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A REVIEW ARTICLE ON NATIONAL ACCREDITATION BOARD FOR TESTING AND CALIBRATION LABORATORIES

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Abstract:

The National Accreditation Board for Testing and Calibration Laboratories (NABL) plays a pivotal role in India's quality infrastructure by accrediting testing, calibration, and medical laboratories across various sectors. Established under the Department of Science and Technology, NABL aims to enhance the credibility of test and calibration data by ensuring laboratories meet internationally recognized standards, particularly ISO/IEC 17025, ISO 15189, and other relevant guidelines. Through a systematic accreditation process involving rigorous technical assessments, NABL enables laboratories to demonstrate their competence, reliability, and adherence to best practices in laboratory management and technical processes.

This review article delves into the evolution, structure, and function of NABL, examining its accreditation procedures, scope, and impact on different industries including healthcare, pharmaceuticals, manufacturing, and environmental monitoring. The article further explores NABL's role in fostering global acceptance of Indian laboratories' data, facilitating trade, supporting regulatory compliance, and promoting public health and safety. Additionally, it highlights the challenges and advancements NABL faces in light of technological progress, increasing regulatory demands, and international competition. Overall, this review offers a comprehensive analysis of NABL's contributions to India's quality infrastructure, its significance in the global testing and calibration landscape, and potential pathways for future growth and improvement in accreditation standards

Keywords --NABL, ISO, QUALITY ASSURANCE, Laboratory Management, Calibration

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1.0 INTRODUCTION:

National Accreditation Board for Testing and Calibration Laboratories (NABL) is an accreditation body, with its accreditation system established by ISO/ IEC 17011.[1] "Conformity Assessment –Requirements for Accreditation bodies accrediting conformity assessment bod bodies" NABL provides voluntary accreditation services to:Testing laboratories by ISO/ IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories 'Calibration laboratories by ISO/ IEC 17025 'General Requirements for The Competence of Testing and Calibration Laboratories 'Medical testing laboratories by ISO 15189 'Medical laboratories -Requirements for quality and competence 'Proficiency Testing Providers (PTP) by ISO/IEC 17043 "Conformity assessment — General requirements for proficiency test testing Ferrous, material producers (RMP) by ISO 17034 "General requirements for the competence of reference material producers".[2] NABL is a Mutual Recognition Arrangements (MRA) signatory to ILAC as well as APAC for the accreditation of Testing and Calibration Laboratories (ISO/IEC 17025), [2-4] Medical Testing Laboratories (ISO 15189), Proficiency Testing Providers (PTP) (ISO/IEC 17043) and Reference materials producers (RMP to provide established 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 100B "Accreditation Process & Procedure".

NABL is self-financing and charges fees to Conformity Assessment Bodies to cover Operational Costs and other expenses expenditure.[3]

NABL offers accreditation services in a non-discriminatory manner. These services are accessible to all testing, including medical and calibration laboratories, proficiency testing providers, and reference material producers in India and other countries in the region, regardless of the size of the applicant CAB [2-3] or its membership in any association or group or number of CABs already accredited by NABL. For applicable fees, kindly refer to NABL 100A "General In for expenses disciplines and groups for which the accreditation services are offered in the respective fields are listed in –

N AB L 120 "Guidance for Classification of Product Groups in Testing & Calibration, field"

NABL 112 "Specific Criteria for Accreditation of Medical Laboratories"

NABL 180 "Application Form for Proficiency Testing Providers (PTP)"

NABL 190 "Application Form for Reference Material Producers Accreditation (RMP)" [3-4]

2.0 What is NABL

The Nation Accreditation Board for Testing and Calibration Laboratories [NABL] is an autonomous body under the guidance of the dept. Of science and technology, govt. Of India, whose purpose is to supply accreditation for testing and calibration of clinical laboratories within the country.

NABL specifics the general requirements for the competence to carry out tests and calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.[4]

fig:1 NABL .0 Need for Accreditation of Labs

Accreditation helps the PDCA cycle or the total quality management to be in place, which includes planning, Doing the Checking acting on this process, the first step is to set a target for improvement Eventuality planning), implement the plan (aquaplaning proceedings, and quality control), ensure whether the plan is working as intended (plainsmen and quality improvement), and, if it is found working appropriately, then make this the new standard.[4] The provision of the right results to the right individual at the right time for quality accreditation assessment compels the laboratory staff to stay on the cutting edge of technology developments as these evaluate the efficiency of the laboratory to Carrying functions scientifically and employing. Qualified personnel who are responsible for and accountable for following metrological traceability using tests to produce reproducible results and maintaining transparency. Undergoing regular assessments enhances staff discipline and a sense of professionalism and also leads to providing a high standard of quality service to customers such as patients and healthcare providers.[5]

Accreditation gives a credential to the laboratory, designating the laboratory as "Qualified and Competent" to provide services in the field in which it is accredited, thereby boosting the confidence of clinicians and the public that reports issued by the accredited laboratory are reliable and trustworthy.[5] Accredited laboratories can become more accountable and less dependent on external support.[6] Health insurance companies always try to tie up with accredited hospitals and laboratories for services and usually give early and easy clearance for any bill claims, thereby enhancing the comfort zone of insured patients. Fundamentally, any laboratory would go for accreditation mainly to ensure customer satisfaction. [5]

3.1 NABL provides accreditation to:
Testing laboratories as per ISO/IEC 17025
Calibration laboratories as per ISO/IEC 17025
Medical testing laboratories as per ISO 15189
Proficiency Testing Providers (PTP) as per ISO/IEC 17043
Reference Material Producers (RMP) as per ISO 1703
NABL grants accreditation to Testing Laboratories in boyo/ IEC 17025

