Original article:

Study on accreditation: A boon in health care , its benefits and implementation in the hospital laboratory set up with reference to National Accreditation Board for Testing & Calibration of Laboratories

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Abstract:

Accreditation is the third party attestation related to a conformity assessment body conveying the formal demonstration of its competence to carry out specific conformity assessment task. Conformity Assessment Body (CAB) is a body which includes Testing, including medical Laboratory, Calibration Laboratory, Proficiency Testing Provider and Certified Reference Material Producer**[1]** Accreditation is a process of validation in which colleges, universities and other institutions of higher learning are evaluated. The standards for accreditation are set by a peer review board whose members include faculty from various accredited colleges and universities.

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Introduction

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The liberalization of trade and industry policies of the Government of India has created quality consciousness in domestic trade and provided greater thrust for export. As a consequence testing centres and laboratories have to demonstrably operate at an internationally acceptable level of competence.

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. Laboratory accreditation activities are administered under the direction of the National Accreditation Board for Testing and Calibration Laboratories (NABL), involving assessment team and accreditation committee as recommending authorities. NABL is a signatory to Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International Laboratory Accreditation Cooperation (ILAC) through Mutual Recognition Arrangements (MRA)**[2].**

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These are based on mutual evaluation and acceptance of other MRA partners. Such international arrangements allow acceptance of test calibration results between MRA partner countries. Similarly, Proficiency testing Provider accreditation gives formal recognition of competence for organizations that provide proficiency testing. Accreditation gives formal recognition of competence to carry out the production of reference materials based on third party assessment and following international standards. Accreditation provides formal recognition of competent CABs, thus providing a ready means for customers to find reliable testing (including Medical), calibration, Proficiency Testing and Reference Material Producer services in order to meet their demands.

Accreditation enhances customer confidence in accepting testing / calibration reports issued by accredited laboratories. Society also needs to know the technically competent laboratory in fields such as Medical, Forensic and Food Testing . The globalization of Indian economy and the liberalization policies initiated by the Government in reducing trade barriers and providing greater thrust to exports makes it imperative for Accredited Laboratories to be at international level of competence

Methodology

The study was conducted at Dr VRK Women's Medical College hospital, Hyderabad ; after prior institutional permission.

Two standard NABL questionnaires **[3]** were formulated according to the NABL guidelines and the study was conducted on our lab to check the efficacy on day to day basis. The answers were typed in bold letters in Questionnaire 1 and Red in Questionnaire II

This study was conducted for a total of 3 months.

1.Questionnaire pertained to laboratories:

(a) **DOCUMENT CONTROL AND REVIEW OF PROCEDURE MANUALS**

Clause 4.3 related questions:

1. How often do you review your documents? **Weekly once**
2. How many documents are due for review? **50**
3. Show me an example of an old version of a document and a new version of the same document? **Done**
4. Where are your Procedure manuals? **There**
5. Are they easily accessible for staff access? **Yes**
6. Is it clear who wrote the documentation? **Yes**
7. How does staff know that they are using the most current version of the document? **They are taught so as they are updated.**
8. What do you do with your superseded documents? **Maintain it in a file**
9. Do you allow handwritten amendments to your documents? **No, computerised**
10. How would you find out if a member of your staff has made a hand written amendments?

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11. Do all your documents show the page number, total page numbers and a version date or number? **Yes**

Clause 5.5, 5.5.2 and 5.5.3 related questions:

1. How many of your procedures are in house procedures? **Very less**
2. Have you validated your in house procedures and if so where are the records of those validations? **Yes**
3. Where you have performed method validations have you complied with the National Association of Testing Authorities (NATA) requirements on page 13 of their Field Application Document (FAD) (4) 5.5.2 (i), (ii) and (iii)? **Yes**
4. For non in house procedures have you evaluated/checked their performance for medical testing using normal and patient samples? **Yes**
5. Do your staff use 'abbreviated procedures' eg method cards, pocket books, flip files etc – if so how have you ensured that they are adequate ? Have you included them into your document control system? **Yes**
6. Do your staff use package inserts from Medical Testing Kits and if so how do you document control them? **No**
7. Do you use the package inserts enclosed with your Quality Control Material and if so how do you document control them? **Registers properly maintained**
8. Do you have any procedure or interpretative documentation displayed on walls, in flip files and if so how do you document control them? **Yes**
9. How do you document control the Procedure Manuals supplied with Medical Testing Instrumentation : **Documentation done**

