



COMPETITION COMMISSION OF INDIA

Case No. 25 of 2020

In Re:

Prem Prakash

Proprietor, Venus Testing and Research Laboratory,
Industrial Area, Khurai Road, Bina

Distt. Sagar (M.P) - 470113

Informant

And

Chairman, Quality Council of India,

3rd floor, Institution of Engineers Building,

Bahadur Shah Zafar Road, New Delhi-110002

Opposite Party

CORAM:

Mr. Ashok Kumar Gupta

Chairperson

Ms. Sangeeta Verma

Member

Mr. Bhagwant Singh Bishnoi

Member

Order under Section 26(2) of the Competition Act, 2002

1. The present information has been filed by Shri Prem Prakash (**‘Informant’**) under section 19(1)(a) of the Competition Act, 2002 (**‘Act’**) against Chairman, Quality Council of India (**‘OP’/ ‘QCI’**) alleging contravention of the provisions of Section 4 of the Act.
2. The Informant is proprietor of *‘Venus Testing and Research Laboratory’*, an engineering material testing laboratory situated in Raigarh, Chhattisgarh.



Facts and allegations as stated in the Information

3. QCI is a society registered under the Societies Registration Act, 1860¹. Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India is the nodal Department for QCI. QCI is the parent body of National Accreditation Board for Testing and Calibration Laboratory ('NABL') established with the objective to provide government, industry associations and industry in general a scheme for third party assessment of quality and technical competence of testing and calibration laboratories.
4. Bureau of Indian Standards (BIS) adopted some international standards such as ISO-17025, ISO-17043 and ISO-15189 as the basis for accrediting laboratories². After consultation with BIS, Government of India can mandate any Indian standard through notification. None of the international standards which are adopted are mandatory in India.
5. To run voluntary accreditation program, some intellectuals formed NABL, and registered it as a society at Technology Bhawan, New Mehrauli Road, New Delhi, which is the building of Ministry of Science and Technology, however as per the Informant, the Ministry never allowed NABL to open its office on such address. Initially, NABL started its office from Qutab Hotel, New Mehrauli Road, New Delhi and later claimed that NABL is the sole accreditation body authorised by the Government of India for Testing and Calibration Laboratories. As per Department of Science and Technology (DST), NABL was never authorised as the sole accreditation body for testing and calibration laboratories.

¹ <https://qcin.org/the-organisation> (last accessed on 22.05.2021)

² The accreditation bodies are presently following ISO/IEC 17025 as the basis for accrediting testing and calibration laboratories; ISO 15189 for Medical testing laboratories; ISO/IEC 17043 for Proficiency Testing Providers Producers. Source: <https://nabl-india.org/faq/> (last accessed on 22.05.2021).



6. The Informant has alleged that on account of such fraudulent misrepresentation on part of NABL, all consumer/ government departments started asking NABL accreditation as per ISO-17025 for purchasing laboratory services. In this manner, NABL created monopoly in the laboratory accreditation service market in India. Though other private accreditation bodies are available, but the accreditation certificates issued by such bodies are not easily recognized due to which laboratories approach NABL.

7. NABL runs accreditation programme as per ISO- 17025, which implies that NABL accredited laboratory in India will follow the same guidelines as any other accredited laboratory in the world. The informant has alleged that:
 - (a) If a laboratory seeks accreditation as per ISO-17025 from NABL, then it compels the laboratory to participate in NABL accredited Proficiency Testing (PT) programme while as per ISO-17025, clause 5.9.1(b), participation in inter laboratory comparison or proficiency testing programme is not mandatory. As the participation in PT programme is costly, laboratory has to add this amount to testing charges and the consumer gets the testing facility at higher rates.

 - (b) NABL compels the laboratory to get their equipment/machines calibrated only from NABL accredited laboratories while as per clause 5.6.1 of ISO-17025, the calibration of equipment used for measurement must have national traceability. If the instruments are calibrated from NABL accredited laboratory, the laboratory must spend additional money which also increases the testing charges.

 - (c) NABL has specified the qualification and experience criterion as per NABL 165 document while as per clause 5.2 of ISO 17025, a laboratory can decide the qualification and experience criteria for its staff.



- (d) NABL mandates 4-day training under ISO-17025 from outsourced agency which is not a standard requirement.
8. The Informant has asserted that it had applied to NABL for accreditation, however, the same was not processed as Informant's laboratory had not successfully participated in at least one PT programme prior to applying for accreditation.
9. The Informant has contended that accreditation is not mandatory but merely adds a level of confidence as 'accredited' means that an accreditation body has independently checked that the laboratory operates according to international standards.
10. Thus, in view of the above facts and circumstances of the case, the Informant has prayed to the Commission to pass order against QCI (as now NABL is a constituent board of QCI) to stop this unfair practice and order an inquiry under Section 26(1) of the Act. The Informant has also prayed that the Commission to direct QCI/NABL to remove the unfair conditions mentioned by it as mandatory which are beyond the requirement of the standard ISO-17025.
11. The Commission considered the matter in its ordinary meeting held on 11.08.2020 and decided to seek comments of QCI, on the information filed. The Commission considered the submission received from QCI on 14.10.2020 and directed the Informant to file his comments on the responses filed by QCI, latest by 16.11.2020. The Commission also directed that, the information, and the response of QCI be forwarded to the DPIIT for their comments on certain queries. In response to the above, the Informant and DPIIT submitted their comments on 17.11.2020 and 23.11.2020, respectively.