4.0 MEMBERS OF NABL

1.	Chairperson
2.	Representative of National Standards Body (Ex-Officio)
3.	Representative of National Metrological Institute (Ex-Officio]
4.	A representative from Govt. / Regulators (Ex-Officio): Secretary, DPIIT; Secretary, Drug Control General of India, Secretary Textile Committee,
5.	Representatives from Associations [5] (Ex-Offices) DG, CII, SG, FICCI, SG, ASSOCHAM Chairman-TIC Council of India, President AOAC, India.
6.	Representative from Industries, VP (Tech.& Sustainability), Hindalco Industries Ltd., HIC, (IS&P), BHEL [Ms. Renuka Gera]; Executive Director (Fuel Management), Executive Director (Lubes), Bharat Petroleum Corporation Limited (BPCL), Head (ITC Life Sciences and Technical Centre), ITC Ltd.
7.	Representative from Laboratories, Director, CSIR IITR Managing Director, Metropolis Healthcare Ltd., Executive Chairman, Vimta Labs Ltd.,
8.	NABL Accreditation Committee Chairman.
9.	Quality Council of India, Secretary General (Ex-Officio).

TABLE 1; MEMBERS OF NBL

5.0 Accreditation bodies

"General Requirements for the Competence of Testing and Calibration Laboratories" The accreditation services to Testing Laboratories are currently given in the following disciplines: An accreditation body is a statutory organization that is usually established by an act of parliament and is intern national and internationally 'Mutual through atonement' [MRA].

Accreditation of the development and maintenance of good practices in testing and vibrations., technical decrements, interesting, and calibration, ii. technical increments compartmentalize and maintain international recognition for its national programs.

6.0 Global level

International Organ (for ISO) is a worldwide federation of national standards body bodies competence, ESA established that contains national its International Organization for Standardization (ISO) is a worldwide federation of national standards body which was conceived in 1947 (in the form of NATA: National was conceived 1947 (the form NATA: National Association of Testing And Accreditation of Laboratories); at present it comprises 140 members with at least one member promoting dev the development and maintenance of good practices in testing and calibration, i.e. technical requirements and competence, establishing maintaining and competence, establishing Organicist Dedication (ISO) is a worldwide federation of national standards body conceived in 1947 (in the form of NATA: National Association of Testing and Accreditation of Laboratories); at present, it comprises 140 members, with at least one member in each country. ISO publishes its guidelines as International Standards.[6] The International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) deal specifically with laboratories. ILAC delegates these tasks to ISO standards bodies like ASE Assia –Pacificatory Accreditation Cooperation (APLAC) for Asia. To make these guidelines acceptable globally and to draw uniformity all over the globe, there is a memorandum of understanding (MOU) quoting complete recognition and agreement among two indentation accreditation bodies [ILA C and IAF]and ISO [MAR]

