federal Regulations
CSA- Canadian Services Association
EA-Environmental Agency
EA-European Co-Operation for Accreditation
ECMPS- Emissions Collection and Monitoring Plan System
EPA-Environmental Protection Agency
EN-European Norms
EU-European Union
IAAC- Inter American Accreditation Cooperation
IAF- International Accreditation Forum
IAS- International Accreditation Service
IEC- International Electrotechnical Commission
ILAC- International Laboratory Accreditation Committee
ISO- International Organization for Standardization
LAB- Laboratory Accreditation Bureau
MCERTS- Monitoring Certification Scheme
MLA- MultiLateral recognition Arrangement
MoEF&CC- Ministry of Environment, Forest and Climate Change

MRA- Mutual Recognition Arrangements
NABL- National Accreditation Board for Testing and Calibrating Laboratories
NVLAP- National Voluntary Laboratory Accreditation Program
PAC- Pacific Accreditation Cooperation
PJLA- Perry Johnson Laboratory Accreditation
QAL- Quality Assurance Level
RATA- Relative Accuracy Testing Audits
SCS- Sir Certification Scheme
TGN- Technical Guidance Note
UBA- Umweltbundesamt
UKAS- United Kingdom Accreditation System

1. Introduction

Continuous Emission Monitoring System (CEMS) is an active and indispensable part of pollution monitoring in developed economies like members of European Union (EU), United States of America (USA), and Japan etc. It has been extensively utilized to regulate emissions of gases and particulate matter in the atmosphere for the last 25 to 30 years. One of the most crucial factors behind the success of CEMS in these countries is the assured systems required such as for certification or quality assurance of devices, extensive testing & verification of devices by independent agencies, defined roles and responsibilities and guidelines.

India adopted the continuous emission and effluent monitoring systems two years back in 2014 when Central Pollution Control Board (CPCB) mandated major industries and common pollution control facilities to install CEMS. Irrespective to the scale of operation, continuous effluent quality monitoring has been mandated in all industries situated in Ganga basin. Now, implementation of this initiative requires all the must have systems such as certifications system, lab empanelment systems and the respective guidelines and protocols for CEMS implementation. Such systems have been available in India but not for CEMS.

Therefore, the best way to achieve this is to look at how these systems have been set-up in other countries, , how existing similar systems work in India and accordingly develop a strategy to create such systems.. This report is an attempt in this direction. It identifies the systems available in other countries like US, UK, Germany etc., existing similar systems in India and discusses how India can move ahead.

2. Laboratory Accreditation Systems

An independent third party testing, verification and certification brings credibility to the results and system. In industries, independent recognized/accredited labs carry the job of pollution monitoring. Accreditation plays a key role through which a laboratory gets formally recognized for its potential to carry out specific tasks and processes. Accreditation gives confidence and justifies the quality of results by ensuring they are valid, easy to trace, compare, and modify. An authorized governmental or non-governmental or private body accredits the labs on the basis of internationally recognized standards.

Economies like EU and USA have recognized/accredited laboratories especially for CEMS. These laboratories are well equipped and have experienced and trained personnel for device testing, installing and performance checking of CEMS. Such a

system for CEMS is not yet developed in India. There is a need to have accredited laboratories for CEMS which ensures the credibility of data obtained.

2.1 Accrediting Bodies

Accreditation of laboratories (also called conformity assessment bodies/CAB) is carried out by an authorized accreditation body. Every country has established accreditation body(ies). For example, National Accreditation Board for Testing and Calibration Laboratories (NABL) is accrediting body in India, United Kingdom Accreditation System (UKAS) is accrediting body in United Kingdom (UK), and Standards Council of Canada is accrediting body in Canada etc.

All these accreditation bodies follow a global system of accreditation headed by two organizations namely the International Laboratory Accreditation Committee (ILAC) and the International Accreditation Forum (IAF)ⁱ under a Mutual Recognition Arrangement (MRA). Under MRA, each signatory mutually recognize and respect the laboratories that are accredited by any other signatory.

