



**National Accreditation Board for
Testing and Calibration Laboratories
(NABL)**



Specific Criteria for Accreditation of Medical Laboratories

ISSUE NO. : 04

ISSUE DATE : 11-Feb-2019

AMENDMENT NO. : 01

AMENDMENT DATE : 26-Apr-2019

AMENDMENT SHEET

Sl	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QM	Signature CEO
1.	25-28	---	26.04.2019	Alignment of clause no. with ISO 15189:2012	Typographical error	-Sd-	-Sd-
2.							
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PREFACE

NABL documents are updated at regular intervals to keep pace with the latest technical developments and to synchronize with the International Standards. The updated issue of NABL 112 elaborates the International Standard ISO 15189:2012 as applicable to Indian setting. The document has been designed to make it user friendly for both NABL assessors and laboratories.

I extend my warmest thanks to all members of Technical Committee for their hard work and outstanding contributions in bringing out this issue of Specific Criteria. I sincerely appreciate the enthusiasm invested by members of NABL to ensure the success of updated document.

I further wish to thank immensely all the stakeholders for their valuable inputs which enabled us to go this extra mile.

My heartfelt thanks to the Chairman, NABL for his constant inspiration and able guidance during this entire endeavor.

CEO, NABL

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ABBREVIATIONS

AERB	- Atomic Energy Regulatory Board
APAC	- Asia Pacific Accreditation Cooperation
CBC	- Complete Blood Count
CLSI	- Clinical Laboratory Standards Institute
CRO	Clinical Research Organization
CSF	- Cerebrospinal Fluid
CV	- Coefficient of Variation
DNA	- Deoxyribonucleic Acid
EDTA	- Ethylenediaminetetraacetic acid
ELISA	- Enzyme Linked Immunosorbent Assay
EQA	- External Quality Assessment
ESR	- Erythrocyte Sedimentation Rate
FNA	- Fine Needle Aspiration
FNAC	- Fine Needle Aspiration Cytology
FISH	- Fluorescence in situ hybridization
H/h	- Hour(s)
H & E Staining	- Haematoxylin & Eosin Staining
HBV	- Hepatitis B Virus
HGVS	Human Genome Variation Society
HIV	- Human Immunodeficiency Virus
HLA	- Human Leukocyte Antigen
HPLC	- High Performance Liquid Chromatography
ICSH	- International Council for Standardization in Haematology
ILAC	- International Laboratory Accreditation Cooperation
INR	- International Normalized Ratio
ISO	- International Organization for Standardization
ISCN	International Society for Human Chromosome Nomenclature
IVD	In-vitro diagnostics
LJ Chart	- Levey-Jennings Chart
MCH	- Mean Corpuscular Haemoglobin
MCI	Medical Council of India
MCHC	- Mean Corpuscular Haemoglobin concentration
MCV	Mean Corpuscular volume
MNPT	- Mean Normal Prothrombin Time
MRA	- Mutual Recognition Arrangement
NACO	- National AIDS Control Organization
NCBI	National Centre For Biotechnology Information
NCCLS	National Committee for Clinical Laboratory Standards
NIH	- National Institute of Health
PAP staining	- Papanicolaou staining



PCR	- Polymerase chain reaction
PND	- Prenatal diagnosis
PT	Proficiency Testing
QBC	- Quantitative Buffy Coat
QC	- Quality Control
RBC	- Red Blood Cell
RFLP	Restriction fragment length polymorphism
RNTCP	Revised National Tuberculosis Control Program
SCF	Sample Collection Centre/ Facility
SD	- Standard Deviation
SOP	Standard Operating Procedure
TAT	- Turnaround Time
UV	- Ultra Violet
WBC	- White Blood Cells
WHO	- World Health Organization



1. INTRODUCTION

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 Accreditation Cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC) through Mutual Recognition Arrangements (MRA). 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.

The requirements in this document on specific criteria are based on the International Standard, ISO 15189:2012 - "Medical laboratories – Requirements for quality and competence". It specifies requirements for competence and quality that are particular to medical laboratories. The laboratory's compliance to requirements of the standard and its technical competence are assessed by NABL for accreditation.

The specific criteria document must be used in conjunction with ISO 15189:2012. It provides an interpretation of the latter document and describes specific requirements. Further, the laboratory shall follow national, regional, local laws and regulations as applicable.

