AAC-7 : LAB QUALITY ASSURANCE

GROUP-6
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OBJECTIVES

- Quality assurance
- SOPs
- Verification & Validation
- Quality control
- Calibration
- Continous quality improvement

QUALITY ASSURANCE

- **QUALITY ASSURANCE**

  - The procedure in place to avoid errors occurring.

  - Purpose of QA is to give relevant, reliable, timely test results which is interpreted correctly.

  - QA involves activities both inside and outside of laboratory.

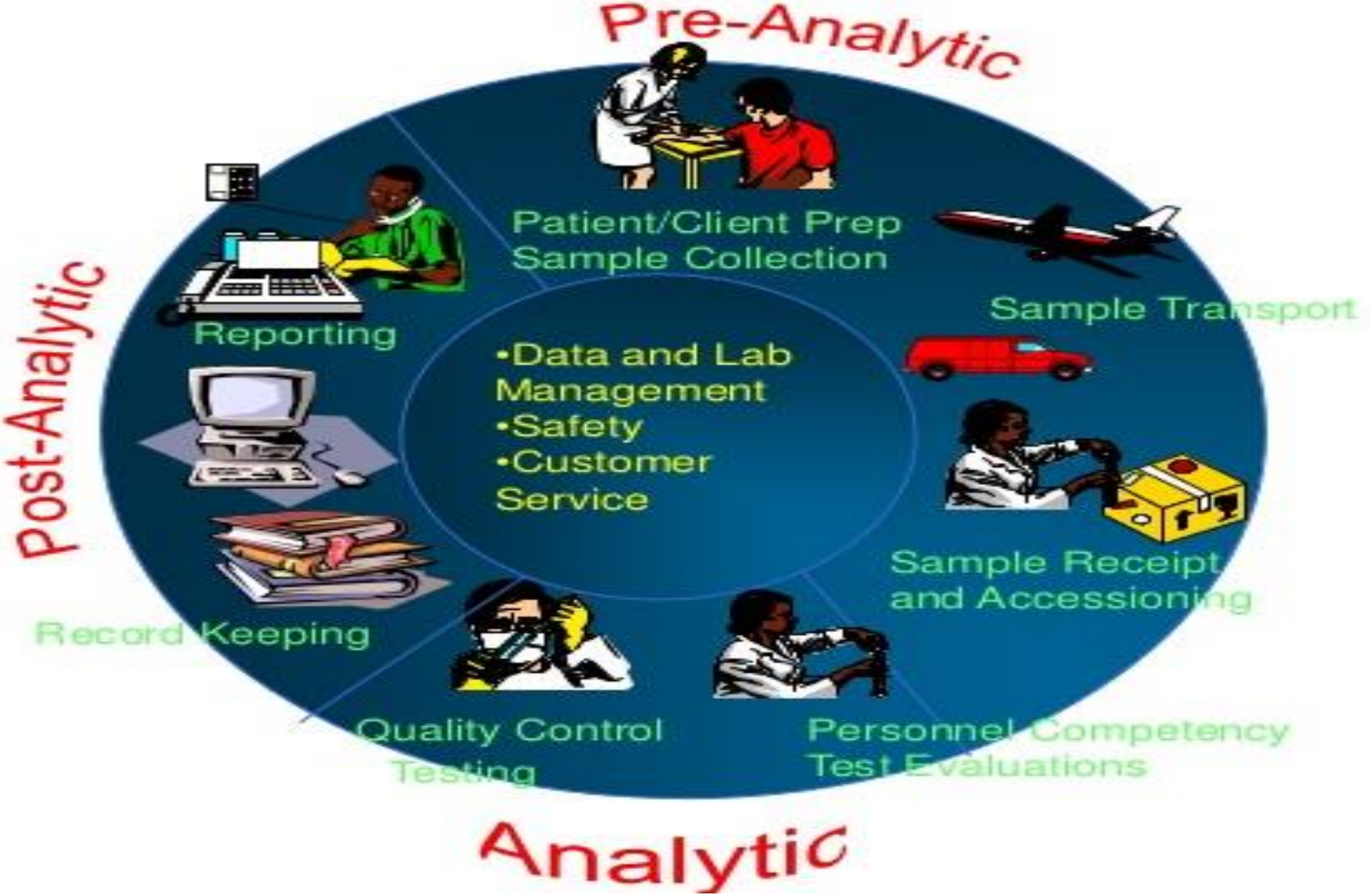
- **QUALITY CONTROL**

  - The process of detecting error.

