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**DEFINING QUALITY:
A BRIEF SUMMARY OF THE TERMINOLOGY**

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Summary

- Quality, QC, QA, QM Qwhat ?
- customers & stakeholders
- products
- non conformances
- who's Deming and what could do for us ?
- improvement
- processes
- documental system
- procedure
- certification
- authorization
- audit

Buying a new gamma camera - I

Probably most of you has been involved in buying new gamma camera in the last few years.

When you both yours, did you consider the choice among a:

- planar, small field camera
- double head camera
- SPECT-CT camera (non diagnostic X rays component)

All of them can be very good pieces of equipment, but most likely you consider them not comparable each other.

Even in an informal approach, in your mind you are emitting ***specifications***.

Buying a new gamma camera - II

Let us now consider three models of gamma camera that you feel “comparable”, let say three different types of variable geometry double head camera.

You will probably ask the companies to supply you with their brochures and data sheets, or ask the companies to fill a form asking them to answer a series of specific questions, regarding performance, up time and reliability, service etc.

Then you will compare the price against your budget.

You will consider as satisfactory the system that fulfills in the best way your requirements: this is a ***quantitative comparison of measurable quantities with a reference standard.***

Buying a new gamma camera - III

Finally, you will take into account also different factors, like the *perception* that you have of the company.

This aspect takes into account several different aspects:

- your previous experience with that company (or experiences of colleagues you trust)
- the level on innovation that you feel they represent
- the training of your staff with their operating system
- the level of after sale support that you expect

Buying a new gamma camera - IV

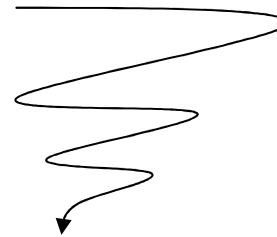
At the end, you will choose the gamma camera that has the best **quality**, taking into account a multiplicity of factors:

- quantitative comparison with your **specifications**
- satisfaction of your **perceptions**

The **quality** that you recognize to the system is given by a combination of both its intrinsic characteristics and your expectations.

A practical definition of Quality

Quality of a product is its capacity to satisfy all the requisites, explicit or implicit, of the customer (and other involved parties).



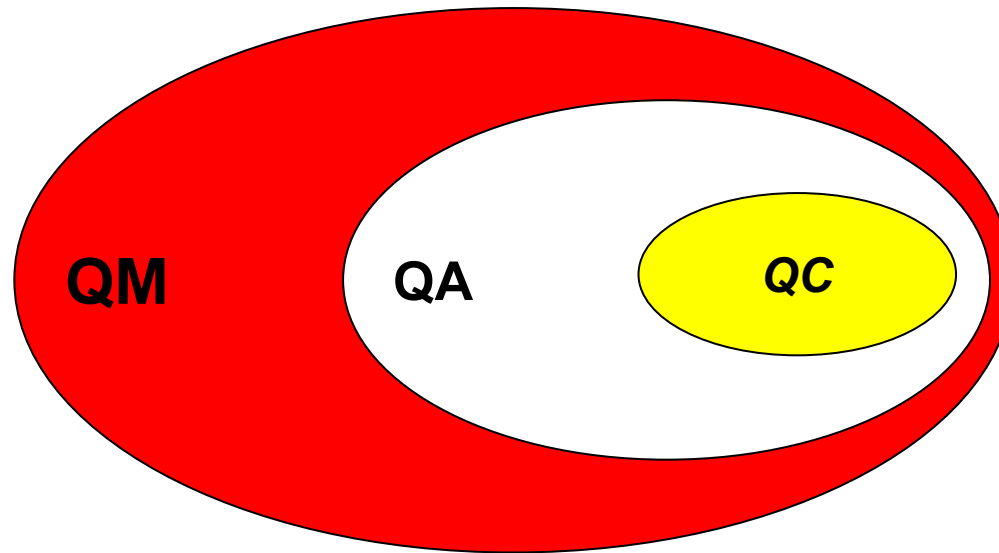
stakeholders

Interests of the stakeholders

What do the stakeholders expect ?

- ethical quality
- information quality
- administrative quality
- work safety quality
- environmental quality

QC, QA, QM



Quality control: is a part of quality assurance. The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

Quality Assurance: all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards.

From EU Directive 97/43

Quality Management: That aspect of the overall management function that determines and implements the *quality policy*

Customers

The customer is the user of a product:

- we can have external customers, when we supply our products to another organization or to a person / entity that is not included in our organization.
- internal customers.

Examples:

- a patient is an external customer
- another Hospital or an Insurance company to which we sell exams are external customers
- Oncology or Cardiology Departments in the same Hospital are internal customers of a Nuclear Medicine Department.
- the Nuclear Medicine Dept. is typically a customer for a Medical Physics Dept.