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2. SCOPE

The scope of accreditation is applicable to the following disciplines of medical laboratory:

- i. Clinical Biochemistry
- ii. Haematology
- iii. Clinical Pathology
- iv. Microbiology & Infectious disease serology
- v. Histopathology
- vi. Cytopathology
- vii. Flow Cytometry
- viii. Cytogenetics
- ix. Molecular Testing

Note:

- i. *Immunological and serological tests are common to many disciplines; therefore, these can be listed under respective disciplines.*
- ii. *For guidance on preparation of scope of accreditation, refer sample scope given as Annexure-I(a) Sample scope has been detailed for Histopathology, Cytopathology, Microbiology & Infectious disease serology and Cl. Biochemistry. For other disciplines the same format and guidelines shall be followed.*
- iii. *The tests of Nuclear Medicine can be applied for accreditation under the discipline of Cl. Biochemistry.*

Accreditation shall be considered only for those tests for which the laboratory itself is equipped and competent to carry out. The tests, for which quality cannot be assured, shall not be included in the scope.

To be eligible for accreditation for disciplines of Histopathology and Cytopathology, a laboratory should receive at least 300 specimens every year in the respective discipline. The latter does not apply to specialized areas viz.: Nephropathology, Neuropathology, where the number of samples received may be fewer. Similarly, in the discipline of Haematology the laboratory should receive at least 100 bone marrow aspiration samples per year for the test to be accredited.

The collection centre / facility for primary sample collection at sites other than its main laboratory shall also comply with the relevant requirements of ISO 15189: 2012.

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3. DESCRIPTION AND TYPE OF LABORATORY

The requirements given in this document are applicable to all medical laboratories applying for NABL accreditation regardless of the level at which they function (small / medium / large / very large / laboratory with multiple locations) or the place in which they are located (village / town / district / city) or whether they are private / government / quasi-government attached to a hospital / stand-alone.

The following classification of laboratories shall be used:

- a) Small sized: A laboratory receiving samples of up to 100 subjects per day
- b) Medium sized: A laboratory receiving samples of up to 101- 400 subjects per day
- c) Large sized: A laboratory receiving samples of more than 401-1000 subjects per day
- d) Very large sized: A laboratory receiving more than 1000 subjects per day
- e) Multiple location: A laboratory with more than one location in the same district with same legal identity

4. MANAGEMENT REQUIREMENTS

Organization and management responsibility

A Medical laboratory must produce relevant evidence of legal identification which can be any of the following: Registration under the Indian Companies Act, Limited Liability Act, Partnership Act, Registration of Business as Sole Proprietor, Indian Trust Act, Societies Registration Act, Any Government notification in support of establishment of institution / laboratory or any approval from local or regulatory bodies. Laboratory shall also comply with local / regional / national requirements.

A laboratory operating at more than one location within a district having the same legal identity will be considered as a single laboratory, provided the analytes measured at different sites do not overlap and the laboratory will be issued a single certificate. For example, facility for cytogenetics could be at another site. However, if a laboratory requires separate certificates for individual location, separate application for accreditation should be submitted for each location.

For Multiple location laboratory, a single certificate will be issued with main laboratory's address on the accreditation certificate and details of all locations in the annexure (i.e. scope of accreditation).

Laboratories operating at more than one location having separate legal identities will be treated as independent laboratories even though they may be part of same organization.

Laboratories having one legal identity but operating in different districts will be treated as independent laboratories even though they are part of the same organization.

The accreditation certificate for a laboratory cannot be transferred and shall be valid only for premises for which it is issued.

Qualification norms for Laboratory Director / Chairman / Head (howsoever named)

The qualifications of Laboratory Director / Chairman / Head (howsoever named) shall be same as given in 5.1. She / He shall have the overall responsibility of Technical / Advisory / Scientific operations of the laboratory.

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The Laboratory Director / designee shall also fulfill the other requirements of ISO 15189:2012. In the case of a laboratory where there are more than one person designated as Laboratory Director, one of them should be available to ensure that she / he is responsible for overall operations.

In a hospital setting or in a large or very large laboratory, each department / discipline may have a separate head. However, one of them, represented as Laboratory Director shall be available at all times for consultation.

Requirements for Quality Manager

Quality Manager / designee shall be trained in 4-days Quality Management as per ISO 15189. She / He should be a full time employee, and can be delegated with additional responsibilities.

