





COMPETITION COMMISSION OF INDIA Case No. 12 of 2023

In Re:

Prem Prakash Informant

Proprietor, Venus Testing and Research Laboratory, Plot No. 45, Industrial Area, Khurai Road, Bina, Distt. Sagar, Madhya Pradesh - 470113

And

National Accreditation Board for Testing and Calibration Op Laboratories (NABL),

(constituent board of QCI), through its CEO, Plot No. 45, Sector-44, Gurgaon - 122002

The Secretary, Department of Science and Technology, Technology Bhawan, New Mehrauli Road, New Delhi -110067

Anurag Jain, Secretary,

Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Room No. 157, Udyog Bhavan, New Delhi -110011

N. Ramesh, Then Director,

Ministry of Commerce and Industry, Udyog Bhavan, New Delhi – 110011

Yogesh Gupta, Then Under Secretary,

Ministry of Commerce and Industry (Department of Industrial Policy and Promotion) (Consumer Industry Section), Udyog Bhavan, New Delhi – 110011

CORAM:

Ms. Ravneet Kaur Chairperson

Ms. Sangeeta Verma Member

Mr. Bhagwant Singh Bishnoi Member Opposite Party No. 1

Opposite Party No. 2

Opposite Party No. 3

Opposite Party No. 4

Opposite Party No. 5

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

1. The present information has been filed by Mr. Prem Prakash ('Informant') under Section 19(1)(a) of the Competition Act, 2002 ('Act'), alleging contravention of the provisions of Section 3 and Section 4 of the Act, against National Accreditation Board for Testing and Calibration Laboratories (NABL), (constituent board of QCI), through its CEO (hereinafter, referred to as 'NABL'/'OP-1'); the Secretary, Department of Science and Technology (hereinafter, referred to as 'OP-2'); Mr. Anurag Jain, Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry (hereinafter, referred to as 'OP-3'); Mr. N. Ramesh, then Director, Ministry of Commerce and Industry (hereinafter, referred to as 'OP-4'); Mr. Yogesh Gupta, then Under Secretary, Ministry of Commerce and Industry, (Department of Industrial Policy and Promotion), (Consumer Industry Section) (hereinafter, referred to as 'OP-5') (OP-1 to OP-5 are collectively referred to as 'OPs').

Facts, as stated in the Information

- 2. The Informant is the proprietor of Venus Testing and Research Laboratory located at Industrial Area, Khurai Road, Bina, Madhya Pradesh and is providing engineering material testing laboratory services.
- 3. The Informant has submitted that International Organization for Standardisation (ISO) is a private foreign standard writing institute which has written many Standards, which are voluntary in India. ISO has published ISO 17025:2017 (*General Requirement for the Competence of Testing and Calibration Laboratories*), which is followed by most of the engineering material testing laboratories.
- 4. The Informant has further submitted that getting accreditation as per ISO 17025:2017 from an accreditation body is just a third-party inspection of the document as per the standard, but maintaining the quality, accuracy and faith of the customer is the sole responsibility of the laboratory and not that of the accreditation body from which a lab avails accreditation service.





- 5. The Informant has relied upon the order of the Commission in Case No. 25 of 2020 [*Prem Prakash vs. Chairman, Quality Council of India*] wherein NABL has been held to be an 'enterprise' having a dominant position despite there being eight other accreditation bodies providing accreditation services in the relevant market in India.
- 6. The Informant has further submitted that NABL has become dominant primarily because of the preference accorded to it over the years by the departments of the government which specifically require in their tender documents that the material or service providers should have their material tested from a laboratory accredited by NABL. Further, NABL is alleged to have violated different provisions of the Act at different occasions, as elucidated in the ensuing paragraphs.
- 7. It has been alleged by the Informant that NABL has imposed many unfair conditions, which are not in accordance with ISO 17025:2017, on the laboratories which avail accreditation certification service as per the said ISO standard from NABL. The Informant has listed certain conditions, which are part of the NABL policy documents or have stemmed from the communication between NABL and laboratories *inter-se*, as follows:
 - (a) NABL compels laboratories which avail its accreditation services to use NABL symbol/logo. NABL has published a document NABL 133, titled as 'Policy for use of NABL Symbol/or Claim of Accreditation Conformity Assessment Body (CAB) and NABL accredited CAB Combined ILAC MRA Mark'. It is submitted that according to ISO 17025:2017, there is no such requirement of using the symbol of accreditation body. It is further submitted that Clause 6.2 of the NABL 133 mandates CAB not to use the symbols of other accreditation body if the report contains parameters accredited by NABL. Further, Clause 6.7 of NABL 133, provides that use of any other accreditation body's symbol or mark is not permitted to be used along with NABL symbol. According to the Informant, these requirements create entry barriers for other accreditation bodies.
 - (b) The Informant asserts that NABL policies regarding calibration of equipment are





