BP CLINICAL LAB
(152314-H)

(GLENMARIE BRANCH)

POCKET GUIDE TO THE ACCREDITATION STANDARDS (ISO 15189:2014)

Know the requirement!!

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INTRODUCTION:

At B.P. Lab, we place equal importance to both the quality of our services as well as to the quality of our analytical test results.

To achieve this, we have developed an effective and efficient quality management system in accordance with internationally acclaimed standards according to requirements of Joint Commission International **(JCI)** Accreditation Standards for Clinical Laboratory and **MS ISO 15189: 2014** standards

OUR STRATEGY

Our Quality Goals

- To provide accurate and timely results
- To communicate effectively with the internal and external customers
- To delight our customers

Our Core Values

Excellence :-

We continuously strive for excellence in our work by being competent, skillful and knowledgeable

Integrity: –

- *We are accountable for our actions, honest, ethical and transparent in all we do*
- *We adhere to the highest standards of professionalism, ethics, accountable and personal responsibility, worthy of the trust our clients place in us*

Teamwork :–

We value the contributions of all, blending the skills of individual staff members in unsurpassed collaboration and work toward a common goal with a positive attitude

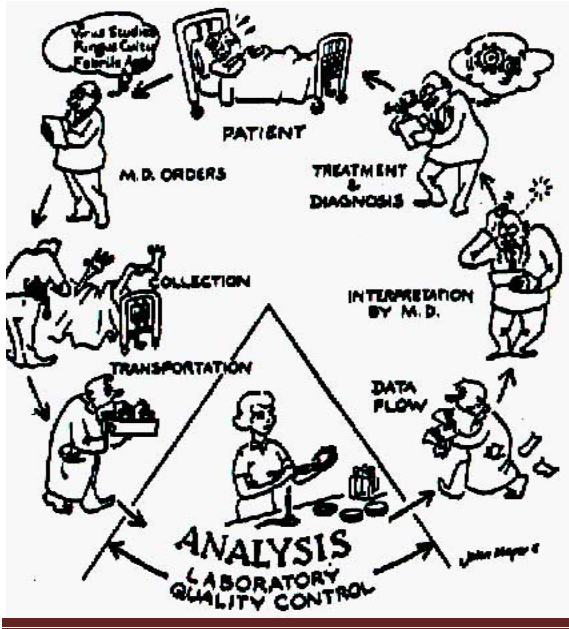
Our Tag Line

"***The Preferred Laboratory"***

What is the role of the laboratory ?

Contribution of medical laboratory service to patient care

* Provide not only testing of the biological samples but , also provide advisory, interpretative and educational services



What is MS ISO 15189:2012, *Medical laboratories - Requirements for quality and competence?*

Specifies requirements for competence and quality that are particular to medical laboratories

A medical laboratory's fulfillment of the requirements of this International Standard means :-

- The laboratory meets both the technical competence requirements and the management system requirements
- That it is necessary for it to consistently deliver technically valid results.

What are the requirements? :

Management requirement - 15

Technical requirements - 10

This pocket guide provides a handy reference for information about the requirements for MS ISO 15189:2014

Detail information may be obtained by reviewing **MS ISO 15189:2014 Medical laboratories - Requirements for quality and competence(Second revision) (ISO 15189:2012, IDT**

MANAGEMENT REQUIREMENTS

4.1 Organization and Management Responsibility

- Lab is legally identifiable
- Lab designed to meet the needs of patients and clinical personnel responsible for patient care
- The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided
- Responsibilities, authorities and interrelationships of personnel in laboratory are defined
- Effective means for communicating with staff and its stakeholders
- Have appointed a quality manager to ensure that processes needed for the Quality Management System are established

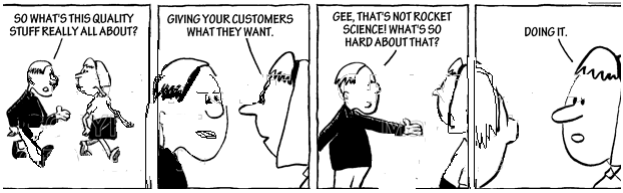
4.2 Quality Management System

- Design, implement, maintain and improve the quality management system (QMS)

- The QMS shall the integration of all processes required to fulfill its quality policy and objectives and meet the needs and requirements of the users.