Service agreements

The users of laboratory shall be explicitly informed about the non accredited status of tests requested while entering into contract. This may be done by providing separate lists of accredited and non accredited test parameters to users. A copy of accredited scope shall also be made available for reference.

Examination by referral laboratories

Referral laboratory is an external laboratory to which the laboratory management chooses to submit a sample or subsample for examination or when routine examinations cannot be carried out. This differs from a laboratory that may include public health, forensics, tumor registry, or a central (parent) facility to which submission of samples is required by structure or regulation.

NABL allows referral for second opinion for the tests of Histopathology, Cytopathology, Bone Marrow examination, Genetic tests and also for supplementary tests. Referral may also be required for confirmation of Biochemical, Microbiological and Haematological tests. The referral laboratory has to be NABL accredited.

NABL also allows referral to experts of good professional standing, some central laboratories (NCDC New Delhi, NIV Pune, CCMB Hyderabad etc.) or other reputed institutions.

A test in any discipline may be referred to another accredited laboratory at the time of temporary incapacity of testing due to unforeseen circumstances such as breakdown of equipment, disasters, strikes etc.

Note: NABL allows this relaxation only under exceptional situations and it is advised that the privilege provided to the laboratory is not misused.

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Referral laboratories and consultants shall be selected as per the criteria laid down by the laboratory.

Laboratory shall maintain records pertaining to lists of tests and the names & addresses of the referral laboratories from which services are obtained. The information is kept both in the 'referral' file and the patient file.

The referring laboratory shall give prior intimation to the users about the tests being referred.

The referring laboratory shall produce the original report of the referral laboratory or transcribe the report without alterations of clinical interpretation with additional remarks (if required) and specify the name of the referral laboratory, identify the tests performed and the results obtained by any such referral laboratory. Records pertaining to this shall also be made available.

Note: The laboratory shall produce:

- 1. Records of evaluation of the referral laboratories and a copy of the NABL certificate along with the scope of each laboratory.*
- 2. MOU which may be maintained in a simple form.*

Advisory services

Stand-alone laboratory shall communicate with their clients (patients / clinicians) with regard to the choice of tests under different clinical conditions, whenever required or sought. Communication may be through direct contact, email and / or documentation. Hospital-attached laboratory personnel are encouraged to participate in clinical rounds and meetings. The records of the above shall be maintained.

Control of records

The laboratory shall decide the retention time of records in accordance with national, regional and local regulations. However, NABL requires the following minimum retention period for ensuring quality service and patient care:

Table 1

Haematology (CBC) / Clinical Biochemistry	1 week
Microbiology and Infectious disease serology	1 year
Molecular testing gel images, Real time PCR raw data	2 years (infectious diseases), 10 years (genetic diseases and cancer)
Flowcytometry / Immunophenotyping data	10 years
Electrophoretogram / Immunofixation	10 years
Haemoglobin HPLC data	10 years
Coagulation calibration / standard graph	Lot changeover
Raw data & LJ chart of daily values of internal quality control / raw data of EQA	1 year or till the next assessment whichever is later
Histopathology Reports, Block & Slides	10 years
Cytopathology Reports, Blocks & Slides	5 years
Cytogenetics, FISH images	10 years

Note:

1. The records can be maintained as physical copies (instrument printouts or as photocopies) or electronically
2. Every effort should be made to retain blocks and slides in Histopathology and Cytopathology. If, however, they are returned to the patient, this must be documented and records kept

Evaluation and audits

The laboratory shall ensure that pre-analytical and post-analytical processes are also covered during its internal audit along with the other processes.

The laboratory shall incorporate salient quality indicators for monitoring its performance. This shall describe the evaluation of various aspects of a laboratory's function such as but not limited to the following:

- sample collection and identification
- transportation and processing
- analysis and reporting of results
- turnaround time
- complaints
- equipment downtime
- uncertainty of measurements
- performance in PT / EQA scheme

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5. TECHNICAL REQUIREMENTS

The technical requirements have been sub-divided into two sections.

The first section includes the general requirements applicable to most of the disciplines and the second section includes discipline wise requirements.

PART 1 – GENERAL

5.1. Personnel

As per the latest Notification issued by Ministry of Health & Family Welfare (MoHFW) dated 18th May, 2018 notifying Clinical Establishment (Central Government) Amendment Rules, 2018, all laboratories are required to comply with it as applicable.