ILAC is involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189) and inspection bodies (using ISO/IEC 17020). It evaluates, recognizes and then links regional cooperating bodies like International American Accreditation Cooperation (IAAC), European co-operation for Accreditation (EA) and Asia Pacific Laboratory Accreditation Cooperation (APLAC) through its MRA which carry out accreditation of laboratories on behalf of ILAC. It also works in harmony with other regional cooperation bodies like African Accreditation Cooperation (AFRAC) in Africa, Southern African Development Community Cooperation in Accreditation (SADCA) in Southern Africa, and Arab Accreditation Cooperation (ARAC) in the Arab region.

IAF carries out conformity assessment in the fields of management systems, products, services, personnel and other such similar programs. IAF Multilateral Recognition Arrangement (MLA) relies majorly on regional accreditation groups- European co-operation for Cooperation Accreditation (EA), Pacific Accreditation Cooperation (PAC), Inter American Accreditation Cooperation (IAAC), African Accreditation Cooperation (AFRAC), ARAB Accreditation Cooperation (ARAC) and Southern African Development Community Cooperation in Accreditation (SADCA) for carrying out the peer evaluation.

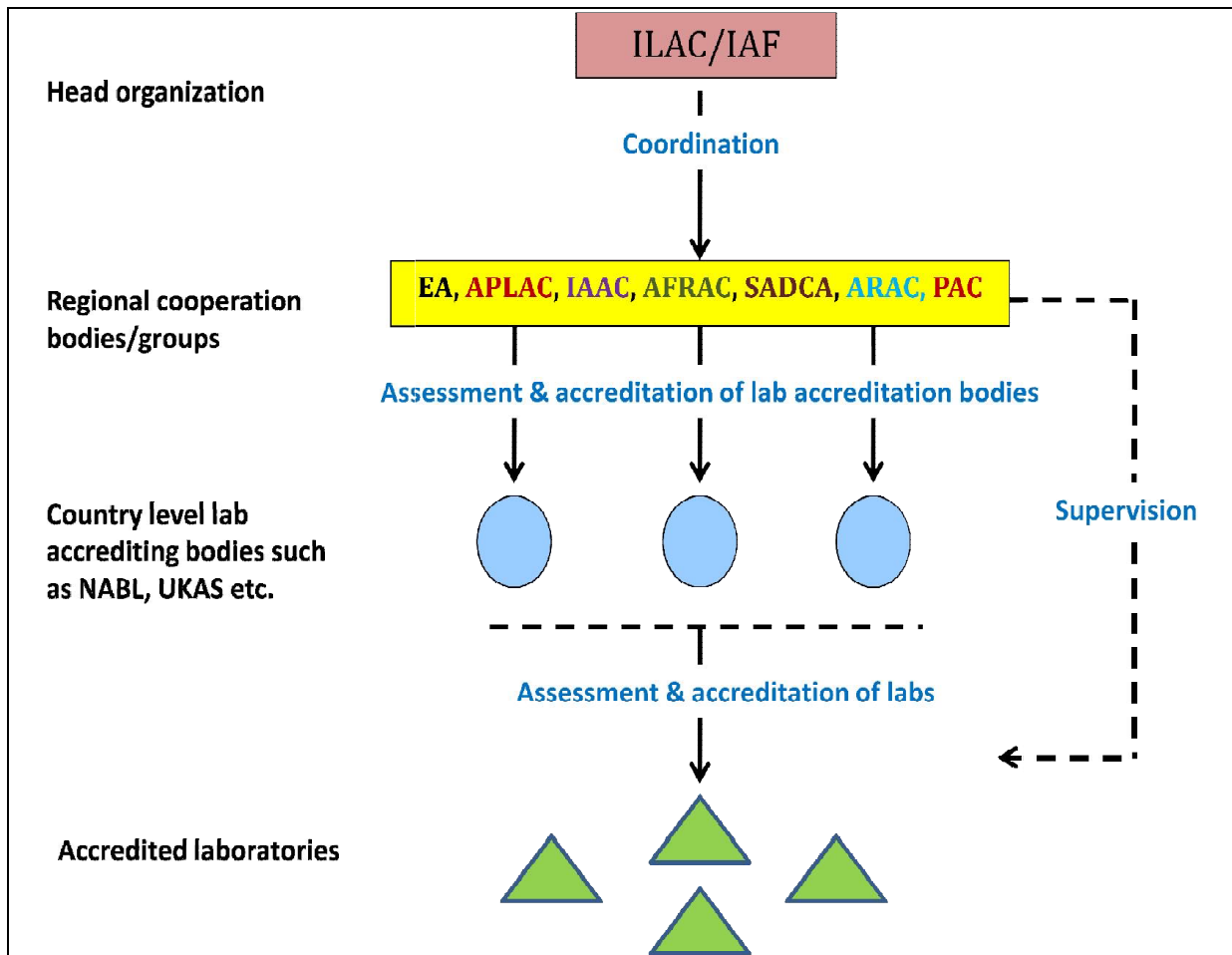


Figure 1: Evaluation carried out by IAF/ILAC

The regional cooperation bodies/groups evaluates and accredits country level lab accreditation bodies/institutions who assess the performance and accredit the labs for respective jobs they apply for. There are nine institutions in the USA who are a part of ILAC and under IAAC, carry out accreditation of Labs. In India, NABL is the institution which is a member of APLAC and carries out accreditation of all labs. However, it doesn't have a system to evaluate and accredits the labs which are dedicated for CEMS.

2.2 Laboratory Accreditation System in Europe

European countries have done well in achieving high air quality. Within Europe, Germany and the United Kingdom (UK) are pioneers of emission monitoring systems. Both of these have similar working processes.

In the UK, United Kingdom Accreditation Service (UKAS) is the national accreditation body.ⁱⁱ It assesses organizations for certification, testing, inspection and calibration services based on national and internationally recognized standards.

