L1 What is Quality

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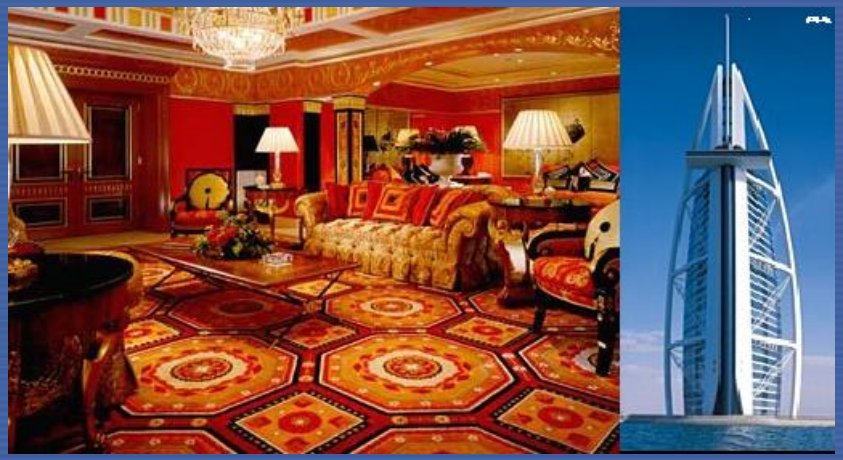
What is Quality ?



This is Quality !

To know not only customer‘s needs

but also his expectations

and to fulfil both to his satisfaction

at reasonable cost

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How to ascertain Quality ?

Ascertaining Quality in a product:

- Tests and measurements during production
- Testing the final product
- Rejecting nonconforming products

COST ??

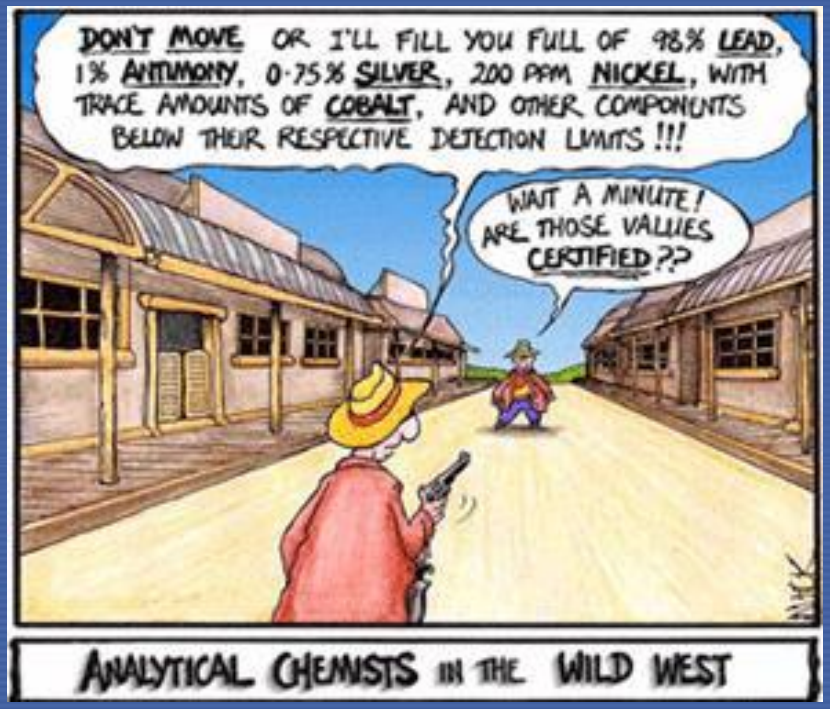
Assuring Quality in a service ?

What is the importance of QA/QC in analytical work?

- Customers of analytical labs require a fast answer for a reasonable price with a clear report, flexibility and an accurate result; the latter being considered as implicit; But, "fast, accurate and cheap don't go together"

What is the importance of QA/QC in analytical work?

- We have to look for a fit for purpose where our technique is **fast enough, accurate enough and for a honest price**.