- Quality assurance includes Internal quality control, External quality control, Pre-analytic phase, Analytical phase, Post-analytical phase, Management & Organization.

Pre analytical	Analytical	Post analytical
Right Specimen	Qualified professionals	Report
Right Collection	Reagents	Interpretation
Right vaccutainer	Equipment	TAT
Right Labelling	SOP	STAT
Right quantity	Documentation	Critical alert
Right transport	Safety	Report to correct patients

The Quality Assurance Cycle



POLICY MANUAL

- Every department should have their own Standard operating procedures (SOP's) – Standard Operating Procedure.
- SOP's for test - approved by signatory.
- Designated individuals to perform & monitor results.

SOP MANUAL TEMPLATE

1. Purpose	9. Calibration Procedure
2. Principle	10.Quality control procedure
3. Performance Specification Linearity Measurement range Sensitivity	11. Calculation of results
4. Primary Sample	12. Reference range
5. Types of container & Additive	13. Critical / Alert level values
6. Reagent	14. Safety Precaution
7. Instrument	15. Interferences
8. Step by step procedure	16. References

VERIFICATION & VALIDATION

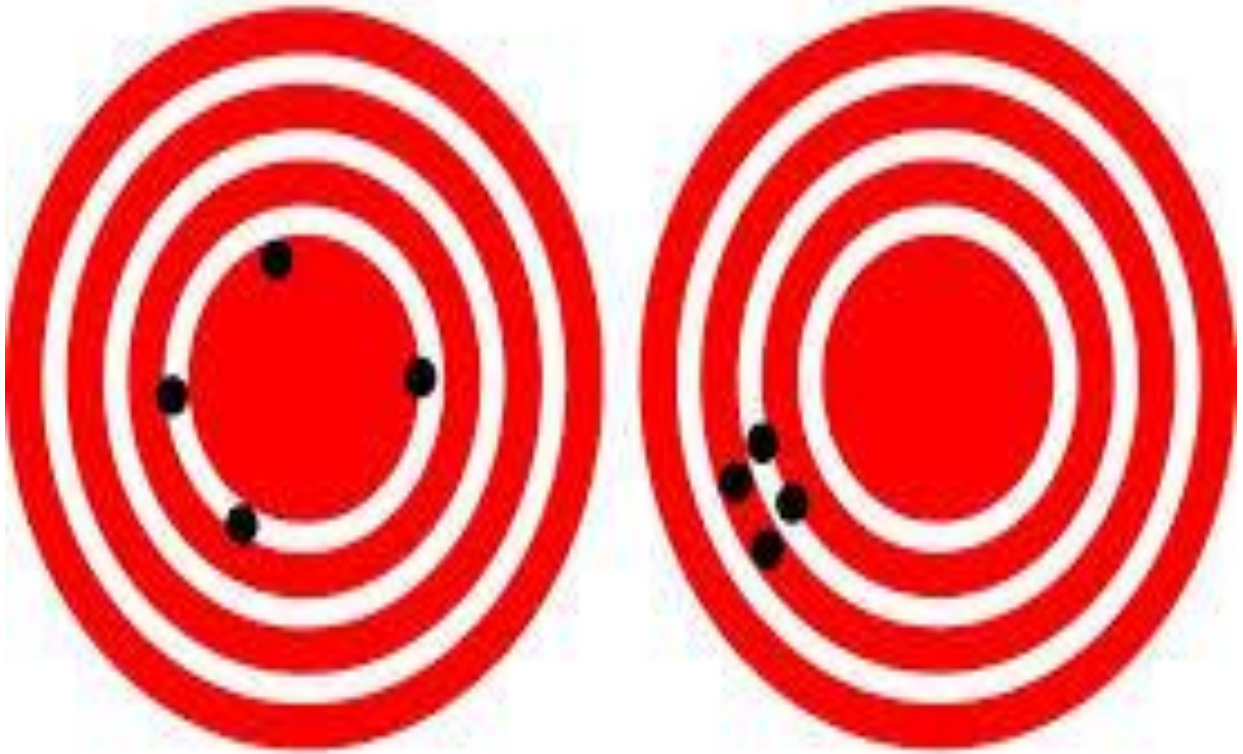
- Standard method need verification to ensure that the laboratory is performing the analysis properly. It indicates accuracy & precision. Verification is internal quality process.