Response from DPIIT



12. DPIIT in its brief response to the Commission's order dated 14.10.2020 has stated that as per Cabinet note dated 31.01.1996, QCI is an autonomous body registered as a Society under the Societies Registration Act, 1860. Government of India approved the setting up of QCI and the nodal responsibility for executing the plan for setting up QCI was entrusted to Ministry of Commerce and Industry. It has also mentioned that no financial assistance is being provided to QCI by DPIIT. In response to the Commission's query whether any policy/ guidelines/instructions have been issued by or on behalf of Government of India, mandating any kind of preference for the services of QCI or that of its constituent bodies by the government departments or any other organizations/bodies/entities under them, it was submitted that no record was available with DPIIT which may determine if any such instruction has been issued.

Preliminary Conference

13. The Commission heard the Informant and the Counsel for QCI as well as officials of QCI and NABL during the preliminary conference held on 10.02.2021. After hearing the parties, the Commission directed QCI to submit its further response on certain queries relating to mandatory proficiency testing, qualifications and eligibility criteria of laboratory personnel. Accordingly, QCI submitted its response *vide* email dated 24.02.2021.

Submissions by QCI

Structure of QCI and its legal existence

14. As per the QCI:

- (a) The accreditation of laboratories was initiated as a plan programme under the Department of Science and Technology during 6th plan period (1980-85). It was then known as the National Coordination of Testing and Calibration Facilities (NCTCF) programme and 175 laboratories were accredited under this programme. The NCTCF was renamed as NABL in 1993, which got registered on 12.08.1998



under the Society Registration Act 1860 under the aegis of Department of Science and Technology (DST) which is now a constituent board of QCI.

- (b) QCI has submitted that the formation of QCI was initiated through the Cabinet Secretariat letter no. 6/CM/96 (i) dated 14.02.1996 in case no. 42/6/96 as Item No.4 which decision of the Cabinet was on the basis of recommendation of Inter-Ministerial Task Force (IMTF) of Department of Industrial Development (DID) later known as Department Of Industrial Policy And Planning (DIPP) under Ministry of Commerce & Industry. The report of IMTF submitted to DID in January 1993 provided for the creation of QCI as a body independent of the Government and in acceptance of the said report the cabinet duly approved the creation of the QCI and delegated the nodal responsibility of setting up QCI to the DID, Government of India.
- (c) As per the Cabinet note, QCI was to be set up jointly with the seed money in equal shares from the Government of India as well as the Industry Associations like Associated Chamber of Commerce and Industry of India (ASSOCHAM), Confederation of Indian Industry (CII) and Federation of Indian Chambers of Commerce and Industry (FICCI).
- (d) In the Cabinet note of 1996 itself, Central Government has stated that the Government would increasingly depend upon the certification bodies that are accredited by QCI or constituent boards of QCI. Besides, as per the cabinet note dated 14.02.1996 referred above QCI was to have in its fold NABL, another society registered under Societies Registration Act which was at that time under the control of Ministry of Science & Technology.
- (e) Acting on the cabinet decision; DID duly took steps for the creation and setting up of QCI and after the finalization of MOA, Bye laws, rules & regulation which were duly vetted by Ministry of Law & Justice, Government of India, as is clear from the letter no. F.No.3245/PP&C/2000- PP&C dated 27.10.2000 of Ministry of Commerce & Industry;



the QCI was registered as a Society on 21.01.1997 with its own MOA, Rules & Regulations.

- (f) After the report of the IMTF, acting upon which cabinet approval was accorded in the year 1996 and pursuant thereto MOA, rules & regulations of QCI were formulated by the Ministry which was assigned the task, *i.e.* Ministry of Commerce & Industry, DID (later DIPP) in consultation with Ministry of Law. Thus, QCI came into being / was born as Registered Society with an initial seed capital of Rs. 75 Lakh contributed by the Ministry of Commerce & Industry, Government of India being Nodal Ministry and the balance 50 percent coming from the Industry Associations.
- (g) In the Year 2016, in pursuance of cabinet decision (February 1996), NABL along with the support mechanism existing under the DST, Ministry of Science and Technology was transferred to the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry (office order No. AI /8/2/2015, dated 20.06.2016) and DIPP (now known as DIIPT) subsequently transferred to QIC as one of the constituent Boards *vide* office order No.3/12/2015/NPC-QCI dated 27.07.2016. Based on the said office orders, NABL (Regn. No. S/33451) was merged with QCI (Regn. No. S/30832) *vide* letter No. SDM (HQ)/ C/2017/881 dated 15.06.2017. NABL, which was erstwhile a Society Registered under the Societies Registration Act of 1860 under the aegis of DST is now a unit of QCI. After the amalgamation of NABL into QCI, the NABL has no legal existence other than QCI.
- (h) QCI has the mechanism and expertise to grant accreditation as it was established as the national accreditation body. It is well equipped and manned by qualified persons of excellence. It functions through the executive bodies (boards/committees) that implement strategy, policy and operational guidance set by QCI with a view to achieve international acceptance and recognition of various accreditation programs offered by the Boards.