also unfair as it requires that the complete measuring instrument be calibrated at a calibration facility authorized by NABL if a laboratory desires a certificate of accreditation from NABL. However, it is argued that Clause 6.5 of ISO 17025:2017 only requires metrological traceability, which calls for all measuring equipment to be confirmed through a chain of suitable references. The Informant describes a chain of reference as follows: long chain traceability occurs if A calibrates its measuring tape at the NPL (National Reference), which calibrates the measuring tape of B, and then B calibrates the measuring tape of C, and so on. However, because of the NABL's alleged unfair policies, laboratories are compelled to contact NABL recognised calibration laboratories, which helps NABL grow its clientele at the expense of consumers. The Informant has annexed a document titled 'Non-Conformities Observed during Pre-Assessment' dated 11.04.2015 wherein universal testing machines and impact testing machines in Informant's laboratory were stated to be calibrated by non-NABL accredited calibration agency.

- (c) The Informant further asserts that NABL has issued a document NABL 100B titled 'Accreditation Process and Procedure' and that, in accordance with Clause 6.5 of the said document, NABL conducts unannounced assessments in order to harass the laboratory's staff, despite ISO 17025:2017 not providing any such assessments.
- (d) Further, Clause 7.8.5, titled as '*Reporting sampling*', of ISO 17025:2017 includes all the details for reporting the results of a sample including unique report number, but NABL through its letter dated 13.12.2021, compelled all laboratories to mention an additional unique laboratory report number, which caused an extra burden on the laboratory.
- (e) As per Clause 7.7 of ISO 17025:2017 titled as 'Ensuring the validity of results', the laboratory has to participate either in proficiency testing or participate in interlaboratory comparisons other than proficiency testing. However, NABL compels laboratories to purchase the service of proficiency testing provider, because it provides accreditation to proficiency testing provider as per ISO 17043

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and charge money for such accreditation. Though, it is not mandatory to participate in the proficiency test, one has to participate in proficiency testing if one wants to get accreditation certificate from NABL. The Informant has further submitted that the application of the Informant's laboratory for accreditation was not accepted by NABL because it had not participated in proficiency testing program. An email dated 22.08.2019 has been annexed in support of this allegation.

- 8. The Informant has submitted that anybody can work as an accreditation body if its system operates as per ISO 17011 and if any enterprise or person promotes NABL or NABL makes any arrangements by itself to restrict the entry of a new accreditation body or drive out the existing accreditation bodies out of the market, it is a violation of Section 3 or Section 4 of the Act. This, as per the Informant, has been done by NABL and some of the departments of the government through their anti-competitive arrangements.
- 9. The Informant has submitted that after registering as a society, NABL launched a website and started writing Department of Science and Technology under its title, because of which everyone believed it to be a part of Department of Science and Technology. Thereafter, NABL started a narration that it is the sole accreditation body authorized by Government of India. To substantiate the same, the Informant has attached copy of claim obtained from the website of NABL, some past orders of the Commission and a document titled NABL 100 issued by it mentioning that the Government of India has authorized NABL as the accreditation body for testing and calibration laboratories. However, the Department of Science and Technology, in reply to an RTI, has refuted the said claim stating that NABL was never authorized by Department of Science and Technology. The Informant has submitted that because of such claims by NABL, it has gained a unique position in the market as a government authorized accreditation body and all other bodies have been driven out of the market.
- 10. Pursuant to some complaints, Department of Science and Technology issued a letter dated 12.08.2014 to NABL asking it not to mention Department of Science and Technology under the title of its website and also advised not to write its registered

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office address as Department of Science and Technology, Technology Bhawan, New Mehrauli Road, New Delhi. In reply to an RTI, Department of Science and Technology also stated that no space was allotted to NABL in the premise of Department of Science and Technology, Technology Bhawan, New Delhi.