Note 1: If the above notification is not applicable, laboratory may give valid justification by producing evidence of alternate applicable rules and regulations.

In all cases, it is the responsibility of laboratory to abide by the National/ Regional/ State/ Local regulatory requirements/ Acts/ Rules/ Legal orders/ Court Decisions/ Orders issued by Government/ Statutory Bodies as applicable and effective from time to time.

Laboratory Director/Head of Laboratory/Technical Head (Howsoever named) shall have the overall responsibility of operations of the laboratory. For review, evaluation and release of results, he may delegate selected duties/ responsibilities to qualified personnel.

Note 2: NABL is a voluntary accreditation body and has no statutory powers. Checking of compliance to the regulatory requirements falls under the purview of respective/applicable regulator.

5.2. Accommodation and environmental conditions

The laboratory shall have adequate space for efficient functioning, a pleasant ambience and conditions to avoid cross contamination.

The laboratory shall have effective separation for incompatible activities. The autoclave for sterile articles and for decontamination should be placed separately with proper exhaust.

Note: The laboratory shall ensure adequate space for patient reception, sample collection, workbenches, equipment and storage of volatile & inflammable reagents and bio-hazardous materials. Radioisotope related work shall be as per requirements of the regulatory agency (AERB).

The laboratory shall have adequate lighting, power plugs and uninterrupted power supply. Use of exposed cables should be kept to a minimum. The laboratory shall ensure that adequate uninterrupted power supply is available so that there is no compromise of stored data. All computers, peripherals, equipment and communication devices shall be supported in such a way that service is not likely to be interrupted. The laboratory shall have procedures in place to ensure the integrity of refrigerated and frozen samples / reagents / consumables in the event of a power failure. Wherever possible the sample processing area should be segregated / separated from the testing area. In particular, centrifuges should not occupy the same working bench as testing instruments where vibration may interfere with the results e.g. centrifuges & balances / analytical instruments like automated analyzers.

Gas cylinders shall be kept secure to prevent unintended movement (ISO 15190: 2003; Cl. 17.1).

Accommodation and environmental conditions are also applicable to primary sample collection facilities at sites other than the permanent laboratory facility.

5.3. Laboratory equipment, reagents and consumables

Verification of all automated / semi-automated systems is also required and includes precision, accuracy, carryover and wherever applicable, linearity.

The laboratory shall check each lot of control and reagent against an earlier tested in-use control / reagent lot. The laboratory can follow guidelines mentioned in Annexure III.

Records of comparative data shall be maintained.

Storage & Labelling

All reagents, consumables, stains, media, kits, and antimicrobials shall be stored as recommended by the manufacturer. The label shall contain information like: content and quantity, concentration or titer, date received / prepared, date of opening, storage requirements and expiry dates wherever applicable.

Similarly, reagents prepared in-house shall have the name & signature of individual who prepared the reagent, storage requirements, date of preparation & expiry.

Calibration:

Policy on calibration and traceability of measurements shall be as per NABL 142. The equipment shall be calibrated from NPL, India or a calibration laboratory accredited by NABL or any MRA partners, accredited for the specified scope.

The nominal maximum periods between successive calibrations of general equipment are illustrated in Table 3 below.

Table 3
Calibration requirements

Item	Recommended maximum period between successive calibration by accredited laboratory	Procedure and comments for calibration verification
Autoclaves	One year	Calibration of pressure gauge and temperature by thermal mapping.
Balances and Scales	One year	In addition balances with in-built calibration facility must be verified using calibrated weights for calibration once a day before use.
Biological safety cabinet	One year	Calibration of manometer, particle count and air flow also to be checked once in a year. For checking the functioning of UV light colony count to be performed once in 15 days.
Laminar Flow	One year	For horizontal laminar flow where sterile work is being done like media preparation, at least one blood agar media plate shall be used once in 15 days and there should be no growth.
Centrifuge	One year	Tachometer (contact / non-contact type) or Stroboscope. Calibrate temperature using PRT (Platinum resistance thermometer) with digital indicator and timing devices (by a stop watch).