- (i) NABL under QCI is full member signatory to the Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC) since 2000. Accreditation to laboratories as per ISO/IEC 17025 can be given by an accreditation body whose system is as per ISO/IEC 17011, however, the credential of an accreditation body is to be ascertained by its users for acceptance. This is achieved through international recognition obtained by virtue of having APAC / ILAC full Member MRA signatory status.

Preliminary objections by QCI

15. The present information is not maintainable and liable to be dismissed in view of the fact that there is no violation or contravention of any provisions of the Act committed by the QCI as alleged by the Informant in his information. The Informant has not produced any facts or evidence which may fairly indicate that NABL had any dominance in the market and indulged in abusing of such dominance. There are substantial number of accreditation bodies in India that are in accreditation and calibration activities and NABL is neither in a dominant position nor commands the market. As per QCI, there are lakhs of laboratories running in India and NABL has accredited only 6357 laboratories since its incorporation, which itself demonstrates that NABL's share in the market is very small and negligible.
16. That there is no *prima facie* case in favour of the Informant, which gives any cause of action to the Informant to make application before this Commission. The Informant has failed to establish in his information that NABL acted discriminatorily while granting accreditation to the laboratories and/or it restricted market access to any other agency and/or acted as a trade barrier causing prejudice to the new entrants or consumers. In absence of any such evidence it cannot be presumed that QCI has dominant position. However, even presuming QCI to be dominant in the market it cannot be said that QCI has abused its position as the provisions of accreditation are uniformly applicable and non - discriminatorily to all the applicant laboratories



seeking accreditation from NABL in consonance with standards and ILAC and APAC guidelines.

17. Accreditation granted by NABL is based on the demonstration of competence by the laboratories to carry out specific tests in accordance with international standards, ISO 15189:2012, NABL 112 and other relevant documents. QCI has claimed that the laboratories are required to demonstrate their capability to carry out test methodology as mentioned in the applied scope, at the time of consideration of the application for accreditation. QCI has submitted that the accreditation is granted for particular scope on the application of the laboratory, where the laboratory applies for the specific scope as per their competence and, accordingly, the assessment is done keeping in mind the said specific scope and prevailing need. No blanket accreditation is given to the laboratories but it is specific to the scope and competence for which the laboratories apply. As per QCI, permitting the laboratories for accreditation and ignoring the basic essential criteria of competency would be lethal for the mankind and medical standard practices.
18. NABL has been established with an objective to provide Government, Regulators and Industry with a scheme of laboratory accreditation through third party assessment for formally recognising technical competence of laboratories. The accreditation services are provided for testing laboratories, calibration laboratories, medical laboratories, proficiency testing providers and reference material producers in accordance with International Organization for Standardization (ISO). NABL accreditation system is a trusted indication of quality. Because of the intrinsic and good standard, the NABL has acquired valuable goodwill and reputation in respect of accreditation/certification.
19. That the Informant has wrongly invoked the jurisdiction of this Commission to achieve his illegal motive, and to defeat the noble aim and object of this Act. The present



information is motivated and has been filed out of revenge for rejection of accreditation to the Informant's laboratory by NABL due to non-observance of the parameters as prescribed under the scheme of the standards and as per guidelines of ILAC of which NABL is a full member signatory. However, the Informant's laboratory which failed to demonstrate its competence during assessment was provided an opportunity to improve its competency and to undergo verification visit to demonstrate their competence and obtain accreditation. But to the utter shock and dismay, the Informant has invoked the jurisdiction of the Commission for relaxing the guidelines and parameters of accreditation by degrading/sub-standardising quality and norms at the cost of the public health rather to improve the competency of its laboratory. The information of the Informant is *per se* devoid of merits, hence, liable to be rejected.