- 11. It is stated that, on the letter head of NABL, the registered office address was written as Department of Science and Technology, Technology Bhawan, New Mehrauli Road, New Delhi and Secretariat as Plot No. 45 Sector-44, Gurgaon-122002. However, it is submitted that as per Societies Registration Act, 1860, societies are required to write only the registered office address under its title, and not Secretariat.
- 12. The Informant has submitted that due to abovementioned arrangements/practices *i.e.*NABL has created an impression that it is part of Department of Science and Technology and that it has sole authorization of NABL by Government of India. Owing to such impression, all the government departments and laboratories are purchasing accreditation services from NABL only, as a result of which more than 99% share of laboratory accreditation service business is with NABL.
- 13. The Informant has further submitted that ISO standards do not prescribe availing of accreditation service from a full member of International Laboratory Accreditation Cooperation (ILAC) or Asia Pacific Accreditation Cooperation (APAC). However, NABL, on its website, mentions that it is Mutual Recognition Arrangements (MRA) signatory of ILAC and APAC and claims that such MRA reduces technical barrier to trade and facilitate acceptance of test calibration results between countries which MRA partner represent. Further, as per the Informant, replies of various RTI's from NABL and QCI points that NABL is misleading people about ILAC and APAC.
- 14. The Informant further submitted that first director of NABL, *namely* Mr. A.K. Chakravarty managed an agreement with Secretary, Department of Science and Technology and mentioned on the website of Department of Science and Technology that Government of India has authorized NABL as the sole accreditation body for





testing and calibration laboratories, which resulted in monopoly and created entry barrier for new entrants.

- 15. It is further submitted that NABL has started showing itself to be a part of Department of Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce. Further, Mr. Venkateswaran, the present CEO of NABL managed an agreement with Mr. Anurag Jain, Secretary, DPIIT, Ministry of Commerce and Industry who issued a circular dated 15.03.2022 advising all laboratories to obtain NABL accreditation.
- 16. It is also submitted that Mr. Anil Relia, Director of NABL managed an arrangement with Mr. N. Ramesh, Director, Ministry of Commerce and Industry, Department of Commerce, who issued a circular dated 23.11.2017 to all the laboratories working for APEDA, Tobacco Board, Spices Board, MPEDA, Tea Board, Coffee Board and EIC stating that they should get accreditation from NABL only. Further, Mr. Anil Relia also managed an arrangement with Mr. Yogesh Gupta, Under Secretary, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, and a circular dated 26.08.2017 was issued on technical regulation of toys mentioning that representative sample of import toys should be tested in NABL accredited laboratory, through which entry barrier for new entrant was created and existing laboratories were driven out of the market.
- 17. The Informant has further submitted that NABL violates the requirement mandated by the Societies Registration Act, 1860 according to which in order to operate on an all-India basis, a Society should have one member each from at least seven states of the Union of India. Therefore, the circular dated 17.05.2022 issued by the CEO of NABL, Mr. Venkateswaran, to all the laboratories stating that they are under his control, is in violation of the Societies Registration Act, 1860, since this Society was not supposed to operate beyond Delhi as it had members from Delhi only.
- 18. The Informant has submitted that despite these irregularities as mentioned above, the officers of DPIIT have issued circular to promote NABL, which is anticompetitive. The Informant has also relied upon some of the earlier orders of the Commission,

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specifically order of the Commission in Case No. 50 of 2014 [*Prem Prakash vs The Principal Secretary Madhya Pradesh Public Works Department & Others*] in this regard.

- 19. Based on the aforesaid facts and allegations, the Informant has prayed for an action against NABL/OP-1 and other OPs, under the provisions of the Act; direction to the personnel of Ministry of Commerce and Industry to withdraw the circular/instructions regarding NABL; opportunity of hearing to the Informant and any other relief as the Commission deems fit.
- 20. The Commission considered the Information in its ordinary meeting held on 14.06.2023 and decided to pass an appropriate order in due course.
- 21. Subsequently, vide letter dated 27.06.2023, the Informant has highlighted another circular issued by NABL, bearing No. NABL/ANCMT/2023/01/22-03, issued on 22.03.2023 which has been stated to be unfair. It has been alleged that through this circular, NABL has denied accreditation services to laboratories operating under sole proprietorship structure and made it mandatory for such entities/persons to register under any of the regulated forms mentioned in the said circular, for availing the accreditation services of NABL. It is alleged that while the Government Department/enterprise cannot refuse to award any business to a proprietorship firm/laboratory, NABL has denied to provide accreditation to proprietorship laboratories. Further, it is stated that if a proprietorship laboratory/firm gets registered under the Companies Act, 2013, then it will have to incur additional expenses and carry out additional obligations, including getting a fresh PAN card and GST number, statutory audit every year, registration under the Companies Act, 2013 etc. These will entail additional expenses on the laboratories. As per the Informant, this is an abuse by NABL of its dominant position.