Products

- the “product” is the result of a process
- is, at the end, what the customer wants !
- a service may be a product as well

Examples:

- A Nuclear Medicine Department buys products like radiopharmaceuticals, syringes, ...
- Scans and other examination are product sold by a Nuclear Medicine Department
- consultancy of a Cardiologists from the Cardiology Dept., the ambulance service that brings back patient to another Clinic, support in QA procedures from the Medical Physics Department are products that Nuc. Med. Buys

Non conformity

The non fulfillment of a requirement.

An organization should activate a procedure for detecting NCs and treating them appropriately, in the sake of improvement of its performance.

Examples:

- report of a scan is prepared and signed in 7 days, while the specified term is 5 days
- the field engineer in charge of planned maintenance to a gamma camera, arrives at 11:30, while start of the maintenance was planned at 9:00

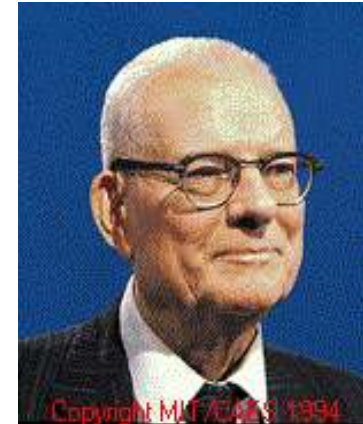
Anomalies

In other cases we have **Anomalous situations**, for example:

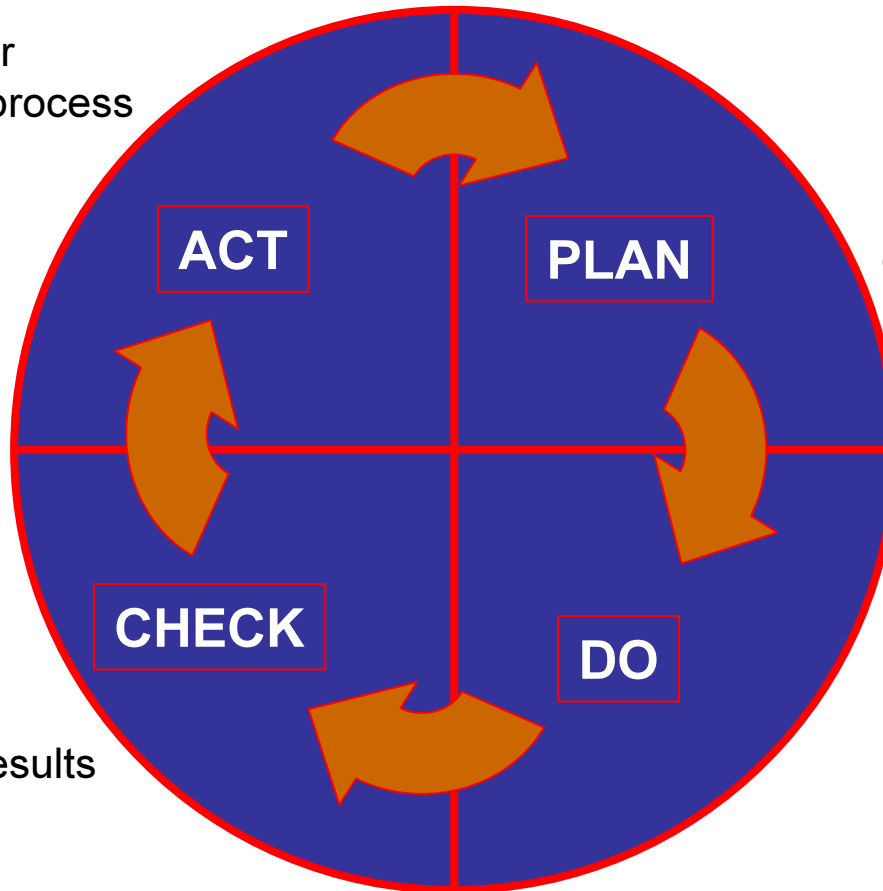
- at a QC test, a gamma camera shows an uniformity of 7 %, while the reference value determined for that equipment is 6 %
- the radiochemical purity of a ^{99m}Tc -MDP preparation results to be 89 %, while the minimum acceptable value stated in the Pharmacopeia is 95 %

These are not Non Conformities, but anomalous conditions that need to be recognized and treated, according to specific procedures aimed to continuous improvement.