UKAS accredits environmental testing laboratories to ISO/IEC 17025; against a wide range of scopes that include the environmental analysis of soils and contaminated land, drinking water, waste water, effluents and leachates, stack emissions and atmospheric pollutants. The other relevant accreditation services include testing and calibration laboratories; certification bodies; inspection bodies; proficiency testing scheme provider; reference material producers.

The typical lab accreditation by UKAS starts with request submitted by applicant. Before application, need to familiarize itself with the process, requirements and other necessary information. After application, an optional pre-assessment visit is carried to evaluate applicant's readiness and scope of accreditation and quotation for the work and report on pre-assessment is submitted. Initial assessment visit (first formal visit) is carried by a lead assessor (may be accompanied by technical assessor) and submits a report on findings including the any improvements required. Within 12 weeks post assessment, the applicant satisfies UKAS that the improvements have been made as recommended during initial assessment. Once any mandatory findings are cleared, the lead assessor/assessment manager recommends UKAS to grant accreditation. The applicant lab receives a certificate of accreditation, and their scope of accreditation is made public UKAS website.

The accredited lab undergoes UKAS surveillance visit every year including first surveillance visit within 6 months. Full assessment is carried every fourth year. See the process flow-chart in figure 2ⁱⁱⁱ.

Sira Certification under the Canadian Services Association (CSA) Group is accredited by UKAS (as per ISO/IEC 17000 series of conformity assessment standards) to undertake the product and personnel certification activities^{iv}. CSA Group is certified by UKAS (as per ISO/IEC 17065:2012 conformity assessment requirements) for certifying products, processes and services. CSA is the Environment Agency of England & Wales (EA) Monitoring Certification Scheme (MCERTS) certification body and provides certification of equipment, personnel and inspection services. The scheme is built around International and European standards to ensure monitoring data is of a high standard.

All testing under MCERTs is carried out by laboratories or agencies accredited to ISO 17025 by UKAS. CSA examines the results of the laboratory tests and field tests using a group of independent experts / Certification Committee. The accredited laboratories follow the monitoring methods specified in relevant Technical Guidance Note (TGN).