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		specialized high speed (> 10000 rpm) centrifuges.
Mass	Two years and can be extended up to five years if the mass is E1 Class (stainless steel)	OIML R111 Calibrated weight shall be kept in proper storage condition to avoid abnormal drift.
Piston-operated volumetric apparatus, pipettes and dispensers	Initial manufacturer's certificate at the time of purchase and calibration checks every one year thereafter	i) In-house gravimetric checks: Repeat at least 10 times volume delivery and weighing. (The laboratory may refer ISO 8655-6:2002 for guidance). ii) Adjustable devices: take readings at several settings of volume. iii) In-house verification of pipette calibration: Volumes less than 100µl should be checked with balances of appropriate sensitivity / resolution.
Thermometers	One year	Calibration of master thermometer at required temperature for other thermometers in laboratory verification by using calibrated thermometer at 2-3 points covering entire range.

All equipment including thermometers, pipettes and centrifuges must be calibrated by an NABL accredited laboratory before being put into service for the first time. A manufacturer's calibration certificate is not valid unless it contains an accepted procedure and traceability (as per NABL 142).

It must be stressed that these calibration intervals depend upon ruggedness of the equipment, frequency of use, quality & periodicity of maintenance and life of the equipment. Laboratory may seek a compliance report for the equipment from the accredited calibration laboratory.

All equipment must be calibrated following preventive maintenance, breakdown and repairs or more frequently as recommended by the manufacturers.

At the time of installation of new equipment, the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) should be performed and documented.

Periodic calibration verification should be carried out to ensure continued stable performance of the equipment.

Calibration of Automated Instruments:

The laboratory shall have a calibration schedule for automated instruments. All automated instruments such as cell counters, Clinical Biochemistry automated analysers, automated coagulometers and ELISA readers shall be calibrated by manufacturer at least once a year and be verified for calibration after preventive maintenance. The calibration certificate shall contain raw data; just a certificate that the apparatus has been calibrated is not sufficient. All raw data or machine printout / screen shots should be captured and documented for future use. The calibration should be as per manufacturer's recommendations and criteria for acceptance of verification.

During calibration of autoanalysers verification of power supply, photometer / illuminometer / fluorimeter / LED that may / may not be dye based, filter or emission light source lamps, pipettor assembly inclusive of metering pump and syringe, pressure checks wherever applicable, probe alignment and their carry over checks, temperature of temperature-controlled chambers, cuvette calibration (wherever applicable) and system checks should be carried out. In addition to the verification, analyte calibration may be performed and appended. In case of semi-automated photometers, sipper calibration is also required wherever applicable.

In-house calibration of equipment

Certain items of equipment (listed below) may be calibrated by the laboratory itself without the service of an external calibration body, provided the laboratory has necessary reference standards and materials (with traceability) and such calibration procedures do not demand special techniques which are outside the capability and experience of the laboratory staff. The calibration status, date of calibration and due date shall be exhibited on the equipment.

pH Meter:

pH meter shall be calibrated each time before use. This is done by using two standard buffer solutions appropriate to the expected pH of the sample being tested and the records of the same to be maintained.

ISE analyzers & ABG analyzers

Calibration verification is in the form of self calibration. However, the electrode slope should be recorded to ensure that there is no deviation. Thereby requirement for change of electrodes is not missed.

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Spectrophotometer and Colorimeter

Calibration checks on all spectrophotometers or colorimeters shall be performed at six months / one year interval preferably by manufacturer or AMC agency. These include checks on absorbance, linearity, matching of cells in accordance with the manufacturer's instructions and / or appropriate procedures using traceable standard / reference materials. A blank and at least three points on the calibration curve must also be checked. These calibrations should be compared over time to detect any system deterioration.

Electrophoresis Apparatus

Instrument performance shall be routinely monitored during use with appropriate controls. System components (e.g. electrodes, tank and power supply), must be checked periodically.

Temperature-Controlled Equipment

Equipment such as water baths, incubators, ovens, refrigerators and deep freezers are verified for accuracy / performance (with calibrated temperature-recording devices) for the intended temperature required. The temperature shall be monitored daily, especially where the deterioration of material (sample or reagents) affects the test results. An attempt should be made to cover various chambers of refrigerator and deep freezer. The temperature is monitored with calibrated recording devices at multiple points with the doors shut. Records shall be maintained till the next assessment.

Refrigerators and deep freezers requiring critical and continuous temperature control shall be fitted with 24x7 temperature recorders / data loggers. Deep freezers shall not have an automated defrosting system without a manual override.

Maintenance of Equipment:

Microscopes:

Microscopes used for screening shall have 10 X and 40 X objectives. Spare bulbs and fuses shall be available in the laboratory.