Deming cycle



ACT to correct discrepancies or adopt the new process

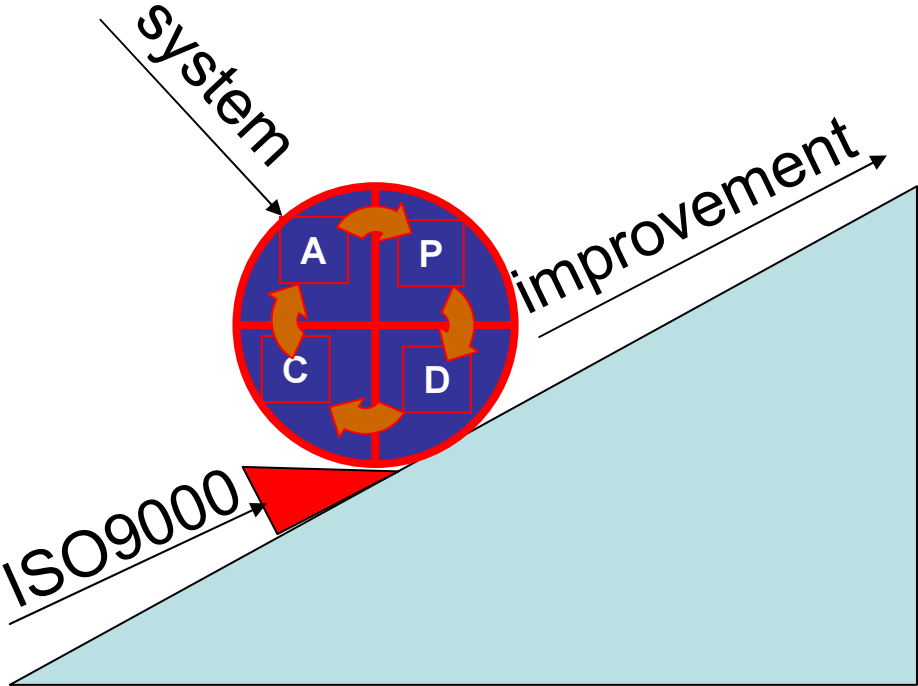


PLAN a process or a change

Try to **DO** what you have planned

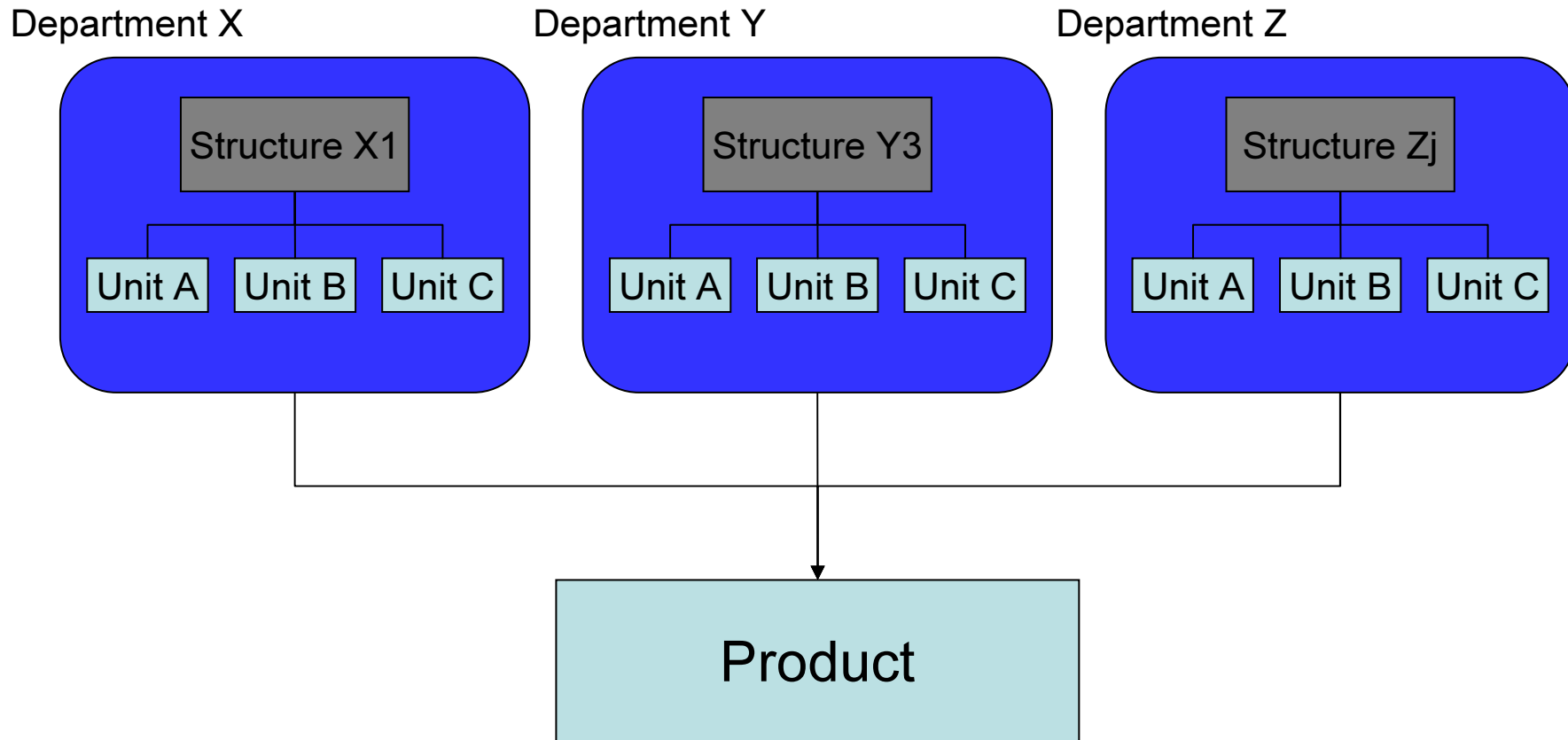