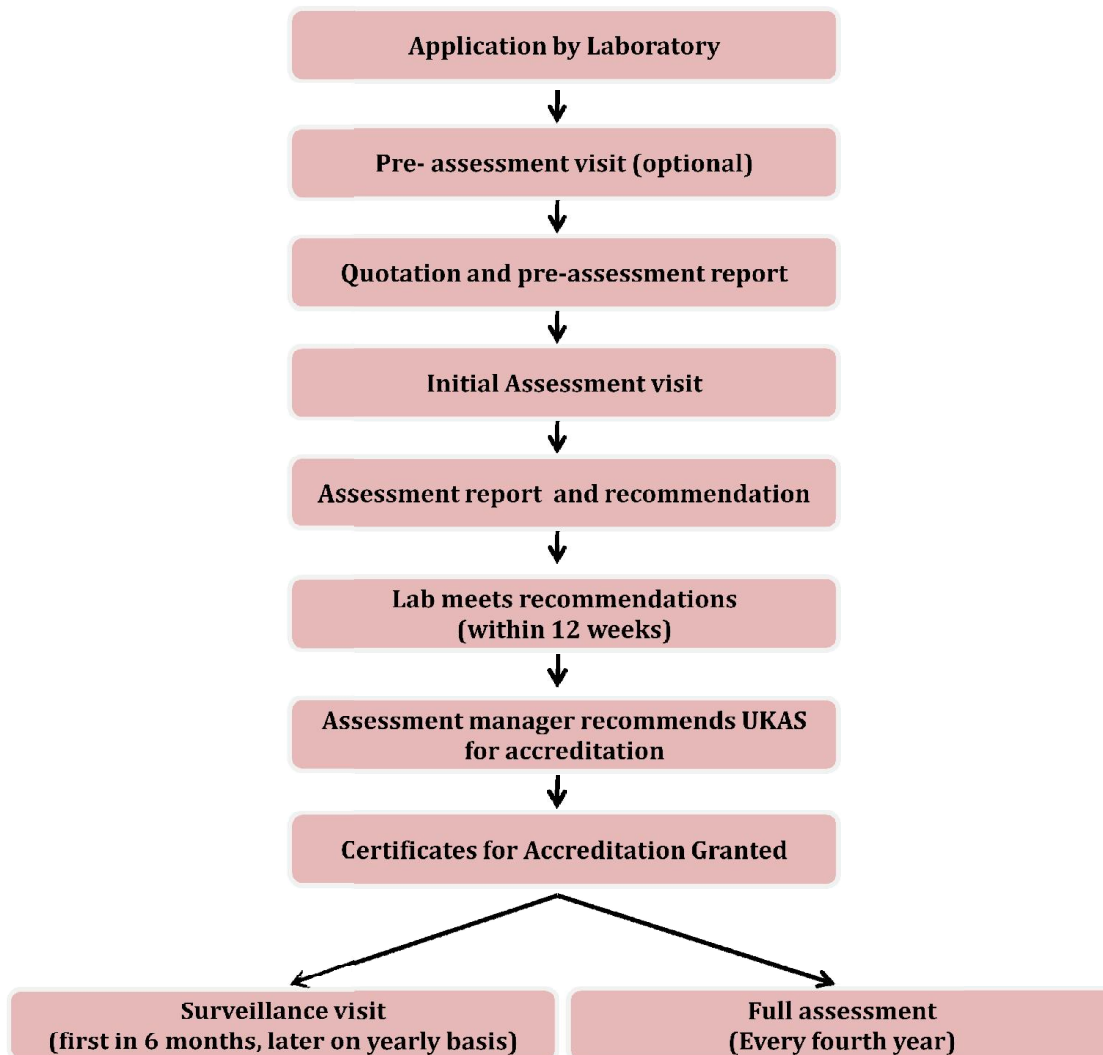


Figure 2: Laboratory Accreditation process in the UK

With respect to CEMS, the laboratories certified under ISO 17025 can perform tests calibration as per the laid standards for CEMS. Laboratories follow ISO 14181 standard for quality assurance of CEMS under three quality assurance levels (QAL 1, QAL2 and QAL3). QAL1 deals with certification CEMS, QAL2 deals with correct installation, functionality tests and calibration and QAL3 includes quality assurance during operation. In addition, Annual Surveillance Test (AST) is carried similar to QAL2.

In Germany, AMS suitability testing is carried out based on procedures mentioned in VDI – 4203 Part 1. Part 2 describes specific procedures to check compliance with minimum requirements on measuring systems for continuous monitoring of gaseous and particulate emissions.