(b) INCIDENT REPORTS AND THEIR CORRECTIVE ACTIONS

1. How many incident reports have been issued in the last twelve months that have involved your area**? Around 20**
2. How many of these incident reports are still 'open' ie the corrective action has not been completed and why? **None**
3. How many corrective action requests have been issued in the last twelve months that have involved your area? **Around 20**
4. How many of these corrective action requests are 'open' i.e. the corrective action has not been completed and why? **None**
5. If there have been no corrective action requests issued in the past twelve months does this reflect that there have been no problems in your area? **NA**

(c) PERFORMANCE INDICATORS – RECORDS AND REVIEW

1. What quality indicators do you use in your area that can pick up potential sources of non-conformance and/or opportunities for improvement? **We use EQAS**
2. What opportunities for further education and training are available for staff in your area? **BMLT courses**

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(d) AUDIT REPORTS AND THEIR CORRECTIVE ACTIONS

1. When your area was last audited? **Not done earlier**

2. Do you have a copy of that Audit Report available for us to discuss?

3. Are there any incomplete corrective actions relating to that last audit?

4. Are there any aspects of your activities that you would like to have audited in the near future?

(e) LABORATORY ENVIRONMENT

1. Do you have adequate space to perform all aspects of your work in? **Yes**

2. Does the physical layout of your area comply with the principles of a LEAN (5) design that ensures an efficient and logical flow of specimens and analytical work through your area?

3. Are there any risks of cross contamination happening? **No**

4. Where do you store your samples that

- Are awaiting analysis
- Have been analysed
- Have to go into long term storage and are all these locations maintained at the correct

temperature for this purpose? **Adequate storage facilities for all samples.**

5. Do you have temperature records for these various storage locations? **Yes**

6. What are the NPAAC Guidelines (6) for long term sample and record storage as they relate to your area and do you comply with them?

7. Where is your Safety Manual? **Yes**

8. Are there additional safety requirements that apply to your area and how do you ensure that staff have been trained in these extra safety procedures/precautions? **Staff trained**

(f) LABORATORY EQUIPMENT, INVENTORY,MAINTENANCE RECORDS AND CALIBRATION

1. Do you have up to date records of Make, Model, Serial Number and purchase date of all your instruments? **Yes**

2. Where are your maintenance records for all your instruments used in medical testing? **Yes**

3. Does your staff have easy access to the maintenance records and do they know who to contact if a particular instrument needs maintenance or repair during your absence eg. While you are on leave? **Yes**

4. Have you documented the frequency (ie a calendar) of preventative maintenance for all your instruments and is this being adhered to? **Yes**

5. What mechanisms are in place that ensures that you are informed if an instrument is considered to be malfunctioning? **Adequate measures are taken as per NABL guidelines**

(g) TRAINING RECORDS

1. Where are your training records and are they up to date? **Yes**

2. Do you training records show the identities of the trainer? **Yes**

3. Do your training records show that both the trainer and trainee sign off at defined stages of the process? **Yes**

4. Have you documented retraining triggers for your area? **Yes**

5. Are you adhering to all the NATA requirements as specified on page 11 of the FAD under 5.1, 5.1.2

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and 5.1.11 for training and continuing education? **Yes**

6. Does any of your staff make interpretative comments on results and if so how is this monitored for consistency? **Yes**

(h) MINUTES OF STAFF MEETINGS

1. Please show me the agendas and minutes of your last six staff meetings for this area? **Done**

2. Are these minutes placed in a location where all staff can access them? **Yes**

3. Do you record attendances at these meetings? **Register maintained**

4. How do staff who are unable to attend these meetings get to know about the business discussed at them and the decisions that were made? **Minutes of meeting recorded**

(i) STAFF RESOURCES : RELEVANT TEXBOOKS AND JOURNAL ARTICLES

1. Where do you keep text books and journals that staff needs to have access to as part of their work? **Library maintained in the lab**