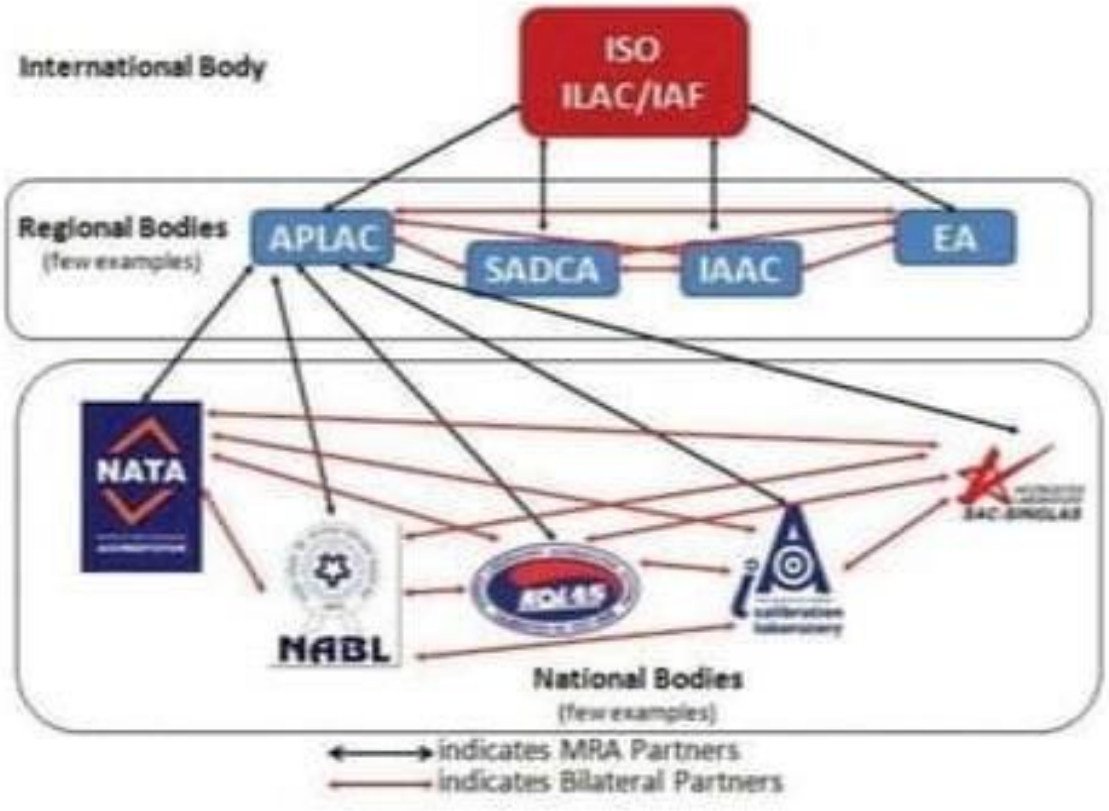

fig:2 GLOBAL LEVEL

7.0 NEEDS OF ACCREDITATION

We all know that by running a successful QA program we can deliver reliable reports in an agreed-upon frame and hence achieve customer (which may be the physician or the patient) satisfaction; and systematises, the system can be Assessed, and through this process, the system can be assessed, and improved upon, which is comprehensively called the Lab QMS. Accreditation re-enforces and reassures quality by creating an opportunity for the laboratory to look back upon the pitfalls that eventually creep into the system as soon as we take our eye off national-level guidelines for good laboratory practice, issued by the y Department of Science and Technology issued by the Department of Science and Technology have existed for d since a long, [8] but the poor response from the laboratories has led to making of a new directive wherein laboratories has led the making of a new directive wherein benefits; and this has served as the biggest driving force for the private laboratories to opt for accreditation.

Nevertheless, initiatives taken, and efforts put in by the laboratories undergoing accreditation have been lauded by the government. [9]

7.1 Laboratory accreditation: A step further than quality assurance and quality control

Accreditation is a procedure by which an accreditation body (like NABL) gives formal recognition that a body (laboratory) or person (signatory authority) is competent to carry out specific tasks (scope).[10] The procedure imparts official credit, authorization and registration of a laboratory and that it has demonstrated its capability, competence and credibility to carry out its specified scope. It is a philosophy of principles and a voluntary process including a wide array of quality tasks beyond QA and QC. Advantages of accreditation include the following.[11]

* Reports are accepted internationally implying the concept “Once Tested, Accepted Everywhere.
* Overseas business is improved
*. Quality of reports is not affected by individuals once the systems are in place.
* User confidence increases.
* Productivity increases as error and wastage decrease

7.3 Existing practices in different laboratories

Laboratories may be divided into two broad categories: among which a few are attached to medical colleges and second are the private sector laboratories wherein again we find a bifurcation:

(a) the class-apart independent laboratories run by big corporate giants or the in-house laboratories of private/corporate hospitals and;

(b) many small scale run-of-mill laboratories which do not even have the basic laboratory structure for doing Microbiology tests.

If we talk about government organizations, then those which are not associated with teaching/CME programs are the least followers of the painstaking path which quality is. On the other hand, laboratories associated with National level guidelines for good laboratory practice, issued by Department of Science and Technology have existed since long, but poor response from the have existed since long, but poor response from laboratories has led to making of a new directive wherein accreditation is a must-have for CGHS empanelment benefits; and this has served as the biggest driving force for the private laboratories to opt for accreditation. Nevertheless, initiatives taken, and efforts put in by the Nevertheless, initiatives taken, and efforts put in by the laboratories undergoing accreditation have been lauded by the government. Existing practices in different laboratories may be divided into two broad categories: first those which are run by government organizations among which a few are attached to medical colleges second are the private sector laboratories wherein again we find a bifurcation:

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The lacunae exist in an un-accredited laboratory, so instead we would like to refer to the article by Rao which quotes "Most of the medical colleges, Microbiology departments are in a poor state due to lack of shortage of staff, etc. the responsibility for this sorry state of affairs, we should admit, is partly ours".[12]

This reference reviewed most of Lab QMS in Six advice which we would like to state concerning the existing situation and see where we have come since 1992

"Reference manuals (quality documents in current parlance) should be prepared": Most non-accredited parlance) Shahabi prepared": Most non-accredited laboratories lack poorly prepared documents not by ISO 15189:2007. Type Culture Collection (ATCC) should be there": This issue has largely been resolved as one can now easily procure ATCC strains.

• "Quality check on production companies (media, disc, etc.)": although many agencies have come up as although many agencies have come up as custodians responsible for upholding quality now it is within easy reach to check the quality of these products at our laboratories.

• "Quality control of laboratory equipment NABL has already accrued A large number of calibration laboratories by 2011, but one should be careful in choosing and interpreting what these agencies report.

• "Mushrooming of private clinical laboratories should be checked": this is where this branch of medicine gets discredited the most.

• "Quality control should be taught to students at appropriate levels": this is being done at most teaching institutions but mostly theoretically.[12]

8.0 Laboratory area

Front office: OPD patients make the first contact here; Thit should displays all the contents carried out in-house and/or out-sourced (i.e., the DOS: Directory of Services), turnaround time (time calculated by subtracting the time reception of samples from the expected time of delivery of reports), names of the various cons, plants, and working hours of the laboratory. There should be a system for lodging complaints (a complaint box, complaint forms) and receiving feedback from customers.

• Sample collection room and a toilet: For essential requirements of this area, one may refer to the check ecclesiasts in NABL 217.[13]
• Processing area: This would need careful evaluation as

Major equipment's

A list of major equipment's must be provided to the NABL office in a format. The format should include the manufacturer's name, model no., year of make, year of installation, availability of operation manual and procedure, and details of periodic maintenance/calibration/validation of all equipment being used in the laboratory.

9.0 Infrastructure and equipment

A Dedicated small room was assigned As a quality manager room (QM Room) for accreditation-related work. Additional storage space was provided for files, forms, records, and equipment documents. The casing of wires, adequate power supply, signage, eye wash, safety alarms, restricted access, and sprinklers were provided. As backup equipment is mandatory in NABL, this aspect was investigated. Basic documents related to equipment (IQ, OQ, PQ, linearity check, carryover, precision check, calibration certificates, annual and preventive maintenance, and labelling) were Compiled. It was ensured that all tests applied for scope had internal quality control processes and were also enrolled for External Quality Assurance programs comparison/split testing as applicable and results assessed.