20. The Informant is a habitual abuser of the state machinery and law enforcement agency by misusing his rights through his motivated, false and frivolous information against QCI. The present information is also an attempt to set the law into motion through his bogus and motivated information just to harass NABL and to achieve his illegal design/object. The Informant is in habit of filing frivolous complaints/ RTI applications against the QCI/ NABL without any justification and just to settle his personal vendetta which started way back November 2013, when his laboratory named '*Venue Testing & Research Laboratory*', was refused from renewal by NABL due to falling short on parameters. The reasons for denial of accreditation to the Informant's laboratory were elaborately communicated to the Informant and he was given an opportunity to defend his case and take corrective actions in absence of which his application was rejected.
21. QCI denies that some intellectuals working with a government organization made a society named as NABL and that such intellectuals working with the Government organization registered this society at the address as alleged by the Informant in his



information. As stated above, the Department of Science and Technology has nurtured the laboratory accreditation program in India during 6th plan period (1980-85).

Reply on merit to Facts of the Information

Market Share of QCI/NABL

22. NABL under QCI charges only one-time fees per the scope of accreditation of laboratory and once the laboratory is accredited by NABL, it does not take any kind of commission/royalty or any other charges from the laboratories. However, the accreditation is granted for a specific time period to laboratories and once that time period expires, NABL after making an assessment that conforms to the applicable standards, renews the accreditation upon payment of renewal fees. Market share of NABL cannot be estimated as it does not possess any information about total number of laboratories in India.

23. Due to its stringent parameters, which are in consonance with international standards and in line with the policies of ILAC/APAC, NABL rejects the laboratories at very initial/primary stage of screening and assessment, where their staffs or establishments are not as per the prescribed norms and devoid of basic know how and information of testing, sampling, reporting *etc.* If such deficient labs are allowed to run, it will lead to public health hazard and be detrimental to the society. Because of its intrinsic value, NABL has acquired reputation and goodwill in the market and the reports made by lab have great credentials and authenticity and wide acceptance.

24. QCI denied that NABL created monopoly in the laboratory accreditation service market in India and submitted that apart from the NABL, other entities/agencies exist which provide accreditation/certification and calibration service in India as per ISO/IEC 17025. A list of such agencies is:



- (a) ABL under QCI is full member signatory to the APAC and ILAC since 2000.
 - (b) Accreditation Commission for Conformity Assessment Bodies, which is an Associate Member of ILAC (Started in 2010)
 - (c) Global Laboratory Accreditation Board, which is an Associate Member of APAC and ILAC (started in 2016)
 - (d) Quality and Accreditation Institute Pvt. Ltd. (QAI), which is an Associate Member of APAC (Started in 2017)
25. Apart from the above-mentioned agencies the following foreign accreditation bodies also grant Accreditation to laboratories in India, which are also full member signatory to ILAC:
- (a) United Kingdom Accreditation Services (UKAS), UK,
 - (b) American Association for Laboratory Accreditation (A2LA), USA,
 - (c) International Accreditation Services (IAS), USA,
 - (d) French Accreditation Committee (COFRAC), France, and
 - (e) German National Accreditation Body (DAKSS), Germany.
26. Thus, NABL under QCI has neither created any monopoly and nor is in a dominant position in the market as many Indian and foreign entities as mentioned above are existing in the market providing accreditation services in India.
27. It is denied that more than 99% of the laboratory accreditation services market is with NABL as alleged by the Informant. The Informant may be put to strict proof of the same. QCI has submitted that there are substantial number of accreditation bodies in India as mentioned above that are in accreditation and calibration services and NABL is neither in a dominant position nor commands the market. It is submitted by QCI that Lakhs of Laboratories are running in India and NABL has accredited only 6357 laboratories till now, which itself demonstrate the share of NABL market is very small and negligible.



Compulsory Proficiency Testing from NABL accredited laboratory

28. As submitted by QCI, NABL is a voluntary accreditation body and provides accreditation in all major fields of Science and Engineering such as Biological, Chemical, Electrical, Electronics, Mechanical, Fluid-Flow, Non-Destructive, Photometry, Radiological, Thermal and Forensics under testing facilities and Electro-Technical, Mechanical, Fluid-Flow, Thermal, Optical & Radiological under Calibration facilities. NABL also provides accreditation for medical testing laboratories. That in order to achieve the objective, NABL provides laboratory accreditation services to laboratories that are performing tests/ calibrations in accordance with International Standards ISO/IEC 17025 and for medical laboratories ISO 15189. These services are offered in a non-discriminatory manner and are accessible to all testing and calibration laboratories in India/Overseas regardless of their ownership, legal status, size and degree of independence. NABL accreditation system complies with ISO/IEC 17011 and APLAC MR001.
29. It is wrong to say that as per clause 5.9.1(b) of ISO 17025 if participation of laboratory in Inter laboratory comparison test is completed then accreditation is granted and participation in P.T. programme is not mandatory. This mentioned clause has been amended and new ISO 17025 has been introduced in 2017. According to Clause 7.7.2 of Clause 7.7 of ISO/IEC 17025:2017, which provides for Assuring the Validity of Results, states that *“The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of following:*
- a) *Participation in proficiency testing*
- Note: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirement of ISO/IEC 17043 are considered to be competent.*