2. Do you comply with NATA FAD minimum requirements on textbooks ? **Yes**

(j) ARRANGEMENTS FOR THE SUPPORT FOR OUT OF HOURS STAFF

1. Do you comply with the NATA FAD clause 5.1 requirements on page 11? **Yes**

2. Are there documented procedures and records to support the effectiveness of these arrangements? **Yes**

(k) REAGENT PURCHASE, INVENTORY AND CONTROL

1. Do you purchase third party reagents or consumables for any of your instruments and if so have you independently confirmed that they are equivalent in practice to the instrument manufacturer's recommended product? **Yes**

2. Do you have an inventory control system for key reagents and consumables used in your area? **Yes**

3. Who is responsible for initiating the purchase of items required to restock your inventory? **Store**

4. Who is responsible for checking the condition, quantities and timeliness of deliveries to your area? **Staff deployed**

5. How do you document events where the supply of reagents and consumables have fallen short of your specifications for timeliness of delivery, quantities delivered, physical condition of the deliveries, frequent breaks/changes in Lot Numbers, deliveries with inadequately short Use By Dates, refusal to take back into store and/or replace free of charge rejected deliveries and other criteria that you have defined as being essential for these materials? **documented**

(l) SPECIMEN REJECTION

1. Where have you documented the criteria for rejecting primary samples and secondary aliquots of primary samples? **Registers maintained**

2. Where do you record the fact that a primary sample or secondary aliquot has been rejected? **Registers maintained**

3. How do you inform clients that one of their primary samples or secondary aliquots has been rejected? **By phone and by written messages**

4. Are there documented circumstances under which you will proceed to process and report results on a primary samples or secondary aliquots which under your criteria you would normally have rejected? **Yes**

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5. Do you involve a Pathologist when any of these adverse events occur? **Yes**

(m) PROVISION OF CLIENT INFORMATION – ie.SPECIMEN REQUIREMENTS, PATIENT PREPARATION, SPECIMEN HANDLING, STORAGE AND DISPOSAL

1. Does your Primary Sample Collection Manual –adequately refer to the patient preparation, sampling and specimen containers required for the tests performed in your area? **Yes**

2. Are all your tests on the Specimen Requirements Database and are they up to date? **Yes**

3. Who can update this information and who covers for that person in this activity when they are on leave, absent etc? **Computer operator**

4. Do any of your specimens require to be transported under controlled conditions eg at 4 degrees, immersed in formalin, must be delivered within 15 minutes etc and if so what mechanisms do you have in place to check that this has been done correctly for your samples? **Sometimes required**

5. Are your clients aware of the tests that you examine in batches less frequently than daily or refer elsewhere and how have you communicated this to them? **Yes**

6. Where do you store your specimens to be analyzed, those specimens that have been analyzed and those specimens that need to be retained and/or referred on to another internal or referral laboratory? **Stored in refrigerators with proper dates mentioned**

7. Do you have long term storage of samples ie longer than one week and if so do you have an inventory of those samples to assist with their retrieval? **Yes**

8. When, where and how do you dispose of old samples? **Proper waste disposal method used**

9. Please show me records of samples that you have rejected for analysis because they did not have the "three points of positive patient ID" on the tubes and/or the request form?

10. Are all your staff aware of the procedures to follow when they receive inadequately labeled samples and forms? Is this part of their documented training?

(n) UNCERTAINTY OF MEASUREMENTS

1. How many of your tests have had their Uncertainty of Measurement quantitated? **Very less**

2. On the basis of the Calculated Uncertainty of Measurement calculations do you have any tests which fall short of the performance required for clinical use? **Yes sometimes**

3. Are you familiar with the NPAAC document on Uncertainty of Measurement (7) and have you followed their guidelines where they have given worked examples for tests that you perform? **Yes**

(o) WORKLISTS

1. Do you use numbering systems (i.e secondary numbers on specimens) in addition to the unique laboratory accession number and if so how do you ensure that there are no opportunities for mismatches? **Bar coding done**

2. Have you documentation that describes how your staff is to perform the secondary numbering (if applicable)?

(p) INTERNAL QUALITY ASSURANCE PERIODIC REVIEW

1. Do you run internal quality controls with all your assays and if so they are all materials that are 'third party' controls, i.e. controls manufactured and calibrated by suppliers independent of the instrument manufacturer? **Yes**