Analysis of the Commission

22. At the outset, the Commission observes that alongside substantive reliefs, the Informant has prayed for an opportunity to be heard. As regards the said prayer, the





Commission notes that in accordance with Regulation 17 of the Competition Commission of India (General Regulations) 2019, the Commission *may* call for a preliminary conference before forming a *prima facie* view, if it deems necessary. This has been deliberated in detail in *CCI v. SAIL* (2010 CompLR 0061 SC), wherein the Hon'ble Supreme Court categorically held as under:

Regulation 17(2) empowers the Commission to invite the information provider and such other person, as is necessary, for the preliminary conference to aid in formation of a prima facie opinion, but this power to invite cannot be equated with requirement of statutory notice or hearing. Regulation 17(2), read in conjunction with other provisions of the Act and the Regulations, clearly demonstrates that this provision contemplates to invite the parties for collecting such information, as the Commission may feel necessary, for formation of an opinion by the preliminary conference. Thereafter, an inquiry commences in terms of Regulation 18(2) when the Commission directs the Director General to make the investigation, as desired.

- 23. Thus, at the *prima facie* stage, the decision of the Commission to call for a preliminary conference is to be guided solely by the sufficiency of information to form a view. As regards the present case, given the information available on record, the Commission finds no reason to call for a preliminary conference. Having dealt with this prayer, the Commission will now examine the Information.
- 24. The Commission notes that the gravamen in the Information stems from the alleged position of dominance achieved by NABL because of the collective operation of circulars issued by various Government departments as well as the mandates issued by NABL from time to time to the laboratories/Conformity Assessment Bodies (CABs). The Informant has highlighted certain circulars issued by OP-2 to OP-5 which allegedly promote OP-1/NABL as the desired accreditation body and are hence, stated to be in contravention of the provisions of Section 3 of the Act. Further, it has been





alleged that NABL has become a dominant entity because of such favourable treatment and, through its abusive strategies, has been able to entrench its already strong position in the accreditation service market, in contravention of the provisions of Section 4 of the Act. This, according to the Informant, has led to an outcome where accreditation is perceived to be done only by NABL, despite there being other accreditation agencies existing in India.

- 25. Before delving into the facts and allegations of the present case, the Commission notes that the Informant has filed several other cases against NABL and/or certain departments of the Government before the Commission in the past alleging similar contravention of the provisions of the Act.
- 26. Most of those cases have been disposed of by the Commission under the provisions of Section 26(2) of the Act for reasons recorded in detail in respective orders. The Commission, *inter-alia*, had found no infirmity, from the competition lens, in the conduct of government departments prescribing testing by an NABL accredited laboratory in its procurement tenders, stating that as a buyer, making a stipulation in procurement tenders regarding accreditation by NABL cannot be seen as an abusive imposition as such government buyers are not dominant in the procurement markets. Further, the Commission had also looked at some specific conditions required by NABL in its accreditation process in an earlier case, *namely* Case No. 25 of 2020, wherein none of those conditions were found to be anti-competitive.
- 27. Be that as it may, the Commission will deal with the allegations raised in the present information in the ensuing paragraphs.
- 28. At the outset, the Commission observes that the Informant has claimed that 'getting accreditation as per ISO 17025 from an accreditation body is just a third-party inspection of the document as per the standard but maintaining the quality, accuracy and faith of the customer is the sole responsibility of the laboratory not of the accreditation body from which the lab have (sic) purchased accreditation service'. The Commission however, observes that accreditation is an official certification of





competence or of conforming to a particular technical threshold/standard by an accreditation body.