- b) *Participation in interlaboratory comparisons other than proficiency testing*
30. To get the accreditation from NABL under QCI, the applicant laboratory shall successfully participate in at least one PT Programs prior to gaining accreditation in each discipline applied. However, where above formal PT Programs are not available/scheduled or not appropriate, alternatively:
- (a) The applicant testing/medical laboratory shall participate in suitable inter-laboratory comparisons with sufficient number of accredited laboratories, as per ISO/IEC 17043:2010 ‘*Conformity Assessment-General requirements for proficiency testing*’.
- (b) The applicant calibration laboratory shall participate in suitable inter-laboratory comparisons, as per NABL 164 ‘*Guidelines for Inter-laboratory Comparisons for Calibration Laboratories where formal PT programs are not available*’.
31. It is not mandatory that a laboratory seeking accreditation has to undertake PT services from an NABL-accredited PT service provider only. There are many international/national PT service providers who are providing PT services in India but are not accredited from NABL. These include: (i) FAPAS, (ii) BIO-RAD, (iii) RANDOX, (iv) ASTM, (v) LGC, (vi) Efftech Ltd., (vii) CPCB, (viii) AIIMS-Histopathology, (ix) Tata Memorial-Flow Cytometry, (x) Organisation for Prohibition of Chemical Weapons (OPCW), (xi) PTB and (xii) European Directorate of Quality Medicine.
32. NABL under QCI also encourages participation of applicant/ accredited laboratories in Proficiency Testing programs conducted by other National and International bodies. Since NABL encourages the participation of applicant/accreted in Proficiency Testing programme conducted by National or International bodies, it is manifest that NABL has not imposed, any directly or indirectly, unfair or discriminatory condition in purchase or sale of goods or services as mentioned under Section 4 of the Act.



Calibration of Equipment from NABL accredited laboratories only

33. NABL under QCI grants accreditation to testing & calibration laboratories based on international standard ISO/IEC 17025. Clause 6.5.2 of Clause 6.5 of ISO/IEC 17025:2017, which provides for Metrological Traceability, states the requirement with respect to calibration as: *“The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:*

- *Calibration provided by a competent laboratory; or*
[Note1: Laboratories fulfilling the requirements of this document are considered to be competent]
- *Certified values of certified reference materials provided by competent producer with stated metrological traceability to the SI; or*
[Note2: Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent]
- *Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards*
[Note3: Details of practical realization of the definitions of some important units are given in SI brochure]

34. QCI has submitted that since requirements with respect to calibration is a part of requirement of the standard based on which accreditation is granted, calibration of equipment from an accredited calibration lab is a mandatory requirement.

35. QCI has denied that measuring of equipment must be calibrated from NABL accredited lab and submitted that NABL under QCI has not made it compulsory that calibration of equipment / machines is to be calibrated from NABL accredited laboratories only. The calibration done as per document NABL 142 is acceptable and, therefore, NABL accredited calibration labs are qualified for issuing calibration certificate and thus accepted. NABL under QCI has not made it compulsory that



equipment / machines are to be calibrated only from NABL accredited Laboratories; and it recognises calibration of equipment and reference standards from the other Organisations as well. Thus, manifestly NABL has not imposed, any direct or indirect, unfair or discriminatory condition in purchase or sale of goods or services as mentioned under Section 4 of the Competition Act, 2002.

NABL has specified qualification and experience criterion

36. NABL has not specified any qualification criterion for hiring of personnel and does not intervene in recruitment process of any laboratory. However, in the application documents there is a mention of minimum qualification and experience requirements for review, report, and release of test results. These requirements are mentioned to ensure uniformity in the requirements, harmonization in the accreditation process with respect to verification of competence of the proposed personnel and also for benefit to public health, safety environment & welfare and support regulations & end users as well as to give confidence in the operation of laboratories which will demonstrate that they are operating competently and are able to generate valid results.

Mandatory 4-day training

37. As per QCI, a 4-day training of ISO-17025 from any recognized institute/organisation is not a requirement any longer. During the period from June 2012 to February 2020, in order to strengthen the level of Quality Manager (being a key personnel) for the implementation of management system in the laboratory which is specified as per clause 4.1.4.1 of ISO 17025, a 4-day training programme was mandatory. QCI also stated that mandatory requirement was made based on the review of number of assessment reports wherein lack of knowledge was observed in laboratory personnel. However, from March 2020, NABL discontinued the requirement of mandatory training of Quality Manager as there was a marked improvement observed amongst



the laboratories in the awareness about the standard. In the new version of ISO 17025: 2017 as per clause 6.2.3 “*the laboratory is required to ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations*”.