2.3 Laboratory Accreditation System in the United States of America (USA)

There are multiple laboratory accreditation bodies recognized by different regional cooperation bodies like IAAC, APLAC etc. under ILAC. Some of the IAAC recognized bodies/institutions are American Association for Laboratory Accreditation (A2LA), ANSI-ASQ National Accreditation Board (ANAB), National Voluntary Laboratory Accreditation Program (NVLAP), AIHA's Laboratory Accreditation Programs, LLC, American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB) etc. Others like Perry Johnson Laboratory Accreditation, Inc. (PJLA), Laboratory Accreditation Bureau (L-A-B), are recognized by APLAC.^v

The laboratory accreditation process in USA is more or less same that of UKAS with minute changes^{vi}. The flow diagram below represents accreditation process adopted by ANAB for- ISO/IEC 17025.

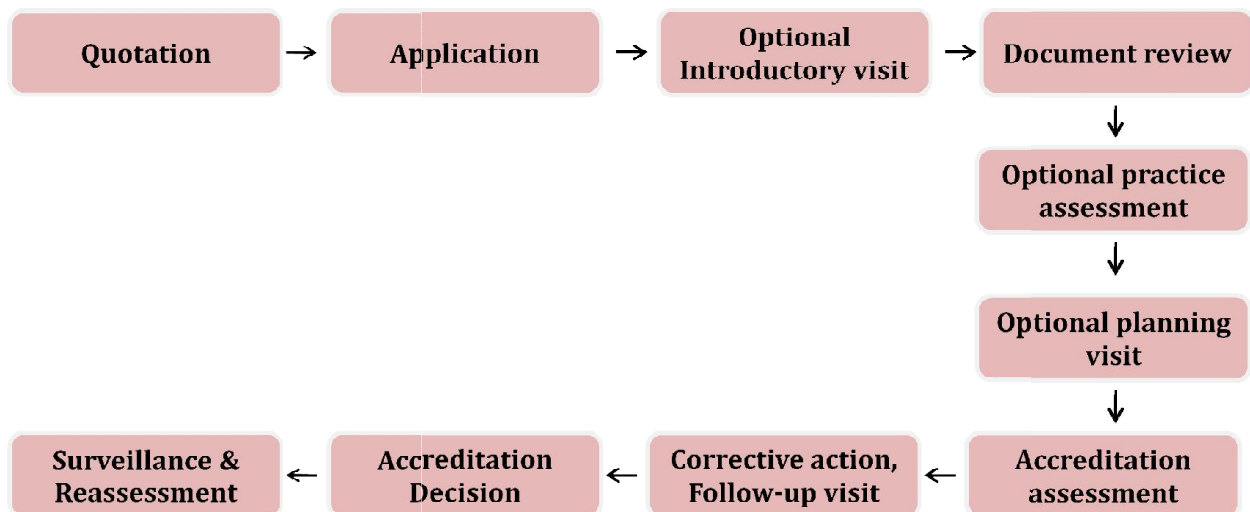


Figure 3: ANAB Laboratory Accreditation for ISO/IEC 17025, USA

The laboratory accreditation for testing and calibration for CEMS in USA is carried under ISO/IEC 17025 standard only similar to Europe or other countries. However, capability of laboratories and competency of the staffs are assessed and evaluated in relation to CEMS. In USA, all the regulations for CEMS are specified under Code of Federal Regulation (CFR) 40, part 75. All the responsibilities of CEMS specifications, tests, quality assurance and control lie with the operator.

2.4 Existing Laboratory Accreditation System in India

In India, NABL is responsible for assessing the quality and technical competence of

testing and calibration of laboratories. NABL is an accredited by APLAC under ILAC and is in the process of becoming a signatory to the APLAC MRA.^{vii}

NABL follows internationally accepted guidelines and process for accreditation. Accreditation seeking laboratory submits application to NABL in a specified format. Application is checked for completeness with reference to the relevant accreditation. NABL appoints an assessment team led by lead assessor to carry a pre-assessment visit of the laboratory mainly to evaluate non-conformities (if any) in the implementation of the quality system and assess the degree of preparedness of the laboratory for the assessment. Size of the assessment team depends on the scope of accreditation, number of key location to be visited etc.

Based on the pre-assessment visit, the lead assessor submits a report to NABL Secretariat and its copy to the applicant laboratory. As recommended by pre-assessment team, the applicant laboratory takes corrective measures, if required, to ensure compliance and submits a report to NABL Secretariat.