10.0 Details of Last Internal Audit and Management Review

Management review meetings (MRMs) can be conducted by QM in the process, a nice technical Manager, Chairman, and Consultants of various specialties. The minutes of the meeting must be documented. Internal audits must be conducted for each echoically by internal auditors from a different department, at least yearly, and the non-compliance, as well as the corrective action taken, have to be documented. The laboratory is required to keep a photocopy of the auditor's certificate issued by one of the recognized Internal Audit Program conducting agencies. At least one internal audit report has to be sent. One may refer to document NABL 161[14] for further details

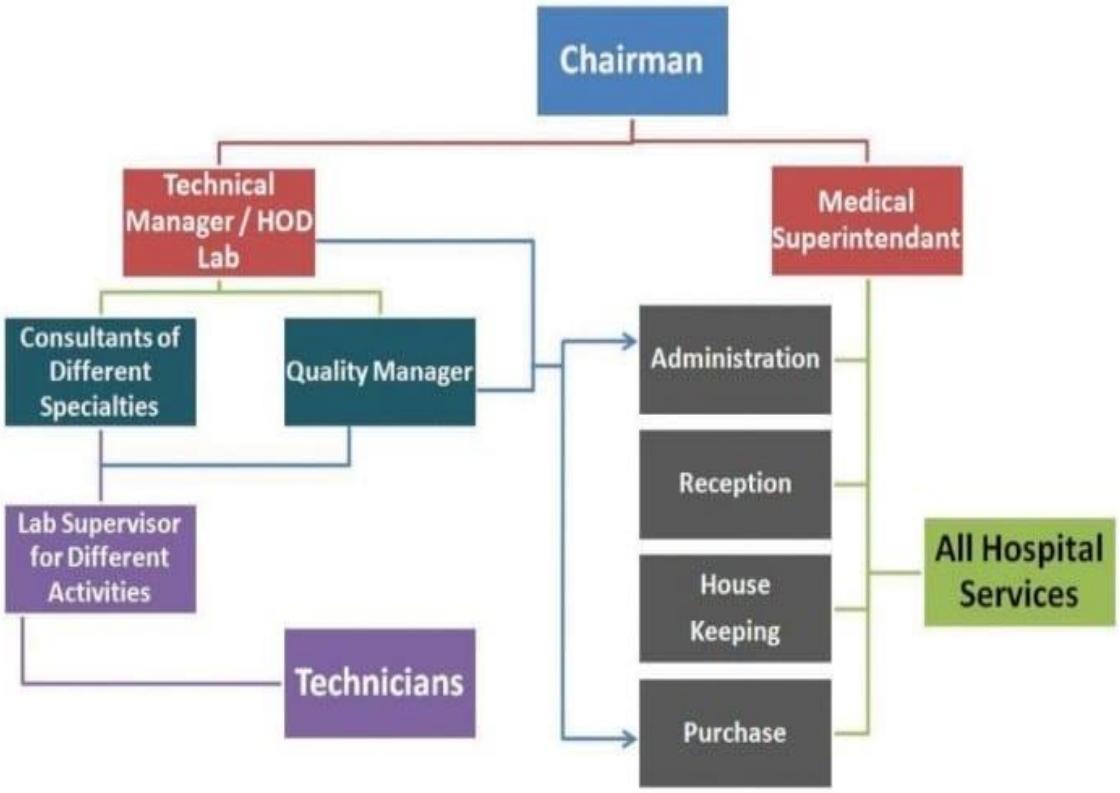

Fig:3 Management review

11.0 Challenges Associated with Accreditation

No process is bereft of challenges. Accreditation process is a prolonged and time-consuming process which at times drain the individuals involved in it. It is a teamwork, and long hours need to be put in by the quality team initially during the planning stages. Once the planning is done, the process of writing the standard operating procedures and the manual also is a time-consuming process. Once the quality processes are in place, educating the other staff members and instilling confidence in each one of them and removing any of the fears associated is a teamwork. Making everyone a part of the team involves plenty of micro - management skills and soft skills training. Once everyone feels that he/she is a part of the system in providing quality and understands that it is a continuous process, and it is easy to deliver. However, there are other issues, such as competition with other labs that are not accredited and are not worried about quality, continual improvement of turnaround time, attrition of staff, and staff refresher training, which need to be addressed as and when they arise. Each of them can affect the quality of results.