Excessive Charges/Pricing

38. It is denied that participating in PT programme is costly and laboratory has to add this amount in testing charges and in this way consumer gets testing facility at higher rates. QCI has submitted that NABL only provides voluntary accreditation to Proficiency Testing Providers (PTP) as per ISO/IEC 17043. During the period 1998-2008, NABL used to fund institutions to conduct PT Program on behalf of NABL on a nominal fee of ₹ 2400/-. During such period, there was no PT provider available in the country. Presently, NABL does not conduct any PT program in view of changes in ISO/IEC 17011: 2017 standard. This activity is now done by other PT providers, and NABL has no control on fee charged by them.
39. It is denied that all the fees charged by NABL such as application fees, auditor fees, *etc.* are too high and NABL also claims that it is a non-profitting society and is exempted from paying income tax. So far as NABL having surplus of more than ₹13 crores for the financial year 2015-16 is concerned, it is a matter of record and needs no reply. QCI has submitted that NABL out of its generated fund organises and imparts several educational programmes, seminar, conclaves *etc.* and also provides financial support to educate and spread awareness relating to quality improvement in health, environment, water, pharma *etc.* sectors and discharge its social obligations as well.



40. It is denied that due to high fees charged by NABL, the consumer gets laboratory services at a higher price. QCI has submitted that the conditions of any such high charges or other stringent conditions as alleged by the Informant are not discriminatory in nature and these have uniform applications. Even if the contentions of Informant are presumed to be true, then also NABL is not limiting / restricting the provisions of service or market thereof and is not causing prejudice to the consumers.

Analysis

41. The Commission has considered the information and subsequent responses and notes that accreditation is the action or process of officially recognizing someone as having a particular status or being qualified to perform a particular activity. Accreditation is sought by business enterprises to increase their acceptability among customers to assure them that they are following international standards. Laboratory Accreditation is the third-party assessment conveying the formal demonstration of its competence to carry out specific conformity assessment task. Accreditation in the present context provides formal recognition to a competent laboratory, thus providing a ready means to customers to find reliable testing, calibration³ proficiency testing and reference material producer services in order to meet their demands.

42. The Commission further notes that the international standards are published by ISO, an organization that develops standards to ensure the quality, safety, efficiency of products, services and systems. As stated by the Informant, the Government of India can mandate any standard through notification, after consultation with BIS, whereas, any international standards which are adopted are not mandatory in India. BIS has

³ Calibration is the process of comparing a reading on one piece of equipment or system, with another piece of equipment that has been calibrated and referenced to a known set of parameters. The equipment used as a reference should itself be directly traceable to equipment that is calibrated according to ISO/IEC 17025.



adopted some international standards such as ISO-17025, ISO-17043 and ISO-15189, among others.

43. As per the website of Quality Council of India it is “, *an autonomous body set up by the Ministry of Commerce and Industry, Government of India jointly with the Indian Industry represented by the three premier industry associations i.e. Associated Chambers of Commerce and Industry of India (ASSOCHAM), Confederation of Indian Industry (CII) and Federation of Indian Chambers of Commerce and Industry (FICCI), to establish and operate national accreditation structure and promote quality through National Quality Campaign.*
44. *Quality Council of India (QCI) is registered as a non-profit society with its own Memorandum of Association and is governed by a Council with equal representations of government, industry and consumers. The Council plays a pivotal role at the national level in propagating, adoption and adherence to quality standards in all important spheres of activities including education, healthcare, environment protection, governance, social sectors, infrastructure sector and such other areas of organized activities that have significant bearing in improving the quality of life and wellbeing of the citizens of India.”*
45. It is further noted that the website of QCI states that “*QCI coordinates its activities through five constituent Boards* “. One of these boards being NABL.
46. As per NABL’s website it is “*an accreditation body, with its accreditation system established in accordance with ISO/ IEC 17011. “Conformity Assessment – Requirements for Accreditation bodies accrediting conformity assessment bodies.” NABL provides voluntary accreditation services to:*
- (a) *Testing laboratories in accordance with ISO/ IEC 17025 ‘General Requirements for ‘the Competence of Testing and Calibration Laboratories’*



- (b) *Calibration laboratories in accordance with ISO/ IEC 17025 ‘General Requirements for the Competence of Testing and Calibration Laboratories’*
 - (c) *Medical testing laboratories in accordance with ISO 15189 ‘Medical laboratories -Requirements for quality and competence’*
 - (d) *Proficiency Testing Providers (PTP) in accordance with ISO/IEC 17043 “Conformity assessment — General requirements for proficiency testing” and*
 - (e) *Reference material producers (RMP) in accordance with ISO 17034 “General requirements for the competence of reference material producers”.*
47. *NABL is Mutual Recognition Arrangements (MRA) signatory to ILAC as well as APAC for the accreditation of Testing and Calibration Laboratories (ISO/IEC 17025), Medical Testing Laboratories (ISO 15189), Proficiency Testing Providers (PTP) (ISO/IEC 17043) and Reference materials producers (RMP). Such MRA reduces technical barrier to trade and facilitates acceptance of test/ calibration results between countries which MRA partners represent.*
48. *NABL has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of Conformity Assessment Body’s accreditation which involves third-party assessment of the technical competence of testing including medical and calibration laboratories, proficiency testing providers and reference material producers. Accreditation process details are provided in NABL 100 “General information Brochure”.*
49. *NABL is self-financing and charges fees to Conformity Assessment Bodies to cover operational costs and other expenditure.”*

QCI as an enterprise

50. Before examining the conduct of QCI (of which NABL is a constituent) from the perspective of Section 4 of the Act, the issue that first needs to be determined is



whether QCI, falls within the scope of definition of ‘*enterprise*’ in terms of Section 2(h) of the Act.