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2. How do you train staff in your area in the performance and evaluation of quality control? **To study the LJ charts daily**

3. Please show me some records/evidence that you periodically discuss internal QC performance with your staff.

(q) **EXTERNAL QUALITY ASSURANCE PROGRAMME PERFORMANCE AND REVIEW**

1. Are there any tests in your area for which there is no external QAP? **None**

(r) REPORTING OF RESULTS

Done properly

(s) **WORK PERFORMED BY REFERRAL LABORATORIES AND ITS REPORTING**

1. Do you have an up to date list of the laboratories that you refer work to? **Yes**

2. When did you last check that they were accredited to ISO 15189 standard to perform this work? **Last month**

3. What mechanisms are in place to check that there are no transcription errors between the hard copy reports received from the external lab and the version/synopsis that appears in your laboratory computer system? **Properly cross checked**

2.CHECKLIST FOR MEDICAL LABORATORY COLLECTION CENTRES Collection Centre:

Premises _____Dr VRK Medical college Hospital,Hyderabad___

1	Type of the Collection Centre	Owned / Managed / Franchise	Remarks
2	Size of premises		
3	Collection Centre is operational from	1/2/2011	
4	Does it meet the requirement of the Workload	Yes / No	Yes
5	Reception and waiting area separate from collection area	Yes / No	Yes
6	Hand washing facilities	Yes / No	Yes
7	Clean toilet facility	Yes / No	Yes
8	Provision of privacy during collections	Yes / No	Yes
9	Hours of operation have been displayed	Yes / No	Yes

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Accommodation and Environmental Conditions

1	Is it adequately lit and clean	Yes / No	yes
2	Is the humidity and temperature suitable	Yes / No	yes
3	Are cleaning policies available	Yes / No	yes
4	Is it adequately ventilated and prevented from dust	Yes / No	yes
5	Does it have adequate space & separation to avoid cross contamination	Yes / No	yes
6	Is the house keeping adequate	Yes / No	yes

Equipment

1	Refrigerator	Yes / No	yes
2	Centrifuge, if needed	Yes / No	yes
3	Proper storage of supplies	Yes / No	yes
4	Suitable chair and/ or couch for collection of blood, etc.	Yes / No	yes
5	Basic first-aid materials	Yes / No	yes
6	Telephone	Yes / No	yes
7	AC for controlling temperature, if needed	Yes / No	yes
8	Power backup for equipments	Yes / No	no

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Materials

1	Material required for specimen collection eg. evacuated blood collection tubes, syringes, tubes, swabs etc	Yes / No	yes
2	No expired material in the premises	Yes / No	yes

Staffing

1	Staff members	___12_ nos	**12**
2	Is it appropriate to the workload?	Yes / No	yes
3	Initial training records	Yes / No	yes
4	Ongoing training records	Yes / No	yes
5	Does the staff possess knowledge of first aid measures to deal with situations they are likely to encounter in the course of specimen collection?	Yes / No	yes
6	Appropriate identification to be worn by the staff	Yes / No	yes

Documentation

1	List of services provided	Yes / No	yes
2	List of services excluded	Yes / No	yes
3	Sample collection manual available	Yes / No	Yes
4	Records of Internal audit (available at laboratory)	Yes / No	Yes

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Health and Safety

1	Collection staff to observe universal precautions (to wear gloves, lab coat & protective mask	Yes / No	Yes
2	Vaccinated against Hepatitis B	Yes / No	Yes
3	Vaccinated against other preventive Disease	Yes / No	Yes

Safety and Waste Disposal

1	Approved receptacles for sharps and for contaminated waste available	Yes / No	Yes
2	Transport and disposal of waste is in accordance with applicable regulatory requirements	Yes / No	Yes

Transport of Pathology Specimens

1	Does the collection centre follow national/international regulations for the transport of infectious and other diagnostic specimens by air and by surface so that in the event of an accident occurring, courier staff and the general public may not be exposed to blood and body fluids	Yes / No	yes
2	Has the specimen collection staff	Yes / No	Yes

