

## \* Internal audit requirements:

- Conduct at planned interval - every 1 year
- Determine all activities in quality management system - pre examination, examination & post examination
- Not necessary to cover ~~each~~ all element of quality management system in depth
- The laboratory may decide to focus on particular activity without completely neglecting others.
- Should be conducted by personnel trained to assess the performance of managerial & technical processes of quality management system.
- Audit programme shall take into account status & importance of processes & technical & management area to be audited & results of previous audits.
- Define & documentation of audit criteria, scope, frequency, method.
- Selection of auditors & conduct of audits shall ensure objectivity & impartiality of audit process.
- Auditors shall, wherever resources permit, be independent of activity to be audited.
- Documented procedure to define responsibilities & requirements for planning & conducting audits & for reporting results & maintaining records.
- When nonconformities are identified - personnel responsible for area being audited shall ensure that appropriate action is promptly undertaken.

- corrective action shall be taken without undue delay to eliminate causes of detected nonconformities.
- Quality manager is responsible for planning & conduct of internal audit.
- Laboratory director is responsible for maintaining records & presenting its report as input to management review.
- Method - Horizontal / vertical.