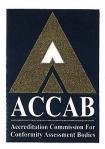
## ACCREDITATION COMMISSION FOR CONFORMITY ASSESSMENT BODIES



Independent & International Accreditation Services for: Certification & Inspection Bodies ♦ Testing & Calibration Laboratories ♦ Medical Laboratories

To,
Dr.T Ramasami,
The Secretary,
Room 24, Administrative Block,
Technology Bhavan,
New Mehrulli Road,
New Delhi – 110016.

Ref: Letter dated 23 January 2012.

Sub: Recognition of Accreditation Services for Testing, Calibration and Medical Laboratories provided by Accreditation Commission For Conformity Assessment Bodies (ACCAB), as per the WTO Agreement on Technical Barriers to Trade and the Competition Act of India.

Respected Sir,

Greetings from Accreditation Commission For Conformity Assessment Bodies (ACCAB)!

Accreditation Commission for Conformity Assessment Bodies (ACCAB) is a trading name for Accreditation Commission for Conformity Assessment Bodies Private Limited, a company limited by shares duly registered under the Companies Act, 1956, Republic of India.

ACCAB operates **VOLUNTARY** Accreditation Programs for Testing, Calibration and Medical Laboratories according to the various international standards such as ISO 17025:2005 and ISO 15189:2007.

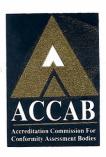
The activity of laboratory accreditation has been around for almost fifty years. With the development of product and quality system certification, technical support such as testing, measurement and calibration has also become increasingly important. Laboratory accreditation is a formal recognition by a third-party authority of a laboratory's capability to perform testing, measurement and/or calibration activities.

The objective of the ACCAB accreditation services is to encourage the local laboratories to enhance their management system, technical capability and competitiveness, as well as to reduce the number of second-party audits (i.e. by the clients of the laboratories). Under mutual recognition agreements, laboratory accreditation could also contribute to a breaking down of non-tariff barriers. These services are offered in a non-discriminatory manner and are accessible to all testing and calibration laboratories in India and abroad, regardless of their ownership, legal status, size and degree of independence.

Accreditation Commission for Conformity Assessment Bodies (ACCAB) is the first private sector accreditation body in India other being National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India, and is registered under the Societies Act 1860.

About Accreditation Commission for Conformity Assessment Bodies (ACCAB):

Corporate Headquarter: Accreditation Commission for Conformity Assessment Bodies Private Limited Suite #113-114, Level I, Master Mind IV, Royal Palms, Aarey Colony, Goregaon (East), Mumbai - 400 065, India. Web: www.accab.org | Email: info@accab.org | Tele/Fax: +91 22 28794410, +91 22 28794411, +91 22 28794412



ACCAB operates in accordance with the requirements, criteria, rules and regulations laid down in the following documents:

- The requirements of the international standard ISO/IEC 17011:2004, which are the general requirements for bodies providing assessments and accreditation of conformity assessment bodies;
- The requirements and other benchmarks as stipulated in the Publicly Available Documents (PAD) published by various International Standardization Bodies and ACCAB;
- Legally established objectives as per the Memorandum & Articles of Association with the Registrar of Companies, Mumbai Maharashtra, Ministry of Corporate Affairs, India.

ACCAB is an Affiliate Member of the International Laboratory Accreditation Cooperation (ILAC), the other member from our country is NABL. Further ILAC has clarified that Accreditation services can also be provided by private sector/nongovernment organizations and there are many instances that such type of organizations are already operating in other economies of the world and they are also members of the ILAC.

## Further it may be noted that:

- The NABL has not been notified as a Statutory Authority by an act of Parliament to provide accreditation services for the Technical Regulations of mandatory nature.
- The ISO 17025:2005 International Standard clause 1.5 stipulates that "compliance with regulatory and safety requirements on the operation of laboratories is **NOT** covered by this International Standard".
- Also, Indian Government does not recognize pathological/clinical laboratory services under mandatory national regulations, hence ISO 15189:2007 accreditation is treated voluntary in India.
- The Laboratory Accreditation Services have not been declared as the "Public Interest Activity" by either the Central or any State Government.

## **ACCAB's Application for Consideration by Your Good Offices:**

In the light of the foregoing, Accreditation Commission for Conformity Assessment Bodies (ACCAB) hereby presents its application to your good offices, seeking recognition, as an Accreditation Services Provider for the Testing, Calibration and Medical Laboratories.

The following salient facts, features and the criteria in support of our application are placed for your kind perusal:

• In keeping with the tone and tenor of the Competition (Amending) Act, 2007 which discourages any dominant position to any entity including any government backed or sponsored agency in terms of providing goods and services as against other competitors which will enable a level playing field for the NABL and the ACCAB.



- The recognition to the ACCAB shall initiate the additional capacity building, shall create Public Private Partnership and shall create multiple options for an Indian industry, trade and commerce in the field of the Voluntary Laboratory Accreditation Services.
- A thorough market study undertaken by ACCAB reveals, that majority of laboratories, who intend to go for accreditation/continuation of accreditation and reaccreditation of NABL services are seemingly deprived of attaining their objectives due to reported huge back log, delays and procrastination due to non-availability of suitable and competent alternative in the market. Just to give, an example from the list of many, the number of pathology laboratories accredited as on date are handful as against total number of pathology laboratories operating in India, which is in the region of 50000-80000, that clearly indicates limited outreach by the NABL.
- The availability of more accreditation bodies in the market shall provide, much needed impetus for the laboratories to go for the voluntary accreditation, considering the tremendous projected growth in the areas of food safety, chemical, pharmaceutical, biological, pathological, environmental, geological and infrastructure related testing & many more hitherto undefined areas in India.
- However, many laboratories have reported to us that they wish to avail the ACCAB accreditation services, however are not in position to do so due to specific guidelines issued by the various government bodies and authorities, wherein only NABL accreditation services have been prescribed/recommended as compulsory, giving rise to an erroneous impression that the laboratories are to be accredited by NABL only. This practice has come to be popularly known as "NABL ACCREDITATION". Whereas internationally it should be referred to or called by its correct nomenclature as ISO 17025 or ISO 15189 Accreditation which is globally accepted and followed.
- It may be considered therefore that such guidelines issued by your office as from time to time for Testing, Calibration & Medical Laboratory Accreditation should be w.r.t. the standard such as ISO 17025 or ISO 15189 accreditation. Alternately if the name of the accreditation body is required to be mentioned then all the internationally recognized accreditation bodies need to be listed in the guidelines. As of now it could be written as laboratory accreditation as per ISO 17025 or ISO 15189 (by NABL / ACCAB).

In view of the forgoing submissions, for according recognition and acceptance to the laboratory accreditation services provided by the ACCAB, kindly place our application on record and expedite the needful in order to fulfill the interest of the stakeholders of the conformity assessment business and support the common objectives of the various national & international institutions. The progressive and demanding growth of the trade in India warrants that suitable options to be created and implemented in order to prevent and preclude **BARRIERS TO TRADE**.

Thanking you and we do look forward to your kind cooperation and assistance in working towards achieving a common goal.



Yours Sincerely,

For Accreditation Commission for Conformity Assessment Bodies Private Limited.

Dilip H. Deshmukh

**Chief Executive Officer** 

## Encl. Copies:

- Order dated 17<sup>th</sup> January 2014 by the Hon'ble Competition Appellate Tribunal New Delhi.
   Competition Appellate Tribunal Order Synopsis
- 3. ACCAB Brochure
- 4. Government of Maharashtra EMN Certificate
- 5. Copyright Certificate issued by the Copyright Office, Government of India.

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