Quality-Why so important? The cost of making mistakes is high

Externally:

- Trade: it could lead to substandard goods risking loosing the customer;
- Environmental monitoring: it could lead to hazards being undetected or to the identification of unreal hazards, impact on safety and health
- Health and safety: a doctor making a wrong diagnosis;
- Reduction of cost -emphasis on free trade –thus one stop testing

Quality-Why so important? The cost of making mistakes is high

Internally

- Redoing the analyses, root cause analysis, results too late, loss of reputation, claims, unsatisfied customers that run away
- So, the aim is zero defects

Why wrong results in laboratories ?

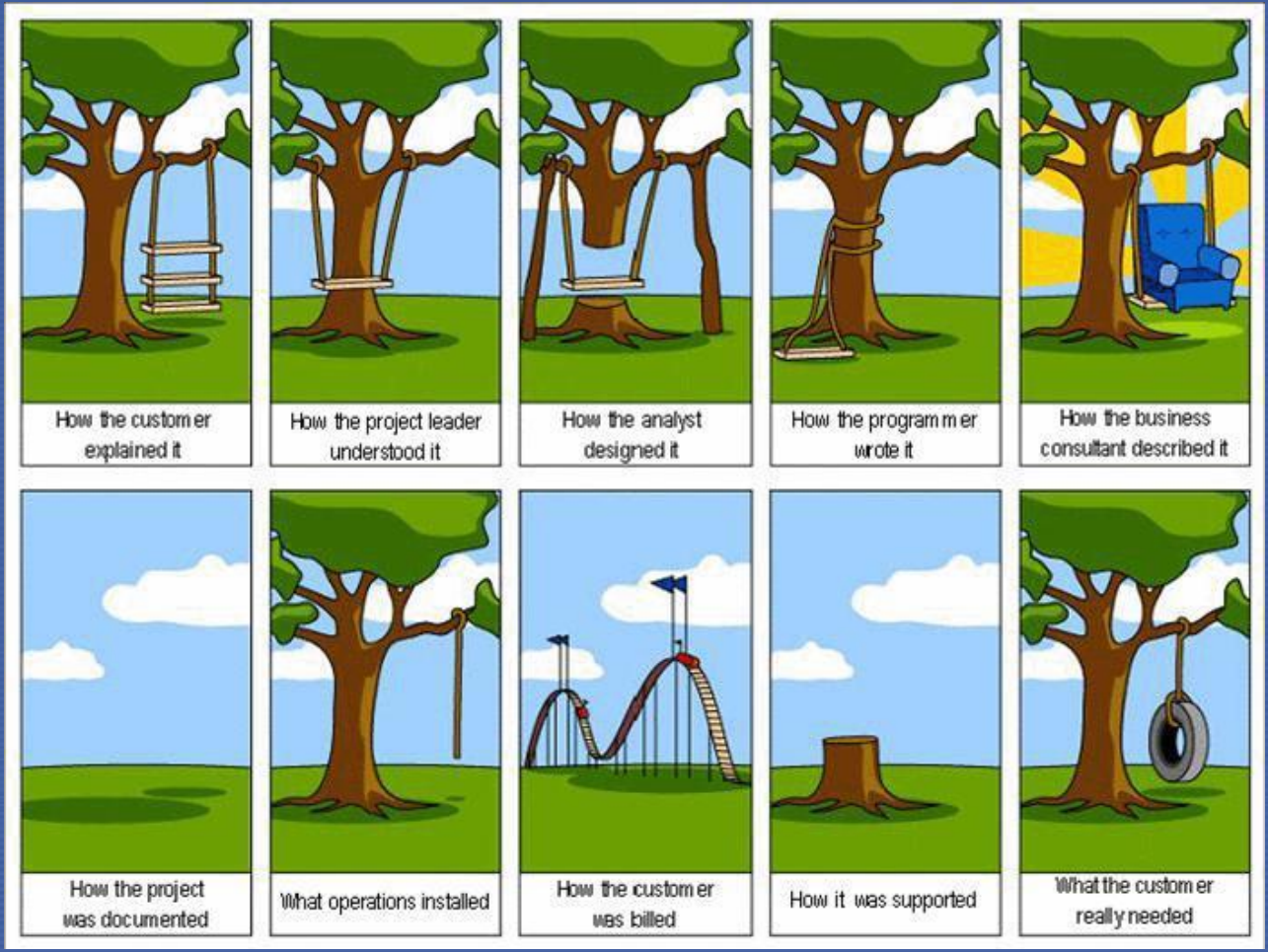
- Analytical sources of errors

- Organizational sources of errors

Analytical Sources of Errors

- Mixing of samples
- Calculation codes
- Calibration errors
- Contamination
- Insufficient sample preparation
- Background subtraction
- Expired standards
- Typing errors