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	participated in training in specimen collection, transport, handling of emergencies etc?		
3	Has the above staff participated in retraining undertaken at not greater than two year interval?	Yes / No	Yes
4	Is the parcel of infectious substances attached with a plastic envelope containing document – '**Bio-hazardous diagnostic specimens**'?	Yes / No	Yes

Packing

1	Is the primary container containing specimen leak proof tube or vial?	Yes / No	Yes
2	Does the secondary container possess sufficient absorbent material to absorb the contents if the primary container leaks?	Yes / No	Yes
3	Are both the above containers properly labelled?	Yes / No	Yes
4	Is the secondary container packed into appropriate outer packing and labelled appropriately?	Yes / No	Yes
5	Is cooling agent included in the outer package if cold chain is	Yes / No	Yes

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	to be maintained?		
6	Is the outer package labelled, addressed and taped securely	Yes / No	Yes
7	Are the pap smears mailed in rigid slide mailers to prevent breakage of the slide?	Yes / No	Yes

Complaints / Feedback

1	Does the collection centre has provision for receiving of complaints / feedback	Yes / No	Yes
2	Are the complaints / feedback reviewed and resolved by the laboratory	Yes / No	Yes

Both the questionnaires were thoroughly discussed and studied and adequate steps were taken on the improvement on the loopholes if any.

Conflict of interest- Nil

Results

1. After stringent studying of both the questionnaire for three months ; it was finally concluded that our laboratory was in par with the NABL requirements and was ready for the internal as well as external audit.

2.These questionnaires can prove to be a benchmark for the NABL assessing programmes and help the laboratories for better functioning.

Discussion

Accreditation is the process in which certification of competency, authority, or credibility is presented. Organizations that issue credentials or certify third parties against official standards are themselves formally accredited by accreditation bodies (such as UKAS); hence they are sometimes known as "accredited certification bodies".The accreditation process ensures that their certification practices are acceptable, typically meaning that they are competent to test and certify third parties, behave ethically and employ suitable quality assurance.

Benefits of accreditation

The process of accreditation helps in realizing a number of benefits, such as:

- Helps the Institution to know its strengths, weaknesses and opportunities.

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- Initiates Institutions into innovative and modern methods of pedagogy
- Gives Institutions a new sense of direction and identity.
- Provides society with reliable information on quality of education offered.
- Promotes intra and inter-Institutional interactions.

Laboratory accreditation activities are administered under the direction of the National Accreditation Board for Testing and Calibration Laboratories (NABL), involving Assessment Team and Accreditation Committee as recommending bodies. NABL is a signatory to Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangements (MRA). These are based on mutual evaluation and acceptance of other MRA partner laboratory accreditation systems. Such international arrangements allow acceptance of test/ calibration results between MRA partner countries. The laboratories are required to comply with all the requirements listed in the international standard ISO 15189:2007 (Medical laboratories - Particular requirements for quality and competence**)[4].**

Benefits of NABL [5,6]

Formal recognition of competence of a laboratory by an Accreditation body in accordance with international criteria has many advantages:

1. Increased confidence in Testing/ Calibration Reports issued by the laboratory
2. Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent
3. Potential increase in business due to enhanced customer confidence and satisfaction.
4. Customers can search and identify the laboratories accredited by NABL for their specific requirements from the NABL Web-site or Directory of Accredited Laboratories
5. Users of accredited laboratories enjoy greater access for their products, in both domestic and international markets.
6. Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.

This approach has proved to be a success for all parties concerned with the internal audit process. An unexpected finding has been that because the questionnaire was issued to Technical Managers before the audit many of them took the opportunity to gather the documentation and records in anticipation of the audit. This also speeded up the process of auditing. Technical Auditors have welcomed the innovation as it makes better use of their time and the audit remains relevant to their roles and responsibilities in the laboratory.

Laboratory shall ensure that internal audits are conducted effectively covering all the elements of ISO 15189:2007. Audit schedule shall include pre and post examination activities and shall be covered in detail during audit.