Calibration is not required for microscopes. However, regular cleaning and maintenance is essential for satisfactory operation. The stage and lenses shall be cleaned after use. Servicing shall be carried out by competent personnel.

5.4. Pre-examination processes

Relevant clinical data are necessary for most specialized tests. Request forms should be designed so that the requesting physician provides this information.

For venipuncture, an evacuated tube system is preferred. Syringes should be avoided for safety reasons. If it is necessary to use a syringe, a safety device for transferring blood to the tubes should be used viz. Luer Adapter.

The guidelines for order of draw as mentioned in Annexure IV may be followed.

Specific instructions for the proper collection and handling of primary samples shall be documented in a primary sample collection manual. The laboratory shall ensure that informed consent has been taken for HIV testing and invasive procedures e.g. FNA, lumbar puncture, body fluid aspiration, bone marrow aspiration.

The above shall be applicable for collection facility at the main laboratory and sites other than the main laboratory viz., collection centers. Additional requirements related to collection centers are mentioned in "Guidelines for Operating Collection Centre(s) of the Medical laboratories", of this document.

The laboratory as a policy shall not accept samples, with labile analytes such as ammonia, acid phosphatase, blood gases and lactate that are not collected in-house.

5.5. Examination processes

The kit insert shall not replace an SOP.

Measurement uncertainty of measured quantity values:

One of the components of measurement uncertainty (MU) is precision / imprecision. This is obtained from running stable controls. The laboratory shall run controls for each analyte where measurements are in metric values with frequency described under each discipline. The SD and %CV shall be derived from the laboratory mean and not from the control's target value assigned by the manufacturer. Actual %CV up to first place of decimal for each parameter shall be used for calculation.

For practical purposes, imprecision data obtained from the routine application of internal quality control is recommended as the quantitative estimate of the uncertainty of measurement. With the caveat that quality control materials may not totally reflect the analytical behavior of patient specimens, this imprecision is most easily derived from long term internal quality control (IQC) data, calculated as standard deviation (SD) or coefficient of variations(%CV).

For the purpose of recording estimates of uncertainty of measurement imprecision should be documented as $k \times \%CV$. k is the coverage factor and at 95% confidence interval it equals to ± 1.96 approximated to ± 2 , so the uncertainty of measurement could be set as:

- a. Coefficient of Variation (%CV)
- b. The uncertainty of measurement would be: $\pm 1.96 \times \%CV$ approximated to $\pm 2 \times \%CV$

It is recommended that a minimum of six months internal QC data should be used to calculate routine imprecision, to be updated annually where possible.

For non quantitative set of tests, the laboratory shall enlist the factors which could contribute to the uncertainty of the results and also ensure that they were given due attention while performing the test.

5.6. Ensuring quality of examination results

The laboratory shall design the internal quality control procedure appropriate to its size & scope. The results will be plotted on LJ charts.

Controls for some analytes such as CBC and blood gases have a short shelf life. Therefore, the laboratory mean cannot be calculated. In such situations the laboratory can use the manufacturer's assigned mean and SDs to detect out of control values. The laboratory shall, however, calculate their imprecision as CV% from the data obtained and shall ensure that the CV% continuously remains in the acceptable range. The laboratory shall perform root cause analysis and take corrective actions as when out of control situations are detected.

Inter-laboratory comparisons

External Quality Assessment (EQA) / Proficiency Testing (PT):

The laboratory shall:

1. participate in EQA / PT in each discipline prior to gaining accreditation
2. have a plan to cover critical tests
3. participate in an EQA program in case of change in test methodology, equipment change and extension of scope

The laboratory shall document corrective actions taken based on the EQA evaluation report.

Testing of EQA / PT samples must be integrated within the routine laboratory workload and analyzed in rotation by personnel who routinely test patient samples. In case of slides received as EQA samples, they are to be reported by appropriate levels of staff involved in the department without sharing of data. They should then collectively discuss the results before they are dispatched.

For some tests, participation in PT program is not a feasible option for one or more of the following reasons:

1. Non-availability of a formal national PT programme for analytes of interest
2. Only few laboratories performing the test
3. The analyte to be measured is unstable e.g. blood gases, ammonia, G6PD
4. Control material of the same matrix is not available
5. The sample is completely consumed during performance of the test (e.g. ESR)

Note: It is unethical to take an extra sample of blood for repeat testing without informed consent

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For utilizing Proficiency Testing reports to improve quality of a laboratory, the guidelines given as Annexure V can be followed.