Next, NABL constitutes an assessment team comprising the lead assessor and technical assessor(s)/ expert(s) in order to cover various fields within the scope of accreditation sought. NABL may also nominate an observer. The assessment team reviews the laboratory's documented management system, verifies its compliance with relevant specific criteria/standards and evaluates technical competence to perform specific tasks.

A report on findings of the visit is sent to NABL Secretariat and recommendation is extended towards grant of accreditation or otherwise. A copy of summary of assessment report and copies of non-conformities if any, are provided to the applicant to take corrective measures. Applicant submits a report on corrective measures to non-conformities to NABL Secretariat within 60 days. After satisfactory corrective action by the applicant laboratory, the Accreditation Committee examines the assessment report and additional information and makes appropriate recommendations regarding accreditation of the laboratory to the Chairman, NABL. When the recommendation results in the grant of accreditation, NABL issues the accreditation certificate.

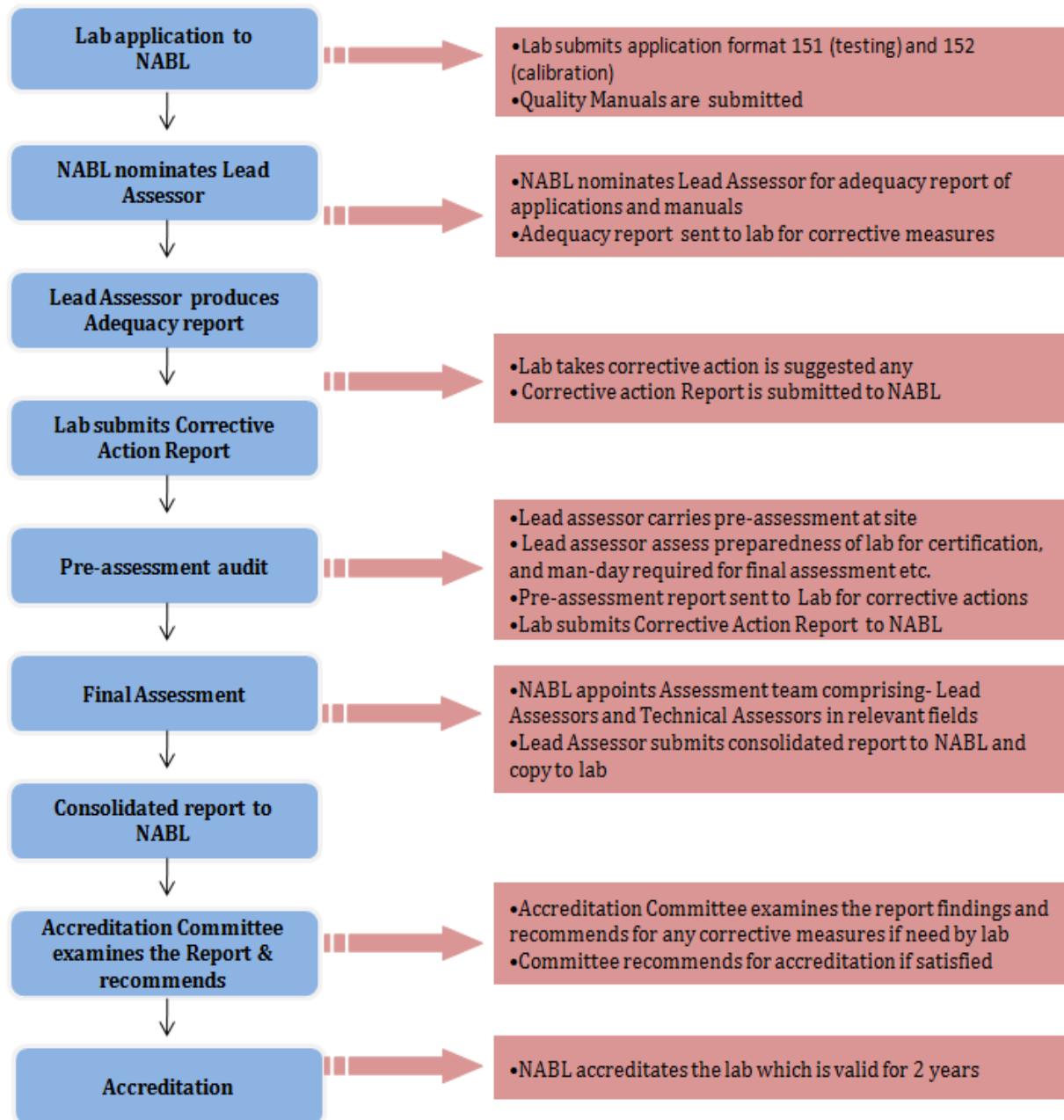


Figure 4: Laboratory accreditation by NABL

The accreditation certificate remains valid for a period of 2 years. NABL conducts annual Surveillance every year which is aimed at evaluating continued compliance to the requirements of relevant standards, specific criteria and NABL Policies. Reassessment of laboratory is carried every 2 years for which laboratory needs to apply 6 months before the expiry of accreditation so that the continuity of the accreditation status is maintained.

NABL accreditation is offered to all types of testing and calibration laboratories including environmental laboratories in India and abroad, regardless of their ownership legal status, size and degree of independence. However, lab accreditation for testing and calibration of CEMS is not available.

2.5 Need of Laboratory Accreditation System for CEMS in India

There are established procedures under ILAC which are followed for accreditation of different types of laboratories for their scope of work. As such, there is no exclusive system for lab accreditation for testing and calibration alone for CEMS. Rather, testing and calibration of CEMS is also done by the laboratories which are accredited to ISO/IEC 17025 but they are assessed and evaluated for handling tasks related to CEMS as well.

Every country that has adopted CEMS, has laid guidelines/standards for carrying tests, performance check, quality assurance and quality control specific to CEMS which needs to be followed by the authorized laboratories. Europe which has the system for CEMS certification also accredits laboratories for their competency for this task whereas in USA laboratories are accredited to carry performance checks during installation rather than certification.