- 29. In case of laboratories, the attestation given to a Conformity Assessment Body (CAB) signifies a formal demonstration of its competence to carry out specific conformity assessment task. As per the information available on NABL's website, a CAB is a body which may be a testing laboratory (including medical laboratory), calibration laboratory, proficiency testing provider, certified reference material producer. Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/ measurements, based on third party assessment and following international standards. Similarly, proficiency testing provider accreditation gives formal recognition of competence for organizations that provide proficiency testing. Reference material producers' accreditation gives formal recognition of competence to carry out the production of reference materials based on third party assessment of a particular standard. The introduction to the ISO 17025:2017 states that the said document has been developed with the objective of promoting confidence in the operation of laboratories and that the document contains requirements for laboratories to enable them to demonstrate that they operate competently and are able to generate valid results. The accreditation bodies certify such conformity to the laid down requirements. Thus, there seems to be an underlying element of trust in the accreditation process which provides a ready means for customers to find reliable testing (including medical), calibration, proficiency testing and reference material producer services in order to satisfactorily meet their demands. Accordingly, the claim of the Informant that accreditation is merely 'a third-party inspection of the document as per the standard' seems to have missed this important characteristic of the accreditation services.
- 30. The Informant has highlighted certain circulars issued by OP-2 to OP-5, which are Departments/Ministries of the Government of India, to allege that there was some arrangement/agreement between these OPs and NABL because of which they issued those circulars whereby NABL was prescribed as the preferred accreditation agency to the laboratories working for various departments.





- 31. The Commission however, notes that there is nothing on record to suggest that such circulars were issued in furtherance to some understanding/arrangement/agreement between the OPs. Section 3 of the Act deals with anti-competitive agreements, requiring existence of an agreement/ arrangement/ understanding in the first place to examine its impact. Further, it needs to be shown that such agreements have or are likely to have an appreciable adverse effect on competition (AAEC) in the market, except in case of agreements falling under Section 3(3) where such AAEC is presumed. There is no evidence, whatsoever, in the Information that can substantiate the claim of the Informant regarding existence of an agreement/arrangement between NABL on one hand and the departments of the Government on the other or amongst OP-2 to OP-5 inter-se. Further, the prescription by the Government to its department for following/observing some standards having direct relevance to the quality of products/services procured cannot be presumed to be in contravention of Section 3 of the Act, much less in circumstances where existence of any agreement/arrangement between the OPs is not demonstrated.
- 32. While examining similar allegations in an earlier matter, *namely* Case No. 25 of 2020, the Commission had sought the comments of Department for Promotion of Industry and Internal Trade (DPIIT) on the allegations made by Mr. Prem Prakash, the Informant in the present matter also. DPIIT had submitted 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. 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.





- 33. In view of the foregoing, the Commission is of the view that no case of contravention of provisions of Section 3 of the Act against the OPs is made out.
- 34. As regards the allegations under Section 4 of the Act, the Informant has alleged that NABL has achieved the position of dominance pursuant to the preference being given to it by various government departments/ministries and that it has abused its dominant position by mandating certain terms and conditions on the laboratories which avail accreditation services from NABL, which are over and above the terms mentioned/prescribed in ISO 17025:2017.
- 35. As regards the assessment framework under Section 4 of the Act, the entity under examination has to be an enterprise as per Section 2 (h) of the Act; it has to be dominant in the delineated relevant market; and lastly, its conduct should fall under one or more of the categories mentioned under Section 4(2) of the Act.
- 36. For ascertaining whether NABL is an 'enterprise' or not within the meaning of Section 2(h) of the Act, the Commission notes that, in Case No. 25 of 2020, it has examined the nature of services provided by NABL and has held it to be an enterprise under Section 2(h) of the Act.
- 37. Delving into the delineation of the relevant market, the Commission observes that Section 2(r) provides that relevant market can be delineated with reference to the 'relevant product market' or 'relevant geographic market' or with reference to both the markets. As regards the relevant product market, since NABL primarily provides accreditation services to CABs/laboratories, it needs to be seen what all products/service providers pose competitive constraint on its behaviour in the provision of such services. Accreditation is the action or process of granting an official recognition of being qualified to perform a particular activity and is sought by business enterprises to increase their acceptability among customers to assure them that they are following certain national/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, calibration, proficiency testing and reference material producer services in order to meet their demands.