Alternative approaches

For those tests where a formal EQA is not available, the laboratory shall adopt alternative approaches to validate performance. Such alternative approaches are:

- Replicate testing
- Examination of split samples (within the laboratory)
- Use of reference methods & materials, where available
- Exchange of samples with other accredited laboratories

When the laboratory exchanges samples with other laboratories as an alternative approach to EQA participation, following needs to be addressed:

- In the case of comparison between 2 laboratories, one will function as the “reference laboratory” against which the other will be compared. This is to be documented as an MoU
- When there are several laboratories, compare the result against the “reference laboratory”-

The results obtained shall be compared statistically and for guidance, the laboratory may refer to the most current edition of CLSI document EP9 - Measurement Procedure Comparison and Bias Estimation Using Patient Samples.

Other quality assurance procedures which are useful in addition to IQC but do not replace split sample analysis are:

- Review of daily mean
- Delta check
- Clinical correlation
- Correlation with other laboratory results

Comparability of results

If the laboratory uses more than one measuring system where the measurements are not traceable to the same reference material / reference method, or the biological reference interval are different, it is essential to perform a comparability study between the systems and prove that there is agreement in performance throughout appropriate clinical intervals at least twice in a year using suitable statistical procedures such as Bland - Altman plot and / or regression analysis. A written procedure and complete record of all such data shall be retained till the next assessment.

5.7. Post-examination processes

The retention period for the samples of various disciplines is mentioned in the respective sections either under clause 5.4 or 5.7.

Disposal of Bio Medical Waste (BMW):

The laboratory shall follow national, state and local guidelines for BMW handling and disposal.

- a) Treatment outside laboratory premises
- b) Treatment inside laboratory

a) Treatment outside laboratory premises:

The laboratory shall have a documented contract with a licensed BMW Management Contractor or common waste management facility as per the local, regional or national guidelines. The laboratory shall follow the protocols laid by the contractor regarding segregation of waste. This shall also be displayed in colored posters at different sites of BMW generation for ready reference of the staff. Evacuated tubes may be treated as per the contractor's requirement.

b) Treatment inside laboratory

- i) Infectious microbiology waste – All infectious waste shall be autoclaved before disposal.
The laboratory shall have a separate autoclave for waste treatment
- ii) Other samples shall be treated with 1% fresh hypochlorite solution for 30 mins. This can then be poured down the drain in running water
- iii) An effluent treatment plant may be placed as per local requirements

5.8. Reporting of results

Identification by name and / or signatures of the person authorizing release shall be included in the test report in accordance with Cl.5.8.3 of ISO 15189:2012.

Biological Reference Interval should be established by the laboratory for the method used only where required e.g.: Activated Partial Thromboplastin Time & Prothrombin Time (PT & APTT) should be reported as time in seconds with a reference interval. This is also the case for PT and INR. The results of coagulation tests vary with the analyzer & the reagent therefore it is necessary to establish biological reference intervals for these tests. If it is not practical to establish the biological reference interval for a particular analyte the laboratory should carefully evaluate the published data for its own reference intervals, and retain documentation of this evaluation.

5.9. Release of results

The laboratory shall establish and display critical limits for tests which require immediate attention for patient management. Test results within the critical limits shall be communicated to the concerned clinician after proper documentation.

Interim report

Practically all hospital laboratories and a few stand-alone laboratories operate round the clock (24X7). After routine working hours the laboratory may not have an authorised personnel on duty. The laboratory shall have the following arrangements in place. If feasible an authorised personnel should be posted to supervise and authorise release of urgent tests in the disciplines of Clinical Biochemistry, Clinical Pathology, Haematology and Microbiology that are required for immediate management of the patient. If there is no authorized personnel on duty, the report will be "Interim".

The laboratory shall ensure that:

- Daily IQC shows no violation of the documented policy and procedure.
- The technical personnel posted during this period shall be well trained and of proven competence to apply IQC rules.
- The regular authorised personnel shall go through the records on the next working day and issues a final report after verifying that the results of these tests showed no trend and that the IQC was valid. The records of these shall be available till the next assessment.