11.1 Laboratory Accreditation – Advantages to the Customer/Client Using the Laboratory Services

The accreditation process has several advantages [15], as listed earlier. However, the most important among them is the advantages to the customer/client(s) using the laboratory services. The advantages could be an increased confidence of the customers in the test reports issued by the laboratory, and this leads to a potential increase in the business due to enhanced customer confidence. With this objective, any laboratory will make continual improvements in its functioning and service. This requires regular feedback from the customers pertaining to their satisfaction. The primary external customers of laboratory services are physicians, and their opinions form key elements in providing the opportunities to the laboratory managers to identify areas for improvement. The efforts put in by the laboratories to achieve the accreditation will never go a waste and leads to plenty of improvement in the management of various laboratory networks by aiming attention on the areas that need improvement such as supply chain, training of technicians and staff members, instrument maintenance, as well as release of appropriate results after clinical correlation. The positive influence of the accreditation does not stop with an improvement in the laboratory. Its efforts are visible in the other areas of health-care delivery too. They include an improvement in clinician's services toward patients and less hospital stay for the patients (short-term benefits) and cost-effectiveness and sustainability of public health programs (long-term benefits).few studies conducted in the earlier years evaluating the laboratory accreditation and customer satisfaction are as follows: A study published in January 2009, evaluated around 138 laboratories using questionnaires pertaining to 15 different service categories of the laboratories which were distributed to around 4300 physicians mainly in the United States (97%) and remainder in Australia, Singapore, and Spain, and the overall mean satisfaction score was found to be 4.1 out of 5. In this study, with an exception for the esoteric test turnaround time, all the other laboratory service categories had excellent-to-good mean percentage values. All physicians surveyed from 57 of the 138 participating laboratories indicated that they would recommend that laboratory to another physician, but the remaining 81 laboratories did not do so. Private institutions tended to have a higher level of physician satisfaction as compared to public/governmental institutions which had the lowest level of satisfaction with laboratory services. The first most important factor which made most of the clinicians recommend the laboratory was the quality and reliability of results followed by the routine test turnaround time.[16]

12.0 PERSONNEL

• Organizational chart: Delineates the designation and hierarchy in the organization, as exemplified in

• Job description: Must be described specifically in a QSP.

• Credentialing: Certificates of professional education, experience certificates of previous employment and on-going training programs must be maintained with the QM. Along with this vaccination and health records should also be kept.

Staff education and privileging: The QM should make a syllabus regarding what needs to be taught to the staff. A typical syllabus should include collection, handling, transport and storage of samples; QSPs; general and biosafety; sterilization and disinfection; waste management; media preparation; sample processing; staining and direct examination; identification of isolate; antimicrobial sensitivity testing and QC. Each work is assessed on the skill he/she is intended to perform. After the worker is assessed on the whole syllabus, we can get to know his skill matrix or competency map. This is the right way of privileging (allowing the staff to work in specific c areas as per skill) and appraisal of the staff. The laboratory should conduct observing tests at regular proposes and present e these documents
as proofs of training. It includes;

13.0 Qualities

Concept Really from SOPs, Quality System Procedures (QSPs) include procedures meant to execute policies and serve as guides to streamline

laboratory work (especially handling of ambiguous stupidness). A long list has been suggested. One would have to use a bit of common sense to make these QSP Documents. They are nothing but how one must essentially approach a situation: Be it any important laboratory finding, a reporting error staff select observation, etc. For example, reporting positive blood culture (comically alert): Once may make a QSP stating that all BancTec positive cultures would be subjected to culture and Gram stain, and if an organism can be observed on Gram stain, the same is to be reported to the doc the next Next day after observing the growth and recording results of preliminary next condescend feedback is given their third day ,other oganisatoin with identification on and sensitivity is finally communicated to the doctor by phone. This system helps in guiding treatment and also ensures quick transfer of critical information.

13.1 Quality manual:

The most important step tord the process toward accreditation is to prepare a quality manual. This is the most exhaustive part and preparing this one can take he of the NABL 160 document which is the Guide for Preparing Quality Manual or a private consultant if required. Ironically, the Quality Manual of the laboratory is the most vital document that must be sent first to the NABL along with the laboratory "scope" when applying for accreditation.

A few tricky points are being discussed here; it should be noted that these points are not discussed in the order given in NABL 160.

13.1 Scope and purpose: Only those areas which are being aimed for accreditation should be mentioned in the scope along with its turnaround time. For example, the laboratory may have culture for Mycobacterium tuberculosis in their scope but not drug susceptibility testing, even though it may be performing the latter.

• Nomination of technical manager (TM), Quality Manager (QM) and their job description:

13.2 Job description of TM: Smooth functioning of laboratory on day-to-day basis, daily analytical work and troubleshooting, reporting of results, inventory management, recruiting staff, training and commencement of new test.

13.3 Job description of QM: To develop QMS, organize participation in proficiency testing program and ILC, daily QC, vendor selection and analysis, training of staff, organize internal audits and planning of MRMs.

• Description of the organization (one may refer to page 19 and 20 of NABL 160[19]), legal identity (registration with registrar of companies), resources and main duties.

• Quality policy: an example, "The laboratory is committed to provide services in the fi eld of Microbiology and is competent to produce accurate and precise results in a manner necessary to ensure appropriate and timely patient care. The laboratory is managed by highly qualified and trained personnel who understand quality policies as laid by ISO 15189". Quality assurance: this part has been covered under the section QC in Microbiology.

13.4 Document control: the laboratory must make a list of all the documents that have to be prepared and controlled by the Laboratory Head. This list which reflects all the necessary documents to be prepared, can be categorized as: document control system, work sheets, general safety, biosafety, QSPs, operation of various laboratory equipment's, staining techniques, media preparation and testing, biochemical preparation and testing, various cultures (technique vary with kind of sample and requisition), antibiotic sensitivity testing, in-house calibration if any and maintenance of ATCC strains. It should give a method of reflecting revisions and reviews done till date.

13.5 Manufacturer supplied data sheet (MSDS): this is available on the internet for all chemicals and describes in length various hazardous properties of the chemical (in flammability, corrosiveness, etc), ways and means to store, control spill and treat body exposure. A document listing all hazardous chemicals, used in the laboratory, should be prepared by the QM and it should cater to the above-mentioned aspects.

• Records of temperature, humidity, housekeeping, disinfection activities, pest control, safety of electrical appliances, fi re safety must be maintained • A list of laboratories accredited by NABL for calibration is available (NABL 500 document). One needs to get equipment's calibrated from accredited laboratories to maintain measurement traceability. Few types of equipment can be validated in-house through calibrated equipment.