- 38. 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. Any laboratory willing to get accreditation with regard to any of the standards recognized by Government of India/BIS, may approach an accreditation agency. NABL is one such accreditation agency. From the information furnished by the Informant and the information available in public domain, including cases dealt by the Commission on similar issues, the relevant product market *prima facie* appears to be '*provisioning of accreditation services to laboratories*'.
- 39. The geographic market in this case appears to be pan-India, since accreditation business is not confined to any particular geographic area and those who are engaged in granting accreditation, do so throughout India. Thus, the relevant market in this case appears to be 'provisioning of accreditation services to laboratories in India'.
- 40. In the relevant market delineated above, the alleged dominance of NABL needs to be examined. The Informant has not provided any evidence to substantiate the claims that NABL is a dominant player in the relevant market. Though the Informant has mentioned that Commission has dealt with this aspect in Case No. 25 of 2020 and has held NABL to be dominant, the Commission observes that in its order dated 05.07.2021 in Case No. 25 of 2020, NABL was observed 'to enjoy market power in the relevant market', and as such not conclusively held to be dominant. The records before the Commission do not warrant a different conclusion on this aspect in the present case.
- 41. Notwithstanding the aforesaid, for the sake of completeness, the Commission finds it appropriate to deal with the allegations of conduct raised by the Informant in the





present matter. The Informant has alleged some of the conditions/terms which are mandated by NABL for the accreditation, are over and above the requirement of ISO 17025:2017, whose accreditation NABL provides.

42. At the outset, the Commission observes that the ISO 17025:2017 lays down the minimum standards which are to be followed by an accreditation agency. Further, at many places, the said standard states 'including but not limited to', which clearly implies that the requirements can be made more stringent by an accreditation agency. Thus, the claim of the Informant that certain requirements have been introduced by NABL which are over and above the requirements laid down in ISO 17025:2017, cannot in itself be termed as abusive. The following narrative from the NABL's official website (FAQs) is also relevant in this regard:

FAQ 7. How is NABL accreditation different from ISO 9000 certification...?

Ans. ISO 9000 Certification is on Quality System Management only whereas the NABL Accreditation provides formal recognition of technical competence of the CABs, thus providing a ready means for customers to find reliable testing (including Medical), calibration, PTP and RMP services in order to meet their demands as well as the Quality system. Accreditation is a higher level activity than system certification. Laboratories can be checked and certified for their compliance to international management system standards such as ISO 9000. This involves the auditing of an organization's quality management system. Although this will give you confidence of the laboratory's quality system, it tells you nothing about its technical competence or its ability to provide reliable and accurate test data that will be accepted by your customers and trading partners. Proper technical evaluation requires the use of technical experts who can assess the CAB against internationally accepted criteria's. These criteria are embraced globally in documents like ISO/IEC 17025 for Testing & Calibration laboratories, ISO 15189 for Medical laboratories, ISO/ IEC 17043 for PTP & ISO 17034 for





RMP. Accreditation bodies may also apply additional technical requirements for evaluating a CAB, as per requirements of different technical fields. Accreditation against these international standards also covers the quality management system elements of ISO 9000. So NABL accreditation, which is based on these standards is a measure of both technical competence and quality management system and is the most appropriate process rather than ISO 9000 certification.

(emphasis supplied)

43. Nonetheless, the Commission finds no harm in dealing with the terms/conditions which have been alleged to be abusive/unfair by the Informant, which are dealt in the following paragraphs.

Mandatory use/restriction on the usage of NABL symbol/logo

- 44. The Informant has alleged that NABL compels laboratories which avail accreditation services to use NABL symbol/logo, which is published in the "Policy for use of NABL Symbol/or Claim of Accreditation Conformity Assessment Body (CAB) and NABL accredited CAB Combined ILAC MRA Mark" ['NABL 133']. Further, clause 6.2 of the NABL 133 mandates CAB not to use the symbols of other Accreditation body if accreditation is availed from any other Accreditation body than NABL.
- 45. In this regard, the Commission perused the aforementioned clauses of NABL 133 which are excerpted below:
 - Clause 6.2: Use of NABL symbol is mandatory in all the reports / certificates / documents issued by accredited CABs for the parameters / tests covered under NABL accredited scope. CABs are not allowed to use NABL symbol or claim NABL accreditation status in any form for the parameters which are not covered under NABL accredited scope. The non-accredited parameters shall not be a part of the report / certificate intended to be issued under NABL symbol, if it is not clearly identified and/or segregated and kept away. Asterisk mark or any other symbol or another accreditation body symbol / logo is not allowed / not permitted





to use in the report / certificate containing accredited parameters, (CABs are encouraged to include those non-accredited parameters in the accredited scope so that the customers are not mislead about accreditation status.