- Validation involves performing laboratory tests to verify that a particular instrument is working properly.

- Accuracy – Closeness of measurement of a quantity to its actual value.

- Precision – Which repeated measurements under unchanged condition show the same results.

WHICH IS ACCURATE & WHICH IS PRECISE…?

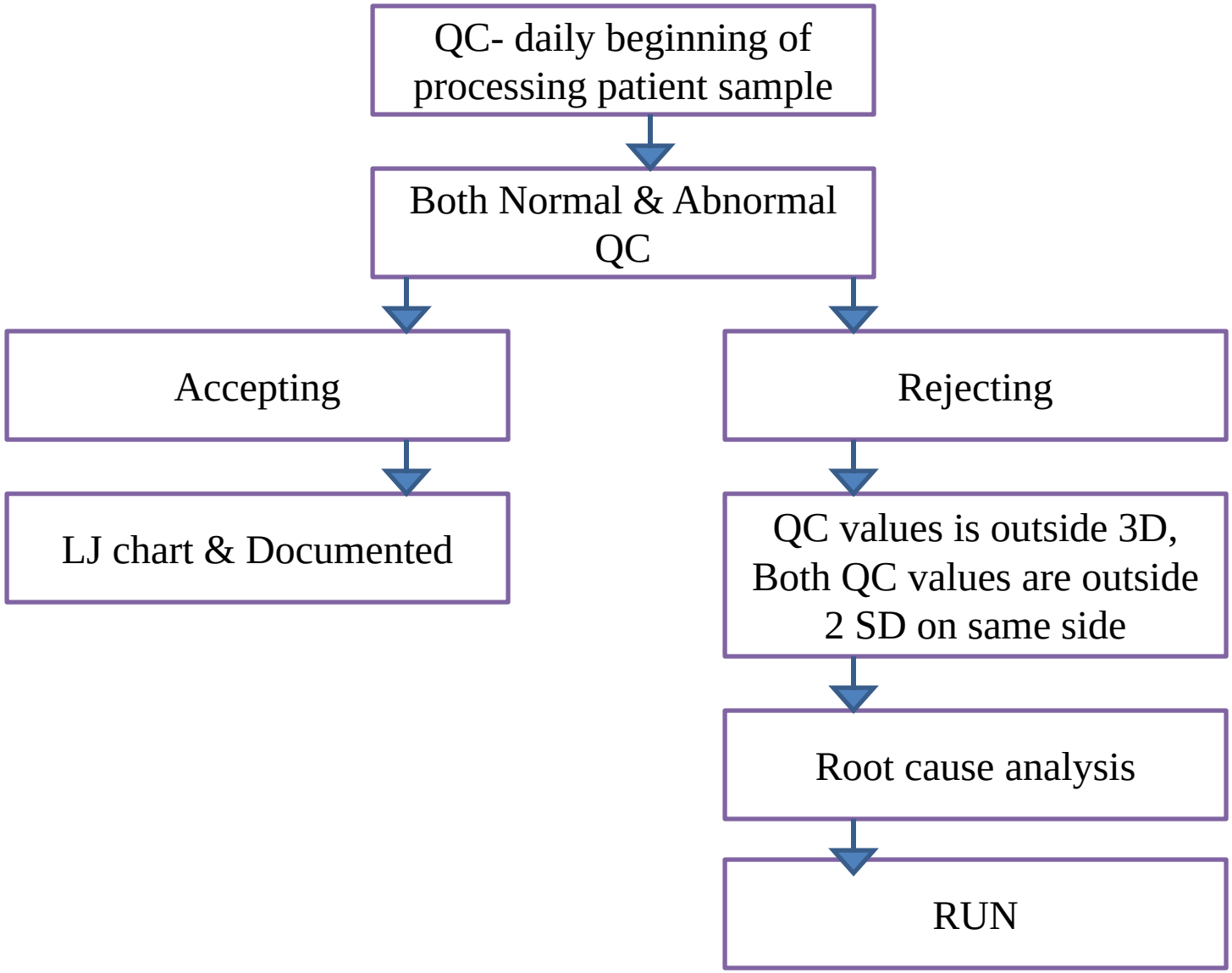


QUALITY CONTROL

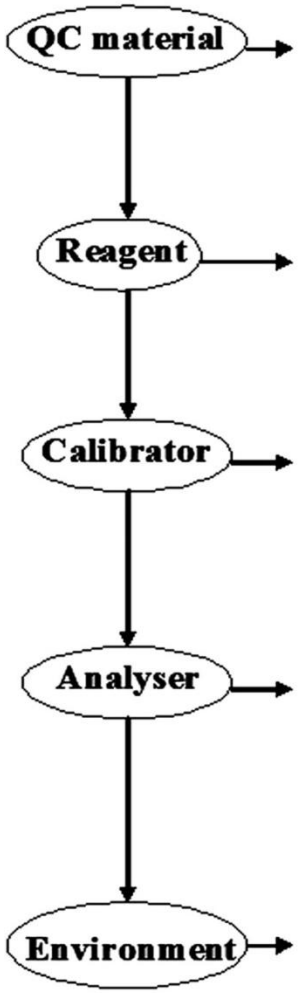
- **Internal Quality Control (IQC)** testing is performed within a laboratory to monitor and ensure the reliability of test results produced by the laboratory.

- **External quality control -** evaluates a laboratory's testing results by comparing them to those of similar laboratories. Specially prepared specimens are obtained by multiple laboratories participating in the proficiency testing program

INTERNAL QUALITY CONTROL PROCEDURE



ROOT CAUSE ANALYSIS



Correct QC material / lot / level ?
Prepared correctly (including check for absence of bubbles)?
Within expiration date?
Stored under correct conditions / run promptly to prevent evaporation?