Laboratory accreditation has a key role in success of CEMS initiative. Though, India doesn't have such a system till date, it needs to. The accreditation of laboratories will be needed for following key CEMS related tasks:

1. to carry tests in order to certify the DEMS device
2. to check the CEMS performance during installation
3. to carry tests and calibration during maintenance
4. to perform third party verification

2.6 Laboratory requirements for CEMS

To perform the tasks related to the CEMS, a laboratory needs to be equipped with the basic infrastructure and skilled manpower. These requirements depend on the scope of the jobs it wants to perform. A number of components need to be tested each with different physical measuring principle which requires specific test equipments. The key requirements can be summarized as follows:

A) Equipment required for lab tests

The laboratory will need major infrastructures such as

1. Climatic Chamber, large enough to test two whole analyzer cabinets
2. Controlled transformer to examine the influence of power voltage fluctuations
3. Vibration simulations stand
4. Data collecting system (mA and maybe digital data transmission)



Figure 5: Pictures of laboratory requirements for CEMS

5. Additional requirement for testing gaseous CEMS
 - Different calibration and test gas cylinders/bottles
 - System for production of test gas mixtures with precise mass flow controller
 - Sample gas pressure measuring unit
 - Sample gas flow measuring unit
6. Additional requirement for testing gaseous CEMS
 - Different calibration and test gas cylinders/bottles
 - System for production of test gas mixtures with precise mass flow controller
 - Sample gas pressure measuring unit
 - Sample gas flow measuring unit

7. Additional requirement for testing PM CEMS -

- Dust emissions simulation facility

8. Additional requirement for testing flow measurement:

- Flow emissions simulation facility (mostly comes with the dust simulation facility)

B) Equipment required for field tests

- Component specific equipment for QAL 2 test
- Equipment for lack of fit test (for example: test gas mixtures with precise mass flow controller, gray filter for dust etc.)
- Data collecting system (mA and maybe digital data transmission)

C) Any other equipment/facility required

- Specific test equipment which belongs to the CEMS like filter etc.
- A lot of small parts and measurement units for temperature, pressure and humidity etc.

Mass flow controller



High precision instruments and test facility equipments



Equipments and skilled manpower for field testing



Figure 6: Pictures of laboratory requirements for CEMS

D) Skilled manpower requirement- the Laboratory must need skilled manpower with practice in CEMS calibration and maintenance.