51. For ascertaining whether an entity is an ‘*enterprise*’ or not within the meaning of Section 2(h) of the Act, it is essential to examine the nature of the activity undertaken by the entity. As discussed earlier, QCI discharges its mandate through Boards and NABL is vested with the responsibility of providing accreditation services to laboratories. The website of NABL⁴ indicates that it charges application fee for accreditation which varies for different laboratories ranging from ₹ 11,000 to 44,000 per discipline, whereas the application fee for Proficiency Testing Providers is ₹ 25,000 per discipline. The Commission accordingly holds that QCI, through NABL is involved in economic activities and, thus, it falls within the definition of the term ‘*enterprise*’ under Section 2(h) of the Act.

Relevant Market

52. As accreditation of laboratories is a specialised activity, the relevant market appears to be service of granting accreditation certification to the laboratories that satisfy certain minimum international standards. The accreditation is granted in different fields and different standards are there for each field. The geographic market in this case would be entire India since accreditation business is not confined to any geographic area and those who are engaged in granting accreditation, do so throughout India. Thus, the relevant market in this would be *providing service of granting accreditation certification to the laboratories after verifying the standards followed by them.*

⁴ Accessed on 20.05.2021



Dominance

53. On the aspect of dominance, QCI has submitted that NABL is not the only accreditation body which can certify laboratories as per the applicable international standards, a fact which Informant has also stated in its initial submissions.
54. In order to gauge the market power, enjoyed by the OP, the Commission sought certain information *vide* order dated 10.2.2021 regarding data on laboratories accredited by domestic accreditation agencies in India (other than NABL) and international agencies having full membership of ILAC / APAC. QCI has provided the names of such accreditation agencies and number of laboratories accredited by it. As per their submission, the domestic accreditation agencies are Accreditation Commission for Conformity Assessment Bodies, Global Laboratories Accreditation Bodies (GLAB), Quality and Accreditation Institute Private Limited (QAI), Federation for Development of Accreditation Services (FDAS), United Accreditation Body of India (UABI), and Foreign Accreditation bodies such as United Kingdom Accreditation Service (UKAS), International Accreditation Services (IAS), German National Accreditation Body (DAKKS), French Accreditation Committee (COFRAC) and American Association for Laboratory Accreditation (A2LA).
55. QCI submitted that as on 22.02.2021, it has provided accreditation to laboratories in the fields of Testing (3496 Nos), Calibration (990 Nos) and Medical (1931 Nos). As sought by the Commission, data was gathered by QCI on accreditation by international accreditation bodies as well as other Indian accreditation bodies. UKAS has accredited 2 laboratories, IAS 6 laboratories, DAKKS 2 laboratories and COFRAC 1 laboratory and A2LA 13 laboratories. As regards other Indian bodies QAI had accredited 14, UABI 6, and FDAS had accredited 2. Data from other agencies was not available with QCI as it was not available in public domain or no response was provided to QCI by them.



56. The Commission observes that though the size of the market relating to provisions of services granting accreditation to laboratories in India is not precisely known, to a large extent an idea of its size and market share of players can be ascertained from the aforesaid submissions on the number of laboratories accredited by accreditation agencies. The available data of laboratories that have accreditation from international and other bodies shows that only a miniscule number of laboratories in India have been accredited, by entities other than NABL.
57. NABL, based on the figures mentioned in the preceding para appears to enjoy market power in the relevant market so delineated. The preference of laboratories for NABL accreditation is, therefore, evident from the data regarding the accreditation by different agencies. This may be because of insistence by customers on NABL accreditation or its presence in India since there is no other Indian body which is full member of ILAC or APAC.

Compulsory Proficiency Testing from NABL accredited laboratory

58. QCI in their response, to the submissions of Informant that as per clause 5.9.1(b) of ISO-17025 if participation of laboratory in inter laboratory comparison test is complete then participation in PT programme is not mandatory, has submitted that aforesaid clause has been amended and new ISO-17025:2017 has been introduced in year 2017 and as per the revised ISO-17025: 2017 to get the accreditation from NABL, the applicant laboratory shall successfully participate in at least one PT Program prior to gaining accreditation in each discipline applied. This implies Proficiency Testing is mandatory as per the new international standard. Hence, the allegation of Informant is not made out as participation is made mandatory in compliance with the new standard that is applicable.



