Accreditation of laboratory with special reference to Quality Assurance and Quality Control

D. R. Arora

Professor & head of Microbiology,
SGT, Medical College, Budhera (Gurgaon),
Formerly, Professor &Head of Microbiology,
Postgraduate institute of Medical Sciences,
Rohtak (Haryana)

Test laboratories in developing contries

In the last few decades, there is **mushrooming of testing and calibration laboratories** in developing countries, including India but very few of these are accredited to internationally recognized boards. The primary reason for this is that test laboratories have not been able to establish **management system to meet international standards**.

Test laboratories in developing contries

With the exception of accredited laboratories the correctness and reliability of tests performed is doubtful. There are many factors which influence the correctness and reliability of the test performed by a laboratory. These include human factors, accommodation and environmental conditions, test and calibration methods, equipment, measurement traceability, sampling and handling of test and calibration items.

Test laboratories in developing contries

Though Government laboratories, in developing countries, may be manned by qualified personnel, there is very little opportunity for further training to upgrade their knowledge. In many such laboratories, there is no system for lateral induction of persons with higher qualification and promotion is mainly by seniority. Therefore, there is no motivation for making special efforts to ensure the accuracy of results and improve the quality of the laboratory.

Laboratory accreditation

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 standard.

Benefits of accreditation

- National and International recognition
- Public and Industry acceptance
- Assurance to customers of good laboratory practice
- Provides Global equivalence
- Decision makers can rely on test results
- Improves staff motivation
- Ensures better support in the event of legal challenge
- Saves money

MANAGEMENT REQUIREMENTS

TECHNICAL REQUIREMENTS

5.1 Personnel

Laboratory management shall have an organizational plan, personnel policies and job descriptions that define qualifications and duties for all personnel

Laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. This information may include:

- certification or license, if required,
- references from previous employment,
- job descriptions,
- records of continuing education and achievements,
- competency evaluations,
- untoward incident and accident reports, and records of exposure to occupational hazards and records of immunization status.

5.1 Personnel

The laboratory shall be directed by a person having executive responsibility and competence to assume responsibility for the services provided.

5.1 Personnel

- The responsibilities of the laboratory director or designees shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters. These shall be relevant to the services offered by the laboratory.

- Laboratory Director or designees for each task should have appropriate training and background to be able to discharge the responsibilities.

5.1 Personnel

There shall be staff resources adequate to the undertaking of the work required and the carrying out of other functions of the quality management system.

Personnel shall have training specific to quality assurance and quality management for services offered.

Laboratory management shall authorize personnel to perform particular tasks such as sampling, examination and operation of particular types of equipment, including use of computers in the laboratory information system.

5.1 Personnel

Policies shall be established which define who may use the computer system, who may access patient data and who is authorized to enter and change patient results, correct billing or modify computer programmes.

There shall be a continuing education programme available to staff at all levels.

Employees shall be trained to prevent or contain the effects of adverse incidents.

5.1 Personnel

The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary.

The personnel making professional judgments with reference to examinations shall have the applicable theoretical and practical background as well as recent experience. Professional judgments can be expressed as opinions, interpretations, predictions, simulations and models, and values and should be in accordance with national, regional and local regulations.

Confidentiality of information regarding patients shall be maintained by all personnel

5.1 Personnel

The Supervisory staff and the authorized signatories shall demonstrate **knowledge and competence** in the concerned specialty.

5.2 Accommodation and environmental conditions

- Enough space must be available, for quality work, safety and patient facilities.
- Patients, staff and visitors must be protected from recognized hazards.
- The resources shall be of a degree necessary to support the activities of the laboratory.

5.2 Accommodation and environmental conditions

- Monitor, control and record environmental conditions (temperature, humidity, sterility, etc.).
- Effective separation between incompatible activities
- Controlled access
- Enough storage space
- Ensure good housekeeping.

5.2 Accommodation and environmental conditions

- Laboratory needs to establish and maintain an environment that provides safety for all. Segregation and disposal of biomedical waste should be strictly according to "Bio-Medical Waste Rules, 1998" (revised 2000). Staff should observe universal precautions and should be offered vaccination against vaccine preventable diseases. Incident/accident reports and action taken should be reviewed and documented.