Organizational errors



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Organizational errors

- Bad communication
- Insufficient supervision
- Insufficient harmonization
- People make shortcuts
- Insufficient documentation
- Insufficient technical competence
- Insufficient planning

Organizational errors

- Insufficient training
- Economical competition
- Working environment culture
- Working pressure

How to avoid this?

Implement Quality Management in accordance to ISO/IEC 17025:2017 standard.

What is Quality Management ?

Quality Management is a set of rules, which an organization uses internally to assure that the products and services, which it delivers to its customers in order to satisfy customers needs and expectations and are produced correctly and accurately at acceptable costs on the first try

Quality or Quality Management System

If we write down what we need to assure our results we would end up writing down the requirements for a quality management system. Thus a ***Management system refers to what a lab does to manage its processes, or activities in order that the results that it produces meet the objectives it has set itself, such as the following:***

- satisfying the customer's quality requirements;
- complying to regulations, or
- meeting environmental or safety objectives, …

Quality or Quality Management System

- In a small lab, there is probably no "system", as such, just "our way of doing things", and "our way" is probably not written down, but all in the head of the lab manager.
- The larger the lab, and the more people involved, the more the likelihood that there are some written procedures, instructions, forms or records.
- These help ensure that everyone is not just "doing his or her own thing", and that the organization goes about its business in an orderly and structured way, **so that time, money and other resources are utilized efficiently.**
- Thus systemizing makes sure that nothing important is left out and that everyone is clear about who is responsible for doing what, when, how, why and where.

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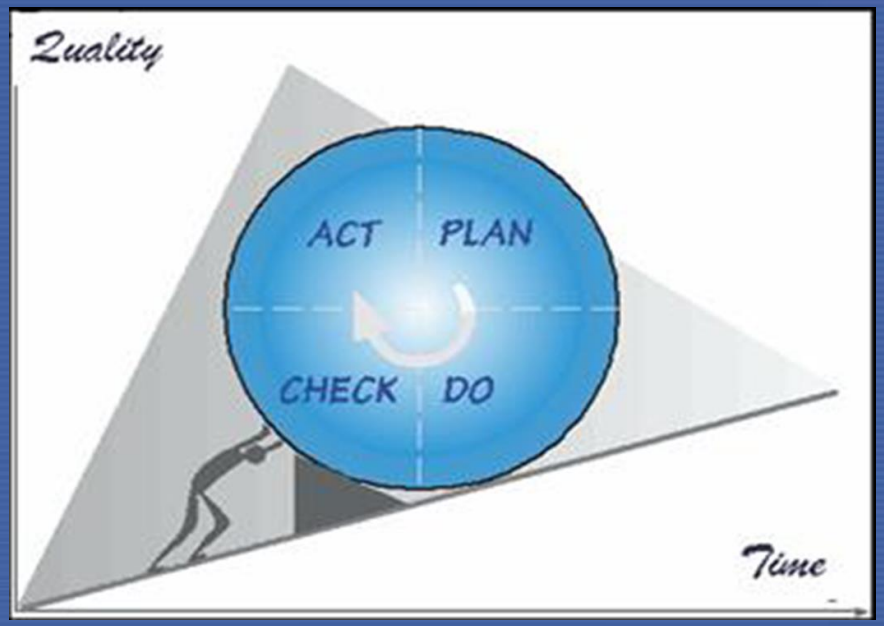
Quality Management

- Quality Assurance: first make sure what your are doing is valid (zero errors), then **say what you are doing and keep on doing what you are saying;**
- **So,**
  - **Implement it**
  - **Prove it**
  - **Control it**
  - **Improve it**
  - **Assure it**
  - **And, start over again**



ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories”

It contains all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.