Clause 6.7: While claiming NABL accreditation, CAB shall use NABL symbol and / or narrative reference to the claim of NABL accreditation only. Use of any other Accreditation Body symbol or mark is not permitted to be used along with NABL symbol.

(emphasis supplied)

46. The Commission notes that these conditions appear to be aimed at avoiding misuse of NABL symbol for the accreditation of services and to apprise the consumers about the accreditation status of the laboratory. The same is also evident from the Clause 5.1 of NABL 133 which clearly states that the 'intent of the para is to avoid misuse of NABL symbol and not to mislead customers about accreditation status. So, NABL symbol was not allowed/not permitted in pages and/or part of a report/certificate where non-accredited parameters occur'. Therefore, the restriction on the usage of NABL symbol/logo in reports where non-accredited parameters cannot be clearly identified and/ or segregated seems justified. Also, the mandatory requirement of using the said logo does not seem to raise any competition concern as the same is only indicative of the accreditation status to anyone relying on the test reports. Therefore, prima facie the allegation of the Informant on this count is not made out.

Mandatory calibration at a calibration facility authorized by NABL

47. The Informant has next alleged that NABL regulations require that the complete measuring instrument be calibrated at a calibration facility authorized by NABL if a laboratory desires a certificate of accreditation from NABL. This is alleged to be not in accordance with clause 6.5 of ISO 17025:2017, which only requires metrological traceability, which calls for all measuring equipment to be confirmed through a chain of suitable references. However, because of the NABL's unfair policies, laboratories





are compelled to contact NABL recognised calibration labs, which helps the NABL grow its clientele at the expense of the consumers.

48. The Commission notes that this allegation has already been examined by the Commission in its order dated 05.07.2021 in Case No. 25 of 2020. The finding of the Commission is reproduced hereunder:

"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."

49. In view of the aforesaid observations of the Commission, this issue requires no further examination.

Unannounced Assessments by NABL

- 50. It is further alleged that NABL has issued a document NABL 100B titled "Accreditation Process and Procedure" and that, in accordance with Clause 6.5 of the said document, NABL conducts unannounced assessments in order to harass the laboratory's staff, despite ISO 17025:2017 not providing any provision for such assessments.
- 51. A plain reading of Clause 6.5 of NABL100B suggests that the unannounced assessments are done to assess continued compliance, effectiveness and also to





investigate any complaint issues against the CAB. It may be important in public interest and safety that the laboratories are compliant to the national/international standards on a continuous basis. Therefore, unannounced assessment of laboratories carried out by NABL *prima facie* do not appear to be violative of provisions of the Act. Such conditions/clauses apply uniformly across all laboratories who avail the accreditation services of NABL and seems to be aimed at ensuring continued compliance with the standard.

Imposition regarding an additional Unique Laboratory Report number

- 52. The Informant has next alleged that Clause 7.8.5, titled as "Reporting sampling", of ISO 17025:2017 includes all the details for reporting the results of sample including unique report number, but NABL through its instruction issued through letter dated 13.12.2021 [NABL/ANCMT/2021/12/13-01] to all laboratories, compelled to mention an additional unique laboratory report number.
- 53. In this regard, the Commission notes that the requirement of NABL asking its accredited labs to mention an additional Unique Laboratory Report (ULR) Number (which according to the Informant is an additional burden on the laboratories) comes with a justification mentioned by NABL in the same letter. The letter states that it is being done to facilitate mapping of claims of the sellers on Government electronic Marketplace (GeM). Therefore, *prima facie*, this condition does not raise competition concern.

Mandatory requirement of Proficiency Testing

54. Further, the Informant has challenged NABL's mandate of asking for at least one proficiency testing before providing accreditation certificate to laboratories/CABs. It is submitted that Clause 7.7 of ISO 17025:2017 titled as "Ensuring the validity of results" requires the laboratory to participate either in proficiency testing or participate in inter-laboratory comparisons other than proficiency testing. However, NABL allegedly compels laboratories to have at least one proficiency testing, as a condition to get accreditation certificate from NABL.





55. The Commission observes that the same issue has already been examined by it in its order dated 05.07.2021 in Case No. 25 of 2020, the relevant observations from which are excerpted below:

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.