Automated selection and reporting of results

Many results on test samples may not require any further interpretations, recommendations or further review by authorized personnel. These results would automatically qualify to be released as such. Further, these could qualify as having been verified by an authorized person if he or she has established the criteria for results to qualify as not requiring further review. For establishing these criteria the authorized person shall make use of available standards (e.g., CLSI Auto 10) or Guidelines (e.g., ICSH for haematology - Laboratory Hematology 2005; 11:83-90. The International Consensus Group for Hematology Review: Suggested Criteria for Action Following Automated CBC and WBC Differential Analysis).

Besides rule based verification, this could bring in the concept of delta check where a patient's result is compared with an earlier one within a predetermined interval making some of the results eligible for automated release. After these criteria are selected, the laboratory shall validate the impact of these rules / criteria and its ability to automatically select the results for release. Once validated all the staff will be made aware of the same and this process will be introduced under supervision. All these criteria and validation of rules are to be part of an SOP. The review of criteria will be required if analytic principle or platform undergoes a significant change.

(Refer Guideline algorithm for automated selection and reporting of results; mentioned in Annexure VI)

Revised reports

If a report is revised, a hard or soft copy of the original and revised reports together with the reason for revision shall be recorded and maintained.

5.10. Laboratory Information Management

Results generated by manual tests or by an automated analyzer shall be communicated to the customers / users through a computerized or paper-based information system which manages workflow, quality and audit trail for the samples processed in the laboratory. The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

Information system management

- a. When there is a comprehensive computerized information system, all functions from accession to reporting shall be verified after installation.
- b. The general process should involve:
 - i. Input patient data and save demographics and clinical information.
 - ii. retrieve the same data
 - iii. capture screen print
 - iv. compare with data on paper form or in a paperless system
 - v. sign and file with date
- c. There shall be a half-yearly review during which the above process is repeated for a minimum of 10 different types of samples / tests.
- d. Interfaces: Interfaces between hardware (analyzer) and LIS or between software systems (LIS-HIS) shall be verified to ensure that the interface transmits data in the intended manner and that there is no misfiling of results in the database or in-appropriate formatting of the report.
- e. Rule based systems for automated selection and reporting of results, shall be verified.
- f. If there is major change in any of the components of the information system, the effect on the entire workflow for a selected sample shall be demonstrated to have no deleterious effect.
- g. Security and confidentiality: There shall be role based authenticated access into the information system and there shall be procedures to inactivate users who are no longer authorized to access these systems. There shall be a facility to demonstrate an audit trail to link the activity undertaken by a user with relation to patient data or software change.
- h. Redundancy (Back-up), manual procedures for down times and disaster recovery systems along with SOPs should be in place and certified by appropriate (local) information technology authority.

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PART 2 – DISCIPLINE WISE

Clinical Biochemistry

5.3 Laboratory equipment, reagents and consumables

A microbial count is not required as long as Grade water I/II is used for reconstitution of reference material and reagents.

5.4 Pre-examination processes

Storage period of examined specimen

The examined specimens shall be stored for re-examination and / or additional tests for a minimum period of 1 day at 2-8°C except for unstable parameters.

Hormone stimulation tests – precautions

Hormone stimulation for these tests is to be done under the supervision of a medical doctor in a hospital-based laboratory where emergency services are available for immediate handling of any adverse reactions if and when they occur.

5.6 Ensuring quality of examination results

Two levels of QC shall be included at least once on the day of performing the test irrespective of the size of the laboratory. If the laboratory is operational 24X7, two level controls shall be run in the peak hour subsequently one level every 8 hours. The daily QC values shall be documented and LJ charts (Levey-Jennings chart) shall be plotted on a daily basis. The laboratory shall derive its own mean and standard deviation (SD) using a minimum of 20 data points to plot an LJ chart. The laboratory shall define its own criteria for accepting or rejecting the run and be able to justify the application.

The laboratory shall analyze QC outliers, their causes and take immediate corrective action.

The laboratory shall analyze the 'out-of-control situation' by applying the following steps:

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

The laboratory shall calculate the monthly mean, SD and %CV. The laboratory shall maintain control charts to demonstrate the stability of the analytical measuring systems.

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 those tests for which calibration and control materials are not available.

Note: The use of third-party controls is advised, though not mandatory.

For blood gas measurements at least one control shall be assayed every eight hours. In addition, one control should be run with each patient sample unless the instrument automatically calibrates itself at predefined intervals.

5.8 Reporting of results

Wherever relevant, reports should have an interpretation.

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