• Once the equipment is purchased the following list of procedures have to be done entry in an inventory register, marking with labels carrying date of purchase, make, date of calibration and due date, name and phone number of service engineer and preparation of maintenance charts (for example, temperature and cleaning records).

• All chemicals are to be labelled for date of purchase, date of opening, date of expiry, storage conditions and special handling/safety instructions,

• Maintenance of records and archiving.

• Review of contracts: the laboratory should have written policy on what all services they are providing so that requests can be addressed according to the laboratory ability. Any change in the service (addition or deletion of a test) has to be notified to the users.

• Selection of referral laboratory: while selecting a referral laboratory, one must make sure that the test outsourced falls within its scope. A Memorandum of

Understanding (MOU) has to be signed between to the two laboratories.

• Purchasing services and supplies: the laboratory has to design criteria for selection of its vendors. This may include price, market reputation, maintenance of cold chain and ability to deliver products in a proper timely manner. A list of suppliers is to be made along with the evaluation scores using above criteria.

• Control of non-conformities, improvement and preventive action: to handle this important aspect, one must nominate a person (maybe a deputy QM) who would note any non-conformity brought to notice by any personnel of the laboratory. For example, if the zone of inhibition of doxycycline is out of range, as per CLSI, for Staphylococcus aureus ATCC 25923, one should perform a root cause analysis for it (which could be a alteration with pH of the media, cation concentration, incubatory conditions, turbidity standard, or the disk antibiotic concentration) as mentioned in the CLSI M-100 document. Once the problem has been identified next step is to take a corrective action at the fi rst go is stopping the release of results for doxycycline and then finally make a preventive action plan. All these activities should be document

14.0 Pre-examination procedures:

• Designing a test requisition form (TRF) and consent forms, examples of which are been provided in the NABL 217 document.

• Sample collection manual for which one may again refer to pages 37-38 of NABL 217 document.[17]

• The laboratory would have to prepare QSPs for sample reception area which should include sample rejection criteria sample numbering system, billing system (if done at laboratory), labelling of urgent requests (this can be highlighted on the TRF), written policy on verbal requests, delivery of critical information (a placard, to display what of critical information, should be present in the reception area), storage of samples and handling of complaints. To monitor quality, one should prepare records of incompletely filled forms, rejected samples, sample label errors and lost sample

15.1 examination procedure:

Internal audit and management review: The readers are advised to refer to NABL 161.Internal quality control in examination procedures Once we have addressed the procedural and document requirements, this section addresses the QC during examination procedures media preparation: Kindly refer to for requirements within the media preparation room. Both Basu Set all and Arora DR, have reviewed this topic, especially Basu S whose article had gone to great details, but both have overlooked an aspect. We have covered the entire features in a practical way and have also evolved our own method to check for the ability of media to support growth. The following QC tests should be conducted:

• pH testing (use pH meter) of every batch. The laboratory can use hydrochloric acid and sodium hydroxide for adjusting the ph. The pH meter can be calibrated in-house with help of at least two buffer solutions covering the test range.

• Sterility testing: A simple thumb rule is to incubate the prepared media at 35°C for 24 h and 25°C for 2 days; one needs to test only one unit for media which are poured and then autoclaved, while those which are autoclaved and then poured the entire lot needs to be tested (more than 10% contamination warrants discard of the entire lot).

• Performance testing. This is done whenever a new lot is procured. If one gets more than one unit of the same lot, then testing is done only for one unit. Ability to support growth: most laboratories quantify isolates on blood agar and use Mueller Hinton agar (MHA) for sensitivity testing. Hence, we would require testing the ability of these media to appropriately support growth. Indicator and selection properties, for which a media is being used, would have to be demonstrated at the time of procurement by a set of American Type Culture Collection (ATCC) strains.

• Staining: Stains should be checked by a known positive and negative control (ATCC strains) at the time of procurement and these records should be preserved. Procedure of staining can be checked on control slides whenever we perform a staining (at least from a culture smear). These slides can be made in-house and have a smear of a positive and negative control (ATCC strains) at two ends. Reagents and other consumables: New lots are tested by known ATCC and in-house controls as highlighted in a previous review. All these quality exercises should be documented, and the results preserved in the records.

• Antibiotic sensitivity testing (AST): Quality check on antibiotic disks should be done at the time of procurement and thereafter once weekly. CLSI on QC of disks with help of ATCC strains can be referred to for making this SOP as well as an SOP on QSP to follow if zones of inhibition are out of range. This is one of the most important aspects of quality check in AST as many-a-times antibiotic disks may not give zones in the required QC range. For QC of media see above. One must use 0.5 McFarland turbidity standard for inoculum preparation (for QC of McFarland, one can refer to CLSI M-100 document [17]

• EQAS and Inter Laboratory Comparison (ILC): For Microbiology, NABL recognizes EQAS program run by various institutes like Land Microbiology Research Centre; Sankara Neth Ralya, Chennai. For tests that are not covered by the above, one can perform ILC by

sending a portion of same sample to an NABL accredited laboratory (quarterly testing of all investigation not covered under EQAS is considered adequate).