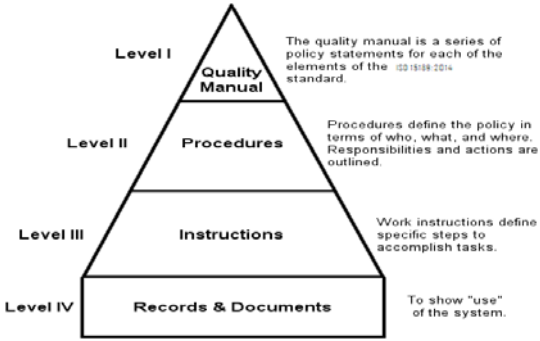
- Have documented & controlled polices, processes, procedures and work instruction

- Have Quality Policy, Quality Manual



4.3 Document Control

- Procedure to control all Documents (internal & external)
- All documents relevant to QMS must be
  - Uniquely identified,
  - are reviewed and approved by authorized personnel before issue.
  - Only current, authorized editions of applicable documents are available at points of use



4.4 Service Agreements

Have documented procedures for the establishment and review of agreements for providing medical laboratory services

Check:

- Requirements of the customers and users.
- Examination procedures selected appropriate.
- Inform customers if there is deviations from the agreement

4.5 Examination by Referral Laboratories

- Selecting and evaluating referral laboratories and consultants
- You are responsible for ensuring that test results from the referral laboratory are provided to the person making the request.

4.6 External Services & Supplies

(which includes external services, equipment, reagents and consumable supplies)

- Selection and approve suppliers
- Maintain list
- Monitor the performance of suppliers.

4.7 Advisory Services

Appropriate lab professional staff shall provide advice on:-

- Choice of test, services,
- Required type of sample and
- Provide professional judgments on the interpretation of the results of examinations

4.8 Resolution of Complaints

- Have policy and procedure for resolution of complaints
- Keep records of complaints, investigation and corrective actions.

4.9 Identification and Control of Nonconformities

Identify and manage nonconformities in any aspect of the QMS including pre examination, examination or post-examination processes.

Example :

- *Clinician complaints,*
- *Internal quality control*
- *Instrument calibrations,*
- *Checking of consumable materials,*
- *Staff comments,*
- *Laboratory Management Reviews,*
- *Internal and External Audits*

Action :

- Take immediate actions
- Determine extent of the nonconformity
- Test are halted and reports withheld as necessary
- The results of any nonconforming or potentially nonconforming test results already released are recalled or appropriately identified, as necessary;
- Every nonconformity is recorded,

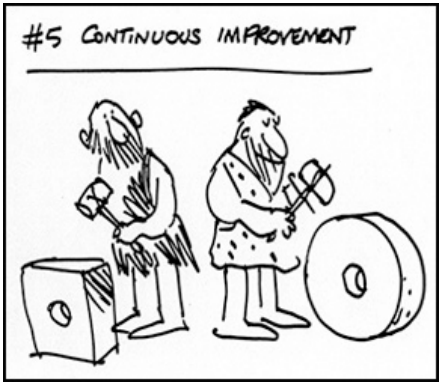
4.10 Corrective Action & 4.11 Preventive Action

- **Review** & determine the root causes of nonconformities
- **Evaluate** if there is a need for corrective action;
- **Determine** and implementing corrective /preventive actions as needed;
- **Record** the actions taken
- **Review** the effectiveness of the corrective & preventive action taken

"To address this mistake we need to utilise our thorough system of root cause analysis. I will begin, if I may, by pointing out that it's not my fault"

4.12 Continual Improvement

Identify opportunities for improvement



4.13 Control of Records

- Records shall be created concurrently with performance of each activity including pre-examination, examination and post-examination processes,

- The date and, where relevant, the time of amendments to records shall be captured along with the identity of personnel making the amendments

- Define the retention period for the various records

4.14 Evaluation and Audits

- Conduct periodic review of requests, and suitability of procedures and sample requirements.
- Do assessment of user feedback.
- Encourage staff to make suggestions.
- Conduct internal audits at planned intervals.
- Conduct Risk management to reduce or eliminate the identified risks.
- Establish quality indicators to monitor and evaluate performance
- Take appropriate immediate actions/ corrective action or preventive for non-conformity identified during external audit

4.15 Management Review

Review the QMS at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

"Ask yourself, 'What is it I'm not doing?', and then ask yourself, 'What is it I'm doing too much?'."

