18-3: Organizational structure

When considering organizational structure to support a quality management system, a number of elements should be considered:

- The **path of workflow** is the route of a sample through the laboratory, from collection to reporting of a result. The organizational structure of the laboratory must support an optimal path of workflow, by allowing processes that yield efficient sample handling while minimizing error. Considerable attention should be given to the design of this system.
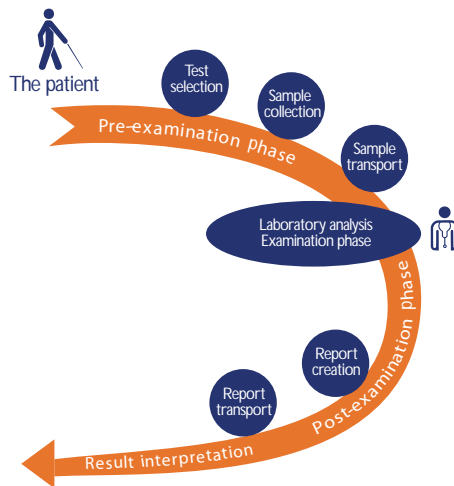
- An accurate and complete organizational chart is necessary. Many problems can be prevented if responsibilities are clearly defined and all members of the laboratory team understand what each is supposed to do.
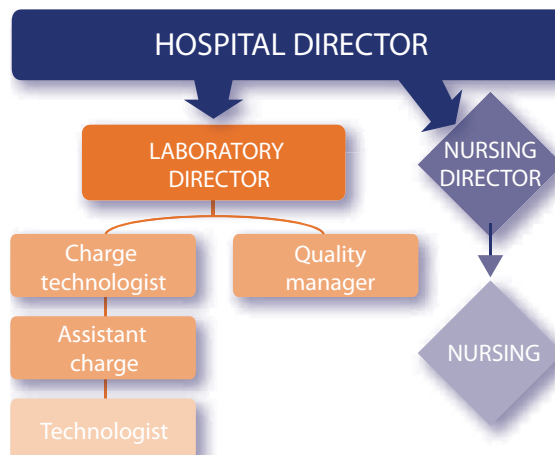
- A quality management system must have a quality manager.
- Resource allocation must be sufficient to ensure that personnel and infrastructure needs are met.

Quality manager

ISO 15189 [4.1.5 i] states that a laboratory must have a quality manager. The quality manager is the person most directly responsible for ensuring that the quality policies and procedures are carried out.

The quality manager should sit high in the organizational structure; they must be delegated the appropriate responsibility and authority to ensure compliance to the quality system requirements. The quality manager should report directly to the decision maker(s) in the organization.

A very large laboratory may need several quality managers, perhaps one for each section. On the other hand, in a small laboratory this may be a part-time job for a senior technologist, or even a job that is carried out by the laboratory manager.

The quality manager may be assigned many tasks. Some typical responsibilities of the quality manager will include:
- monitoring all aspects of the quality system;
- ensuring staff are following quality policies and procedures;
- regularly reviewing all records; for example, quality control and external quality assessment that are part of the quality system;
- organizing internal audits and coordinating external audits;
- investigating any deficiencies identified in the audit process;
- informing management on all aspects of the quality system monitoring.