59. The Commission further observes from the submissions made by QCI that a laboratory seeking accreditation from NABL can seek PT service from any other PT service provider which has not received accreditation from NABL. If any laboratory wishes to avail accreditation, it has the option to participate in PT programme either with a NABL accredited PT provider or any other body providing such accreditation under the ILAC arrangement. Additionally, the Informant is free to approach any accreditation body providing such services in the country, either a national or international body, for the purposes of gaining accreditation as per the relevant international standards. QCI has also confirmed that while there is a requirement to participate in PT programme, there is no requirement to participate in such a programme conducted by NABL accredited laboratory. Thus, this allegation of participation in NABL accredited laboratory for PT programme is also not made out.

Calibration of Equipment

60. While the Informant has alleged that calibration is not necessary, QCI/NABL has stated that calibration is now an essential requirement of the revised standard ISO 17025. For the purposes of calibration of equipment, QCI has clarified that calibration from any laboratory is acceptable which is accredited by an accreditation body covered by the ILAC Arrangement. Further, QCI has submitted there are five such foreign accreditation bodies with full membership of ILAC which grant accreditation to testing laboratories in India. Based on the above, it emerges that the laboratories have option to choose accreditation bodies to get their equipment/machines calibrated. As QCI has informed that calibration is now necessary and further it can be done by any of the other 5 accreditation bodies, the allegation of Informant is also not made out.



Eligibility / Qualification criteria

61. Regarding eligibility/ qualification criteria of personnel, QCI has categorically stated in its response that it has not specified any qualification/ criterion for hiring of personnel and does not intervene in recruitment process of laboratory. However, certain minimum standards are prescribed by NABL which are in the interest of public health, safety environment & welfare and support regulators and end users to give confidence in the operation of laboratories which demonstrate that they are operating and can generate valid results. Therefore, perusal of minimum standards do not reveal anti-competitive conduct on behalf of NABL.

Mandatory 4-day training

62. The Informant has raised the issue of 4 -day training stipulated by NABL which is not an international standard. QCI has given a detailed explanation as to why it was earlier required and has stated that as standards have improved it is no longer mandatory since March 2020. As discussed in para 37, the Commission finds the explanation plausible and reasonable.

Excessive Pricing

63. In respect allegations of excessive pricing, NABL has stated that during 1998-2008, NABL used to fund institutions to conduct PT Program on behalf of NABL on nominal fee of ₹ 2400/- from participating laboratories, but presently, NABL does not conduct any PT program in view of changes in ISO/IEC 17011: 2017 standard and the PT providers have their own system for charging fees from participants. Thus, the Commission observes that the issue of pricing is also found to be a decision/prerogative of an individual service provider to decide the fees charged. As NABL does not conduct such PT Programmes there is nothing further to comment on this issue by the Commission.



64. As regards government departments seeking NABL accreditation, there is no evidence to show that it arises out of any abusive conduct on behalf of QCI. QCI, on behalf of NABL, has pointed out that there are other accreditation agencies, both Indian and foreign which provide these services. It is noted that it is not binding on any government department to prefer NABL accredited laboratories. DPIIT has also confirmed that no record of such instructions is available for reference to NABL. It is further noted that in Case No. 50 of 2014 dated 17.03.2017, arising out of information filed by the same Informant against Madhya Pradesh Public Works Department and CPWD, the Commission had noted that para 53.20 of CPWD Works Manual 2014 was modified by changing the sentence “*Lab approved by NABL*” to “*for the purpose of lab accreditation by NABL or any other accreditation body which operates in accordance with ISO/ IEC 17011 and accredits labs as per ISO/ IEC for testing and calibration shall be eligible*” . It would be desirable if the other procuring agencies also do something similar.

Conclusion

65. The Commission observes that in order to keep up with new international standards, certain requirements pertaining to accreditation are modified by NABL from time to time. It is further noted that one of ISO standards quoted by informant has been amended in 2017 and NABL has accordingly modified the procedure. Further, on the basis of the response/clarification provided by QCI, on PT programme, calibration, mandatory training or qualification of personnel working in the laboratories, it cannot be concluded that the conduct of QCI is abusive. As regards pricing, QCI has stated it to be a prerogative of an individual service provider to decide the fees charged, and that NABL does not conduct such PT Programmes anymore and does not have a role in the fees charged by the service provider. Moreover, the Informant has also not submitted any comments in rejoinder on the submissions made by QCI regarding the



issues relating to proficiency testing, calibration, qualifications and experience of employees and mandatory 4-day training.

66. The Commission is therefore of the view that no *prima facie* case of contravention of provisions of Section 4 of the Act can be stated to have arisen on part of QCI, warranting an investigation and the information filed is closed herewith under Section 26(2) of the Act.

67. The Secretary is directed to inform the parties accordingly.

Sd/-
(Ashok Kumar Gupta)
Chairperson

Sd/-
(Sangeeta Verma)
Member

Sd/-
(Bhagwant Singh Bishnoi)
Member

Date: 05.07.2021