56. Though the Informant has alleged that the QCI's assertion regarding proficiency testing is incorrect, the Commission is of the view that NABL, as an accreditation





agency, can mandate that the laboratories/CABs, coming to it for accreditation, to follow both of the requirements given under Clause 7.7.2 of the IS/ISO/IEC 17025:2017. The standard says that to ensure validity of its results, the laboratory shall monitor its performance either through participation in proficiency testing or participation in interlaboratory comparisons or both. The Informant's claim that NABL cannot mandate both to be fulfilled as a condition under its accreditation policy does not seem correct in view of Clause 7.7.2 of the IS/ISO/IEC 17025:2017. Clause 7.7.2 clearly states "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 limited to, either or both of the following: [....]" and this is followed by the requirement of participation in proficiency testing and inter-laboratory comparison other than proficiency testing. Thus, apparently, the IS/ISO/IEC 17025:2017 itself provides for discretion to the accreditation agency to mandate either or both of these requirements, and an extension to such requirement cannot be seen as an abuse. In view thereof, the allegation of the Informant with regard to proficiency testing is not made out.

Laboratories under sole proprietor or partnership models to convert to Companies

57. Lastly, the Informant has challenged a Circular dated 22.03.2023 whereby NABL has recognised certain kinds of enterprise forms as acceptable legal forms for CABs. The Informant has argued that this amounts to abuse of dominant position by NABL. In this regard, the Commission observes that the Informant had filed the present Information (dated 28.04.2023) with the Commission on 03.05.2023. Thus, the Circular, which was apparently issued on 22.03.2023, could have been made part of the Information instead of filing later with the Commission, in a piecemeal manner. Even otherwise, the Commission finds no reason to intervene with the impugned Circular, as the same is mandating a structure which a laboratory has to follow if it wishes to seek accreditation services from NABL. The ISO 17025:2017, as adopted by BIS, also mandates certain requirements as regards the structure of a CAB seeking an accreditation at Clause 5, which is reproduced below:





5. Structural requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

NOTE - For the purpose of this documents, a government laboratory is deemed to be legal entity on the basis of its government status.

- 5.2 The laboratory shall identify management that has overall responsibility for the laboratory.
- 5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with the document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.
- 5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.
- 5.5 The laboratory shall:
 - (a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;
 - (b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
 - (c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.
- 5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:
 - a) implementation, maintenance and improvement of the management system;
 - b) identification of deviations from the management system or from the procedures for performing laboratory activities;
 - *c) initiation of actions to prevent or minimize such deviations;*





- d) reporting to laboratory management on the performance of the management system and any need for improvement;
- e) ensuring the effectiveness of laboratory activities.
- 5.7 Laboratory management shall ensure that:
 - a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirement;
 - b) the integrity of the management system is maintained when changes to the management system are planned and implemented.
- 58. Thus, the ISO 17025:2017 lays down certain requirements with regard to the structure of a laboratory/CAB. While dealing with other allegations in the present case, the Commission had opined that accreditation of a CAB has an underlying trust element as regards the working of a CAB. On its website, in response to an FAQ, NABL has linked the enterprise form to the functioning of the CABs. Thus, as stated therein, the business entities that are not separate from their owners are required to review their business models and convert to such a model that the liability of the legal entity is not linked with that of the person running the business. In that context, a One Person Company (OPC) or any other form of legal structures, as mentioned in the Circular dated 22.03.2023, seem to have been suggested as a business model to be adopted by CABs seeking accreditation and a timeframe has been given for transition. In the FAQs, it has also been stated that an OPC provides a more standardized and accountable approach, corporate governance, separate personal and business assets, and facilitate better compliance with legal and financial obligations thereby reinforcing trust and confidence in CAB services such as testing, calibration, etc. Thus, the Circular requiring transition to any one of the legal forms mentioned under the said Circular cannot be stated to be abusive merely because it may entail an additional expense and formalities on part of the CABs. In view thereof, the Commission finds no reason to examine this circular any further.
- 59. Based on the foregoing discussion, the Commission is of the view that the allegations regarding abuse of dominant position by NABL are not made out. Thus, there exists





no case either under Section 3 or Section 4 of the Act, and the information filed is directed to be closed forthwith under the provisions of Section 26(2) of the Act.

60. The Secretary is directed to communicate to the Informant, accordingly.

Sd/-(Ravneet Kaur) Chairperson

Sd/-(Sangeeta Verma) Member

Sd/-(Bhagwant Singh Bishnoi) Member

New Delhi

Date: 22/08/2023