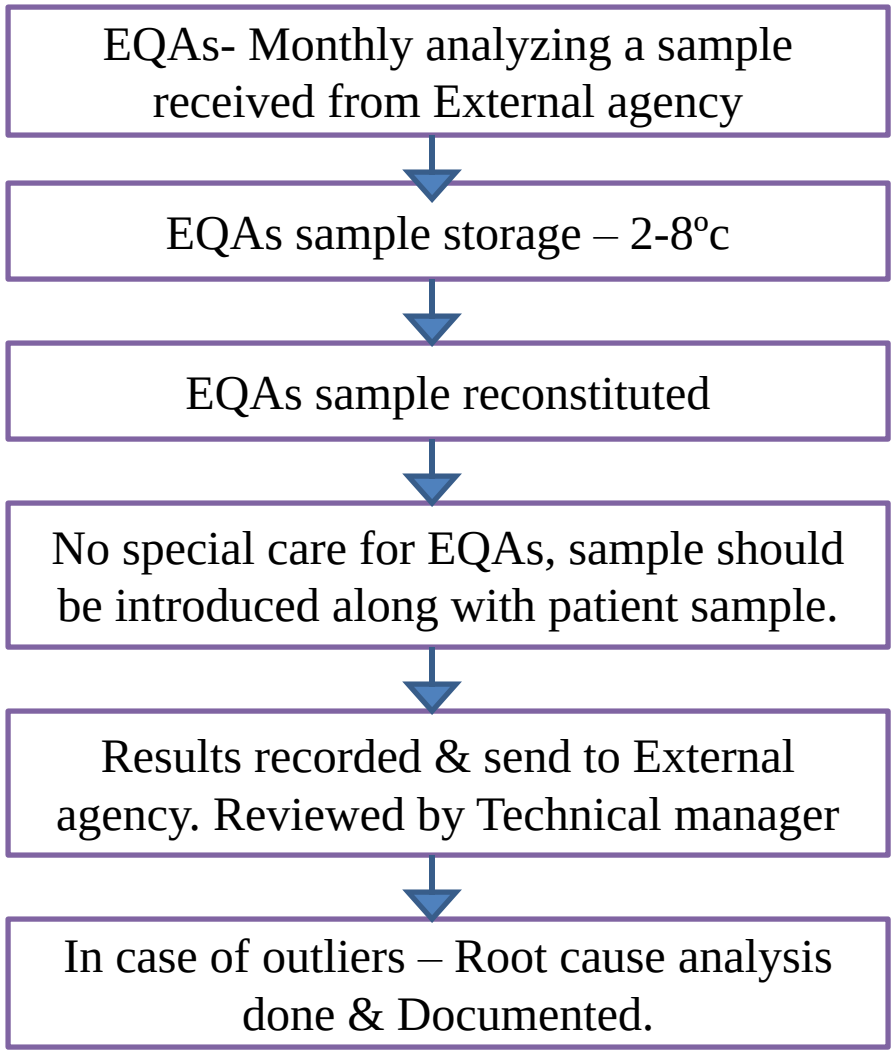
Correct reagent / lot ?
Prepared / loaded correctly?
Within expiration date / on board stability?
Stored under correct condition?

Calibration curve correct?
Standards stored and prepared correctly?
Standards loaded in correct order?
Correct calibration lot?
Within expiration date ?

Is maintenance up to date?
Was any recent maintenance completed correctly?
Were wash solutions correctly prepared / stored / within onboard stability?
Are there any problems on visual inspection e.g. leaks, worn syringe plungers, bent probes etc ?

Is the DI water system functioning properly?
Is the waste system functioning properly?
Is the laboratory temperature and humidity monitored and maintained at an appropriate level?

EXTERNAL QUALITY CONTROL PROCEDURE



CALIBRATION

- Calibration means adjusting or standardizing the equipment
- Traceability certificates of the calibration & Preventive maintenance plan of (AMC) annual maintenance contract should be documented.
- Corrective action – The implementation of solutions resulting in the reduction of an identified problems.
- Preventive action – Action taken to improve a process, before occurrences of an non conformities.

TRAINING

- Training must include an understanding of why quality is important
- Training should be need based, for all staff and reviewed
- Competency assessment and training should be done.
- Continuing education program should be provided.
- All documentation should maintained.

CONTINOUS QUALITY IMPROVEMENT

- Continous quality improvement - To reduce the percentage of deviation in Critical alert, TAT, & Repeats.

Indicators:	To reduce percentage of the deviations in Lab Critical value Intimation					
Lab						
Month	Jan	Feb	Mar	Apr	May	Jun
No. of deviations in critical value intimation						
Total Critical values						
% deviation of Critical value intimation						
Indicators:	To reduce percentage of the Redo tests in lab					
Lab						
Month	JAN	FEB	MAR	APR	MAY	JUN
No. of redo's tests						
Total tests						
% of Redo tests						
Indicators:	To reduce percentage of the deviations in Lab Turn Around Time (TAT)					
Lab						
Month	Jan	Feb	Mar	Apr	May	Jun
No. of test not reported on time						
Total no. of test done						
% deviation of TAT						

THANK YOU….