5.2 Accommodation and environmental conditions

Laboratory shall ensure adequate space in relation to the following:

1. **Patient reception**
2. **Sample collection**
3. **Workbench**
4. **Equipment**
5. **Storage of volatile and inflammable reagents**
6. **Radioisotope related work as per the regulatory agency (AEA) requirement**
7. **Washing and decontamination**
8. **Isolation for biohazardous materials**
9. **Fire safety**
10. **Waste disposal**

5.2 Accommodation and environmental conditions

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

5.3 Laboratory equipment

- **The laboratory shall be furnished with all items of equipment** required for the provision of services.
- Upon installation and in routine use the equipment shall be shown to be **capable of achieving the performance required.**
- **Equipment shall be regularly calibrated and major equipment shall be on AMC.**

Quality control surveillance procedures of commonly used microbiology equipment

EQUIPMENT	PROCEDURE	SCHEDULE	TOLERANCE LIMITS
Refrigerators	Record temperature	Daily	2^0C to 8^0C
Freezers	Record temperature	Daily	-8^0C to -20^0C -60^0C to -75^0C
Incubators	Record temperature	Daily	$35.5^0C \pm 1^0C$
Water baths	Record temperature	Daily	36^0C to 38^0C 55^0C to 57^0C
Autoclaves	Test with spore strip (*Bacillus stearothermophilus*)	At least Weekly	No growth on subculture indicates sterile run
Anaerobic jars	Methylene blue indicator strip	With each use	Conversion of strip from blue to white indicates low O_2 tension

Contd…

Quality control surveillance procedures of commonly used microbiology equipment

EQUIPMENT	PROCEDURE	SCHEDULE	TOLERANCE LIMITS
Serology rotator	Count revolutions per minute	With each use	180 rpm ± 10 rpm
Centrifuges	Check revolutions with tachometer	Monthly	Within 5% of dial indicator setting
Safety hoods	Measure air velocity across face opening	Semiannually or quarterly	50 feet airflow per minute ± 5 feet per minute

Laboratory equipment

- **Acquisition of equipment** accounts for only 25% of the solution, **training of personnel** another 25% and scheduled **contracts and preventive maintenance accounts for 50% of equipment functionality.** Therefore, it is recommended, a registry of all equipment, schedule of calibration, maintenance and vendor contracts be documented and followed for every piece of equipment. **Human resource** is the most valuable resource in quality management system. Policies and processes for **obtaining and retaining highly qualified persons** should be explicitly indicated by the organization.

Temperature-controlled equipment

The performance of temperature-controlled equipment such as water baths, incubators, ovens, refrigerators and cold room should be monitored daily.

5.3 Biological safety cabinet

Separate biological safety cabinets, certified at least annually to ensure that filters are functioning properly and that air flow rates meet specifications, must be available for mycobacteriology and mycology work.

5.3 Culture media

- Laboratory shall ensure that **in-house prepared media** are sterile, able to support growth and are appropriately reactive biochemically. Therefore, the laboratory must **maintain the stock of reference organisms**. These should be used to test the culture media.

- **Blood-based media shall be prepared using sheep blood and not human blood.**

Quality control of commonly used media: suggested control organisms and expected reactions

Medium	Control organism	Expected reactions
Blood agar	Group A *Streptococcus* *S. pneunoniae*	Good growth, β -hemolytic Good growth ά-hemolytic
Bile-esculin agar	*Enterococcus* species Group A *Streptococcus* (Not Group D)	Good growth, Black No growth
Chocolate agar	*H. influenzae* *N. gonorrhoeae*	Good growth Good growth
Christensen urea agar	*Proteus mirabilis* *Klebsiella pneumoniae* *Escherichia coli*	Pink throughout (Positive) Pink slant (Partial positive) Yellow (negative)
Simmon's citrate agar	*K. pneumoniae* *E. coli*	Growth or blue color (positive) No growth, remains green (negative)

Quality control of commonly used media: suggested control organisms and expected reactions