5.0 TECHNICAL REQUIREMENTS

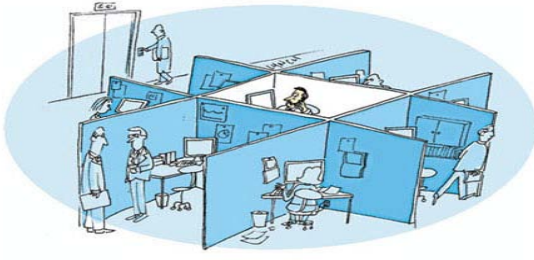
5.1 Personnel

- Document the Job Descriptions, Qualifications and Duties
- Personnel need to be trained in Quality Assurance and Quality Management
- Management must authorize personnel to perform particular tasks:-
  - Sampling.
  - Examination (test analysis).
  - Operation of equipments,
  - Use the computer system and access patient data

- Provide Continuing education programme
- Staff must be trained to prevent/contain adverse incidents
- Provide training and competency of each person must be assessed periodically
- Personnel making professional judgments/ opinions/interpretations must be appropriately qualified and experienced.
- Confidentiality of patient information must be maintained
- Ensure staff are free from any undue internal or external commercial , financial pressures

5.2 Accommodation and Environmental Conditions

- Have adequate space allocated for the performance of work and suitable environment
- Space for office facilities
- Control access to areas affecting the quality of test performance
- Provide adequate storage space
- In patient sample collection facilities there should separate reception/waiting and collection areas
- Work areas shall be clean and well maintained.



"Sorry dear, I can't get away now."

5.3 Laboratory Equipment, Reagents and Consumables

Equipment

- Acceptance testing must be done upon installation and before **use**
- Identify equipment using unique label, mark or other means
- Must be operated at all times by trained and authorized personnel
- Have readily available current instructions provided by the manufacturer of the equipment,
- Have documented Preventive Maintenance Program
- Report any equipment Adverse Incident
- Maintain records for each item of equipment.

Reagents and consumables

- Have adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration
- Conduct acceptance testing or verification for performance before use
- Establish an inventory control system
- Instructions including those provided by the manufacturers, shall be readily available
- Report any adverse incident
- Maintain records for each reagent and consumable

5.4 Pre-Examination Processes

- Provide information to patients and users of the laboratory services.
- The request form should have space for
  - Patient details,
  - Name of requestor,
  - Type of primary sample,
  - Examinations requested;
  - Clinically relevant information;
  - Date and, where relevant, time of primary sample collection;
  - Date and time of sample receipt

- Have documented procedures for the proper collection and handling of primary samples.
- Sample reception;-
  - Samples are unequivocally traceable.
  - Have criteria for acceptance or rejection of samples.
  - Problem with sample documented.
  - Records of samples received are maintained.
- Urgent requests are rapidly processed
- Pre-examination handling,

preparation and storage for patient samples

- Have storage facility to avoid deterioration, loss or damage during pre-examination activities and during handling, preparation and storage .

"HE FAINTED WHEN HE SAW THE NEEDLE."

5.5 Examination Processes

- Select test methods which have been validated for their intended use
- Verify validated test methods
- Determine measurement uncertainty for each measurement procedure
- Define the biological reference intervals or clinical decision values
- Test methods shall be documented

"I imagine this was mentioned in the solvent handling instructions I didn't read."

5.6 Ensuring Quality Of Examination Results

- Design quality control procedures that verify the attainment of the intended quality of results
- Use quality control materials which is close as possible to patient samples.

- Quality control data
  If quality control rules are violated and indicate that test results are likely to contain clinically significant errors,
  - The results shall be rejected and
  - Relevant patient samples re-tested after the error condition has been corrected and within-specification performance is verified.
- Participate in appropriate EQA program

5.7 Post-Examination Processes

- Review the test results before release and evaluate them against **internal quality control** and, as appropriate, available **clinical information** and **previous examination results**.
- Store the retained sample according to established retention time and ensure safe disposal of clinical samples

"I have your lab results. Some of your readings are too high and some are too low. No, they don't balance out."

5.8 Reporting of Results

Reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.

5.9 Release of Results

- Documented procedures for the release of examination results, including details of who may release results and to whom
- If the quality of the primary sample received is unsuitable for conducting the test , or could have compromised the result, this should be indicated in the report.
- If the test results fall within established “alert” or “critical” intervals:-
  - a physician (or other authorized health professional) is notified immediately [this includes results

received on samples sent to referral laboratories for examination

— records are maintained of actions taken that document
  - date, time,
  - responsible laboratory staff member,
  - person notified and
  - test results conveyed, and
  - any difficulties encountered in notifications

5.10 Laboratory Information Management

Have documented procedure to ensure that the confidentiality of patient information is maintained at all times.