E) Certifications requirement- for recognition and traceability, the laboratory needs relevant certification. For international accreditation, the laboratory may need ISO 17025 certification under ILAC/IAF. It may require any other accreditation mandated by national government.

2.7 Recommendation for Laboratory Accreditation System for CEMS in India

The above discussed tasks to be done by laboratories bring accuracy to the CEMS device and credibility to the CEMS framework. An accurate and credible CEMS framework is crucial for improving the environmental compliance enforcement and leading towards self monitoring and control regime in India.

Following can be done to develop a laboratory accreditation system for CEMS in India:

- The government, precisely MoEF&CC or CPCB, needs to take initiative for this and approach the competent agencies and develop strategy for developing such a system within six months. Similarly, the government should plan to develop a CEMS device certification system within two years. Keeping the timeframe in mind, CPCB should mandate-
 - The certification of domestically produced CEMS within two years of timeframe.
 - Until the certification system is developed, performance check of CEMS device during installation should be mandated.
 - All the installed CEMS should also be tested and verified by accredited laboratories within one year. The report should be approved by SPCB or CPCB.
 - Every industry should get the CEMS installation verified by an accredited laboratory on yearly basis and report should be submitted to SPCB and/or CPCB.
- NABL appears to be most suitable organization for developing the CEMS certification system. It already follows the international standard- ISO/IEC 17025 for laboratory accreditation for testing and calibration. CEMS can be included in the scope of accreditation. However, NABL may require government's support to develop the additional infrastructure for this purpose.
- The expert laboratories such as TUV Rheinland, TUV SUD etc. which have been successfully carrying this task in Europe and other countries for many decades.

They have expertise and set-ups in India which can be upgraded for this purpose. MoEF&CC or CPCB can approach them and develop the strategy.

- These agencies may be asked to prepare a proposal and plan for setting up a facility in a given time line for this purpose.
- Since these agencies will have to invest in developing adequate infrastructure, Government's support and assurance will be encouraging to them.
- As happens in Europe and other countries, other governmental, non-governmental and private agencies can be allowed to become a certification agency by developing required infrastructure. However they would need to develop entire infrastructure from scratch which could be time taking.
- The existing laboratories recognized by NABL and EPA, can be invited to build the required infrastructure and given opportunity for easy recognition or empanelment for CEMS tasks if meet the criteria. They can be trained to carry these tasks. Capacity building for stakeholder will also be needed so should be given importance.
- The laboratory accreditation system should be financially self-sustainable. A constitutional/legal set-up, group of experts for assessment and evaluation of laboratories, guidelines, protocols, standard operating procedure to be followed and, role& responsibilities of every stakeholders etc. need to be defined.
 - The regulations/standards mandating tasks/tests for CEMS, similar to EN 14181 of Europe should be laid down for certification purpose.
 - The regulation/standards mandating tasks/tests for CEMS for performance tests, similar to USA, as mentioned under 40CFR part 75, need to be laid down.
 - The detailed guidelines and instructions to perform the tasks need to be laid down. These guidelines and process of tests etc. are well established in the countries where CEMS has been implemented. These can be customized as per the competency, suitability and need in India.

Since CPCB has been instrumental in CEMS initiative, it has opportunity to play the key role. It can propose and recommend for such a system to be in place. The relevant expert agencies from other countries can be consulted and roped in for required support in this initiative. CEMS extends huge business opportunities, therefore, it will attract

immense interests from leading laboratories to come forward and build their infrastructure and capacity for accreditation/ empanelment for CEMS tasks. A time-bound strategy needs to be developed for this.

3. References

ⁱ ILAV website, ILAC MRA and Signatories

<https://ilac.org/ilac-mra-and-signatories/>

ⁱⁱ UKAS website, Accreditation standard

<https://www.ukas.com/about/about-accreditation/the-accreditation-process/accreditation-standards/>

ⁱⁱⁱ UKAS Website, The Route to Accreditation

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^{iv} CSA Group website, MCERTS

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^v Standardsportal.org, ANSI, Resources: US Laboratory Accreditation Bodies

https://www.standardsportal.org/usa_en/resources/usaccreditation_bodies.aspx

^{vi} ANAB website, How to Achieve ISO/IEC 17025 Accreditation

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^{vii} NABL Website, Accreditation Scheme

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