Facing accreditation: Some practical tips No matter how well the laboratory follows its QMS, there are always a few gaps left and it would be wise that the laboratory head, well versed with the NABL standards, conducts a self-audit (not to be confused with internal audit which should not be done by lab head themselves) as per the checklist (NABL 217) which the assessors also make use of. After this self–audit, one should conduct a MRM and discuss the non-conformances observed; alongside one can use this opportunity to have a dialogue with the management about the transportation and accommodation for the assessors. Minutes of all MRMs should be maintained as record

16.0 Quality plan and preparation of documents:

Preparation of documents is easier if one begins with the lowest tier among the hierarchy of documents i.e. "End point documents". FIGER 4 This would include the pre-analytical (test requisition form and consent form), analytical (worksheets/registers) and post-analytical (test reports, records) documents along with others like feedback/complaint forms and formats for QC tests as microbiologists, we are aware about the standard operating procedures (SOPs) but we do not have them in print at least not in the format prescribed by ISO 15189: 2007 guidelines; so, we can start first with the end point documents and once these are streamlined, we may start writing our SOPs. Obviously, one would keep on improving the end point documents as and when one gains more perseverance standard operating procedure: An SOP should incorporate the following points which are being addressed here through the example of culture of aerobic bacteria in blood by automated system, Bactec 9050 TM. This SOP along with commensurate references must also include a copy of the Bactec 9050 TM manual:

• Purpose: To culture aerobic bacteria in blood.

• Principal of examination: Fluorescence-based detection.

• Performance specifications (unit of measurement): positive (if growth is detected) and negative (if no growth).

• Primary sample system: Blood (however, the laboratory may have a separate SOP

• Container: Bactec bottle; type depending on the patient [adult / paediatric].

• Equipment and reagents required: Biosafety cabinet-IIA, Bunsen burner, bacteriological loop, incubator, sheep blood agar, MacConkey agar, peptone water, antibiotic discs, Mueller Hinton Agar (MHA), McFarland standard, ATCC control strains.

• Calibration procedures: For calibration requirements of equipment's refer to the section j of Quality manual. Machines like Bactec 9050 cannot be calibrated by NABL certified laboratories and hence have to be placed under periodic maintenance contract with the placed under periodic maintenance contract.

• Procedural steps: This should include the eria for recessing (whenever the Bactec signals a growth.

• Responsibility: To be operated by authorized technician.

• Safety precautions: Follow standard safety precautions.

• Turnaround time: Described in detail in scope of tests.

• Internal quality control (IQC): Bactec 9050 bottles: each batch should be tested for both positive and negative results (refer to the Bactec 9050 manual).

• Interferences: Laboratory can write a comment that solation rate of Bactec 9050 increases with three cultures samples

Fig:4 quality plan

17.0 Importance of NABL Accreditation:

The NABL accreditation talk for evaluating and ensuring the quality and competence of testing and calibration laboratories. It benefits both the laboratories and their customers by promoting confidence, reliability, international recognition, compliance with regulations and a cycle of continuous improvement.

NABL accreditation is important for several reasons:

1.Quality assurance: NABL accreditation signifies that a laboratory meets international quality standards and is competent to provide accurate and reliable test results. It assures customers that the laboratory's

testing and calibration services are of the highest quality.

2.Competency assessment: Through the accreditation process, laboratories undergo a thorough evaluation of their technical competence, including personnel, equipment, procedures, and quality management system. This helps identify areas for improvement and ensures continuous development and enhancement of skills.

3. International recognition: NABL is a signatory to the International Laboratory Accreditation Cooperation (ILAC) and Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangements. This means that NABL-accredited laboratories are recognized internationally, facilitating acceptance of test results across borders.

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5.Compliance with regulatory requirements: Many industries and regulatory bodies require laboratories to hold NABL accreditation for certain types of testing and calibration. Accreditation helps laboratories comply with these requirements and enables them to participate in tenders and contracts where accreditation is a prerequisite.

6.confidence: NABL accreditation builds trust and confidence in the laboratory's services among its customers. It demonstrates the laboratory's commitment to quality, accuracy, and reliability, leading to increased customer satisfaction and loyalty.

7.Potential increase in business: Due to enhanced customer confidence and satisfaction, accredited laboratories receive a form of international recognition, which allows their data and results to be more readily accepted in overseas markets. Accreditation helps to reduce costs for manufacturers and exporters who have their products or materials tested in accredited laboratories, by reducing or eliminating the need for retesting in another country.

8.Improvement in performance via Proficiency Tests: Many laboratories operate in isolation from other laboratories and do not have ongoing opportunities to compare their data with others. Without such opportunities, there are risks that the data of a laboratory may have errors, biases or significant differences when compared to data from other similar laboratories. Proficiency testing provides an opportunity to undertake such comparisons and to have an independent appraisal of the laboratory's data compared to reference values (or other performance criteria) or to the performance of similar laboratories. The results from such participation provide laboratory managers with either a confirmation that the laboratory's performance is satisfactory or an alert that an investigation of potential problems within the laboratory is required.

18.0 Applying for accreditation

Under ideal conditions, one must first set up a laboratory, establish a Lab QMS, start processing, perform an internal audit, improve the system as per ISO 15189 or NABL 112 , apply for External Quality Assurance Scheme (EQAS) and once having achieved satisfactory results, apply for accreditation, but if we follow this, we may never get accreditation as the intended state of perfection aimed by the above standards may never exist with no training or external assistance; so the most practical way would be to apply for and develop alongside because as the date of inspection, for accreditation, comes near, an intense pressure improve mounts.

The best thing about NABL is the large number of self-help publications freely available on its website for the purpose to facilitate people opting for a "Do it Yourself" and to reduce dependence on private consultants.