Medium	Control organism	Expected reactions
Deoxyribonuclease	*Serratia marcescens* *E. cloacae*	**Zone of clearing (add 1N HCL)** **No zone of clearing**
Motility (semisolid agar)	*P. mirabilis* *K. pneumoniae*	**Media cloudy** **No feather edge on streak line (negative)**
MacConkey agar	*E. coli* *P. mirabilis*	**Pink colonies (lactose positive)** **Colorless colonies, no spreading**
Sucrose	*E. coli* *N. gonorrhoeae*	**Yellow (positive)** **No color change (negative)**
Maltose	*Salmonella* **species** *N. gonorrhoeae*	**Yellow (positive)** **No color change (negative)**
Lactose	*N. lactamica* *N. gonorrhoeae*	**Yellow (positive)** **No color change (negative)**

Quality control of commonly used media: suggested control organisms and expected reactions

Medium	Control organism	Expected reactions
Lysine	*K. pneumoniae* *Enterobacter sakazakii*	**Bluish (positive)** **Yellow (negative)**
Arginine	*E.cloacae* *P. mirabilis*	**Bluish (positive)** **Yellow (negative)**
Orthinine	*P. mirabilis* *K. pneumoniae*	**Bluish (positive)** **Yellow (negative)**
***o*-Nitrophenol-p-D galactopyranoside (ONPG)**	*Serratia marcescens* *S.* **Typhimurium**	**Yellow(positive)** **Colorless(negative)**

Quality control of commonly used media: suggested control organisms and expected reactions

Medium	Control organism	Expected reactions
Phenylalanine deaminase	*P. mirabilis* *E. coli*	**Green (add 10%$FeCl_3$)** **No color change (negative)**
Salmonella-Shigella (SS agar)	*S.* **Typhimurium** *E. coli*	**Colourless colonies, black centre** **No growth**
Voges-Prauskauer	*K. pneumoniae* *E. coli*	**Red (add reagents)** **No development (negative)**
Xylose- Lysine- Dextrose (XLD) agar	*Salmonella* **species** *E. coli* *Shigella* **species**	**Red colonies (positive)** **Yellow colonies (positive sugars)** **Transparent colonies (negative)**

5.4 Pre-Examination procedures

The request form shall contain information sufficient to identify the patient and the authorized requester, tests requested, relevant clinical information, date and time of primary sample collection, and date and time of receipt of samples by the laboratory.

5.4 Pre-Examination procedures

Specific instructions for the proper collection and handling of primary samples shall be documented and implemented by laboratory management and made available to those responsible for primary sample collection. These instructions shall be contained in a **primary sample collection manual.**

Pre-examination procedures

- For specimen collection use specimen containers that are leak-proof, clean, dry and free from traces of antiseptics and disinfectants. If anticoagulated blood specimen is required, use a suitable anticoagulant, e.g., sodium citrate for microfilariae, and EDTA for malaria parasites and trypanosomes. The EDTA blood specimen must be examined within one hour of collection to avoid morphological changes in the appearance of parasites. Mix blood well but gently with anticoagulant. Specimens must arrive in the laboratory as soon as possible after they are collected . When needing to transport specimens use suitable preservative.

5.4 Pre-Examination procedures

Primary samples lacking proper identification **shall not be accepted or processed** by the laboratory. However, in case of instability of analytes in the primary sample (e.g., CSF, biopsy, etc.) and the primary sample is irreplaceable or critical, the laboratory may choose initially to process the sample but not release the results until the requesting physician or person responsible for the primary sample collection **takes responsibility for identifying and accepting the sample**. In such case signature of the person taking responsibility of the primary sample identification should be recorded on the request form.

5.4 Pre-Examination procedures

Laboratory shall monitor the transportation of the samples to the laboratory such that they are transported:

- ⇨ Within a **time frame** appropriate to the nature of requested examination.
- ⇨ Within a **temperature specified** in primary sample collection manual to ensure the integrity of the samples.
- ⇨ In a manner that **ensures safety for the carrier**, the general public and the receiving laboratory.

5.4 Pre-Examination procedures

CSF must be transported to lab immediately, if delay is anticipated it shall be kept at room temperature

Unless fecal specimen can be delivered in the lab immediately, it shall be transported in transport media

5.4 Pre-Examination procedures

Criteria for rejection of primary samples:

- Missing or inadequate identification
- Incomplete forms
- Leaking container or blood-stained container
- Specimen collected in an inappropriate container
- Haemolysed blood sample
- Insufficient quantity
- Dried up specimen
- Contamination suspected
- Specimen for culture collected in formalin
- Inappropriate transport/storage

5.5 Examination procedures

- Use of test procedures which meet the needs of users and are appropriate.
- Preferred procedures are those that have been published in established/authoritative textbooks.
- In-house procedures must be validated.