The Laboratory must establish and document procedures for monitoring and evaluating analysis of testing processes including procedures for resolving ‘out-of-control’ situations, biomedical waste management**[7]** and electronic reporting **[8].** The laboratory is encouraged to use control material similar to or identical with patient sample matrix **[9,10].**

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The laboratory shall incorporate in the procedure, the multi-control QC rules used to detect systematic (trends or shifts) and random errors. The laboratory shall include a minimum of one level QC at least once a day. However, where the number of patient samples analysed for any parameter exceeds 25 per day, the laboratory shall employ 2 levels of QC at least once a day for such parameters. Further, if the number of patient samples analysed for any parameter exceeds 75 per day, the laboratory shall employ 2 levels of QC at least twice a day at appropriate intervals. The daily QC values shall be documented along with the calculation of %CV from the monthly QC data. The laboratory shall maintain control charts to demonstrate stability of the analytical measuring systems **[11].**

The laboratory shall follow the multi control QC rules as described below:

The rules to follow when one level QC material is used:

Reject QC if:

a. it is outside 3 SD (13s)

b. two consecutive values obtained are outside 2 SD on the same side but within 3 SD (22s)

c. ten consecutive values are above or below the mean, but within 2 SD (10x)

The rules to follow when 2 level QC materials are used:

Reject QC if:

a. either QC values is outside 3 SD (13s)

b. both QC values are outside 2 SD on the same side, but within 3 SD (22s)

c. difference between both QC values is >4 SD i.e. one level QC is > 2 SD and other level QC is <2SD (R4s).

d. ten consecutive values of the same level QC are >/< the mean, but within 2 SD (10x).

e. five consecutive values of one level QC and five consecutive values of other level QC are >/< the mean but within 2 SD (10x)

The laboratory shall have step-by-step flow chart to manage ‘out-of-control situation’ such as:

- Search for recent events that could have caused changes
- Examine environmental conditions.
- Follow manufacturer’s troubleshooting guide.
- Refer to manufacturers of equipment, reagents or QC/calibrator.

Conclusion:

The laboratory shall employ suitable reference material traceable to international standards for calibration of measuring systems and methods. Traceability certificates for calibrators shall be obtained from kit suppliers and appropriately documented. Alternate methods shall be employed for verifying accuracy of results of such of those tests for which calibration and control materials are not available.

References

1. USDA ISO Guide 65 Program Accreditation for Certification Bodies Archived September 27, 2007, at the Wayback Machine. U.S. Department of Agriculture, Agricultural Marketing Service, August 9, 2007
2. National Accreditation Board for Testing and Calibration Laboratories
   Doc. No: NABL 112 Specific Criteria for Accreditation of Medical Laboratories

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3. An audit questionnaire that examines specifically the management of technical activities clauses in iso 15189. Indian Journal of Clinical Biochemistry, 2010 / 25 (1) 92-98
4. ISO 15189:2007 Medical laboratories– Particular requirements for quality and competence.
5. National Accreditation Board for Testing and Calibration Laboratories Doc. No: NABL 102 Specific Criteria for Biological Testing Laboratories Issue No: 04 Issue Date: 25-Apr-2016 Amend No: 00 Amend Date: -- Page No: 6/72
6. ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories.
7. National Accreditation Board for Testing and Calibration Laboratories Doc. No: NABL 102 Specific Criteria for Biological Testing Laboratories Issue No: 04 Issue Date: 25-Apr-2016 Amend No: 00 Amend Date: -- Page No: 38/72
8. National Accreditation Board for Testing and Calibration Laboratories Doc. No: National Accreditation Board for Testing and Calibration Laboratories Doc. No: NABL 102 Specific Criteria for Biological Testing Laboratories Issue No: 04 Issue Date: 25-Apr-2016 Amend No: 00 Amend Date: -- Page No: 44/72
9. NABL 102 Specific Criteria for Biological Testing Laboratories Issue No: 04 Issue Date: 25-Apr-2016 Amend No: 00 Amend Date: -- Page No: 34/72
10. National Accreditation Board for Testing and Calibration Laboratories Doc. No: NABL 102 Specific Criteria for Biological Testing Laboratories Issue No: 04 Issue Date: 25-Apr-2016 Amend No: 00 Amend Date: -- Page No: 36/72
11. National Accreditation Board for Testing and Calibration Laboratories Doc. No: NABL 112 Specific Criteria for Accreditation of Medical Laboratories Issue No: 03 Issue Date: 01.02.2008 Amend No: 00 Amend Date: -- Page No: 29 / 45