Therefore, even if consultants are hired, the fi rst step is to download and read thoroughly the following documents from NABL website besides NABL 112: Application form for Medical Laboratories (NABL 153), General Information Brochure (NABL 100), [18] Guide for Preparing Manual (NABL 160) and Guide for Internal Audits and Management Review (NABL 161). NABL 131 document which highlights the Terms and Conditions for Maintaining NABL Accreditation should be read and signed by Laboratory head. NABL 153[18] details necessary documents required to apply for accreditation. The following aspects need to be investigated.

• Laboratory registration under "The Companies Act."

• Laboratory must apply for EQAS. One needs to register by pre-assessment but till final assessment this system should be fully functional.

• Scope: A list of tests, for accreditation, is to be prepared and send to the NABL office. The details can be sent in the format cited in Table 1. Before deciding the scope of the test, one must ensure availability of relevant space and equipment's as highlighted below

CONCLUSION:

In summary, the National Accreditation Board for Testing and Calibration Laboratories (NABL) has proven to be a cornerstone of India's quality and standards framework, promoting excellence in laboratory practices across testing, calibration, and

medical sectors. By establishing and enforcing internationally recognized standards such as ISO/IEC 17025 and ISO 15189, NABL ensures that accredited laboratories in India adhere to stringent guidelines for accuracy, competency, and integrity in their measurements and data outputs. This fosters confidence among industry stakeholders, regulatory bodies, and the public, driving improvements in product safety, environmental protection, healthcare quality, and industrial efficiency.

The global acceptance of NABL-accredited laboratories has also been a critical factor in enhancing India's position in international markets, allowing domestic laboratories to achieve mutual recognition in global trade, reducing technical barriers, and supporting India's export potential. Furthermore, NABL's efforts facilitate regulatory compliance across sectors, aligning India's practices with global standards and supporting national initiatives for health, safety, and environmental quality.

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Mandla Neeraja.

REFERENCES:

1. Bartlett RC, Sullivan MM, Tetreault JZ, Lobel S, Nivard J. Evolving approaches to management of quality in clinical microbiology. Clin Microbial Rev 1994; 7: pg. 55-88.
2. Arora DR. Quality assurance in microbiology. Indian J Med Microbial 2004; 22:81-6.
3. Basu S, Pal A, Desai PK. Quality control of culture media in a microbiology laboratory. Indian J Med Microbial 2005; 23: pg :159-633.
4. [11:11 AM, 10/20/2024] Sreenu Chinni: Burtis CA, Ashwood ER, Bruns DE. Tietz Textbook of Clinical Chemistry and Molecular Diagnostic, e-book 5th End St Louis Mo Elsevier/Saunders, 5th January 2012 Chapter 8.1 Klee GG, Westgard JO. Principles of laboratory medicine, Quality management [, 10/20/2024]
5. Unger P. Laboratory accreditation Lab Manager. 2014:9 Available from: https://www.labmanager.com. [Last accessed on 2020 May 04]
6. Peter TF, Rotz PD, Blair DH, Khine AA, Freeman RR, Murtagh MM. Impact of laboratory accreditation on patient care and the health system Am J Clin Patrol. 2010; 134: pg:550–555
7. Iso 9000 [QMS] - FAQS. Available from; http;// www.bio,org. In/cert/faqmscd.htm. [last accessed on2011dec11] pg:900-993.
8. guidelines for good clinical Laboratories practices [GCLP]. Available from: http//WWW.icmr.nic. In/ guidelines/GCLP.pdf. [Last accessed on 2011 Dec 11]
9. NABH accreditation lauded. Available from: http://www.qcin.org/nbqp/qualityindia/Vol-2-No5/health_page_4_9.php. [Last accessed on 2011 Dec 11]
10. ISO/IEC Guide 2: 2004 (Standardization and Relative Activities – General Vocabulary: Availablefromhttp://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+Guide+2%3a2004andsource=googleandadgroup=iso10andkeyword=ISO%2FIEC%20guide%202andgclid=CO2HuKLImKwCFUkb6wodMUBGPQ. [Last accessed on 2011 Dec 11]
11. ISO 9000 (QMS) – FAQ's. Available from: http://www.bis.org.in/cert/faqmscd.htm#. [Last accessed on 2011 ;12::231-254.

12. About ILAC. Available from: http://www.ilac.org/aboutilac.html. [Last accessed on 2011 ;12::11.
13. Assessment Forms and Checklist (Based on ISO 15189: 2007) (NABL 217; Issue No: 02, Issue Date: 01.02.2008, Amendment No: 05, Amendment Date: 01.09.2008). Available from: http://www.nabl-india.org/nabl/asp/users/documentMgmt.asp?cp=4anddocType=both. [Last accessed on 2011 Dec 11]
14. Guide for Internal Audit and Management Review for Laboratories (NABL 161; Issue No: 03, Issue Date: 25.03.2008, Amendment No: 00, Amendment Date: 00). Available from: http://www.nabl-india.org/nabl/asp/users/documentMgmt.asp?cp=3anddocType=both. [Last accessed on 2011 Dec 11]
15. NABL India. About Accreditation FAQs. Available from: https://nabl-india.org/faq/. [Last accessed on 2020 May 03]
16. NABL India. About Accreditation FAQs. Available from: https://nabl-india.org/faq/. [Last accessed on 2020 May 03]
17. NABL India. About Accreditation FAQs. Available from: https://nabl-india.org/faq/. [Last accessed on 2020 May 03]
18. General Information Brochure (NABL 100; Issue Date: 17.08.2010). Available from: http://www.nabl-india.org/nabl/asp/users/documentMgmt.asp?cp=1anddocType=both. [Last accessed on 2011 Dec 11]