5.5 Examination procedures

- Procedures should be documented in the form of SOP's and be available, at the workstation, to the staff in a language commonly understood by the staff.

- Biological reference intervals shall be periodically reviewed. Review also, when procedure changes.

Quality assurance (QA)

Total process whereby the quality of a laboratory reports can be guaranteed. It has been summarized as

- the *right result*,
- at the *right time*,
- on the *right specimen*,
- from the *right patient*,
- with the result interpretation based on *correct reference* data, and
- at the *right price.*

The purpose of quality assurance (QA) in laboratory practice is to provide test results that are relevant, reliable, timely and interpreted correctly.

Quality control (QC)

- The term quality control covers that part of QA which primarily concerns the control of errors in the performance of tests and verification of test results. QC must be *practical, achievable and affordable.*

Quality assurance (QA)

- Effective QA detects errors at an early stage before they lead to incorrect test results. Laboratory personnel need to be aware of the errors that can occur when collecting specimens (pre-analytical stage), testing specimens (analytical stage), and reporting and interpreting test results (post-analytical stage)

Standard operating procedures

- Implementing QA requires preparation and use of standard operating procedures with details of QC for all laboratory tests and activities. These are required to improve and maintain the quality of laboratory service to patients; to provide laboratory staff with written instructions on how to perform tests; and to prevent changes in the performance of tests which may occur when new members of staff are appointed. These further facilitate the preparation of a list and inventory of essential reagents, chemicals and equipment.

Standard operating procedures

Standard operating procedures should have at least three appendices:

- First appendix should have information on stains/ reagents: method of preparation and QC; any associated-hazard; labeling; storage and shelf-life; and sources of chemicals and stains.
- Second appendix should have information of each item of equipment: name (including model) and supplier; instructions for use; daily QC; maintenance schedule; and trouble shooting and action to be taken if equipment fails.
- Third appendix should have information on the safe handling and disposal of specimens; decontamination procedure; personal safety measures; and first-aid measures.

5.6 Assuring quality of examination procedures

Design internal quality control system by:

- Use of certified reference material
- Examination by another procedure.

5.6 Assuring quality of examination procedures

- Laboratory shall participate in external quality assessment scheme (EQAS)/ inter-laboratory comparison (ILC).

- Laboratory management shall monitor the results of EQAS and shall document any corrective actions taken based on EQAS evaluation report.

5.6 Assuring quality of examination procedures

- For those analytes where a formal EQAS is not available laboratory shall exchange samples with other NABL accredited laboratories.

- For some rare analytes where EQAS/ILC is not available laboratory shall ensure accuracy and precision by one or more of the following:

  * Replicate testing.
  * Testing of retained samples.
  * Use of reference material, where available.
  * EQAS samples must be integrated with routine laboratory workload and analyzed by personnel who routinely test patient samples.

5.7 Post examination procedures

- Authorized personnel shall **review the results** and authorize the release of the results.
- Storage of primary samples and other laboratory samples shall be in accordance with approved policy.
- **Safe disposal of samples** when no longer required shall be carried out in accordance with local/regional/ national regulations or recommendations for waste management.

5.8 Reporting of results

Report to include tests conducted including, where appropriate, the test procedure, identification of the laboratory that issues the report, unique identification and location of the patient, date and time of primary sample collection and time of receipt by the laboratory, date and time of release of report, results in SI units or units traceable to SI units, biological reference intervals, interpretation of results where appropriate, signature or authorization of the person checking or releasing the report, etc.

5.8 Reporting of results

- The report shall indicate if the quality of primary sample received was unsuitable for the examination or could have compromised the results.
- Copies of reported results shall be retained by the laboratory such that prompt retrieval is possible.
- Procedures to alert clinicians when results are outside “critical” or “alert” intervals.
- For results transmitted as an interim report, the final report shall always be forwarded to the requester.


ThanKS