CHECK the results

Continuous improvement

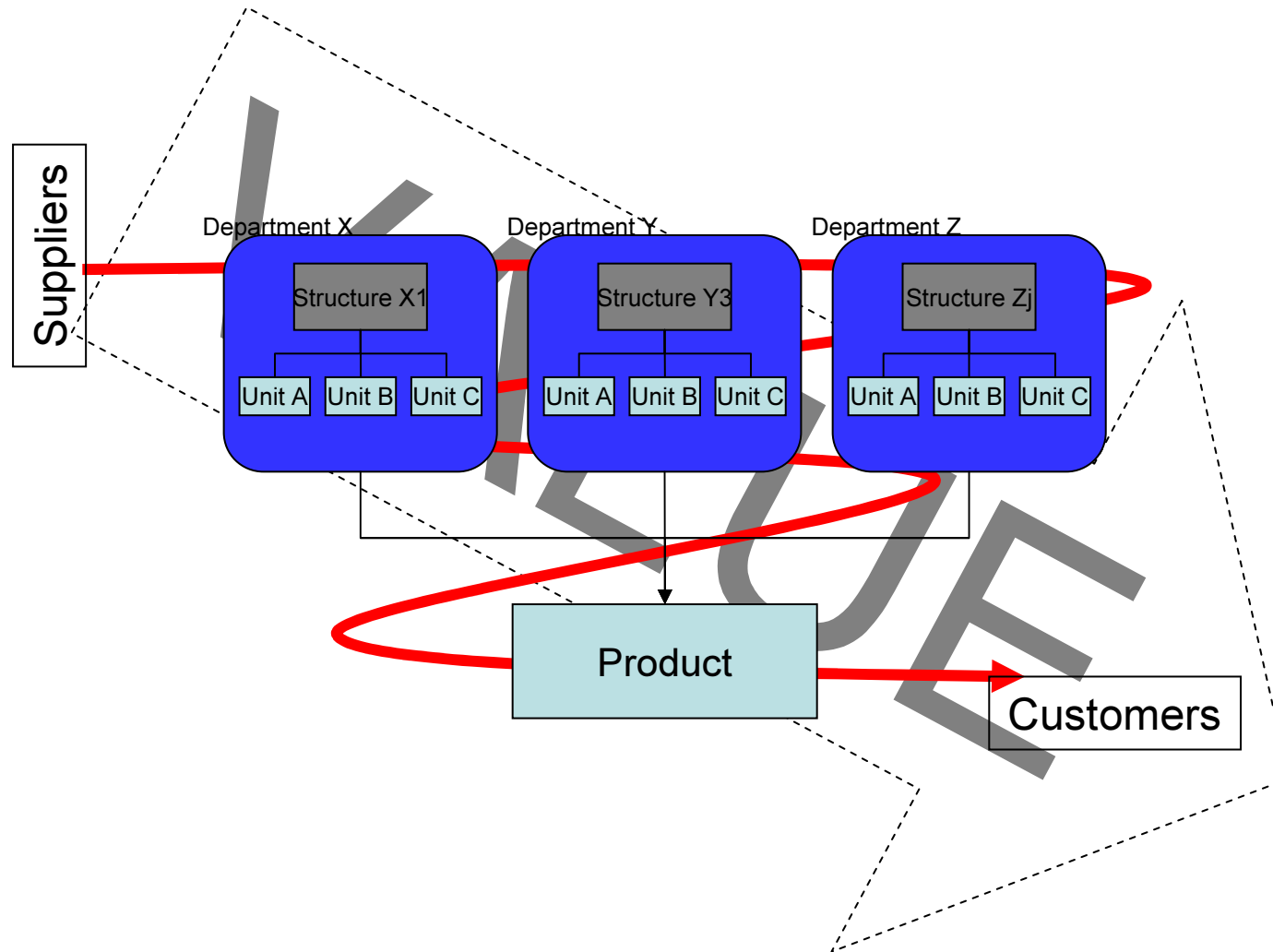


Processes

Big organizations are structured in vertical functions, but their production activities are determined by horizontal processes



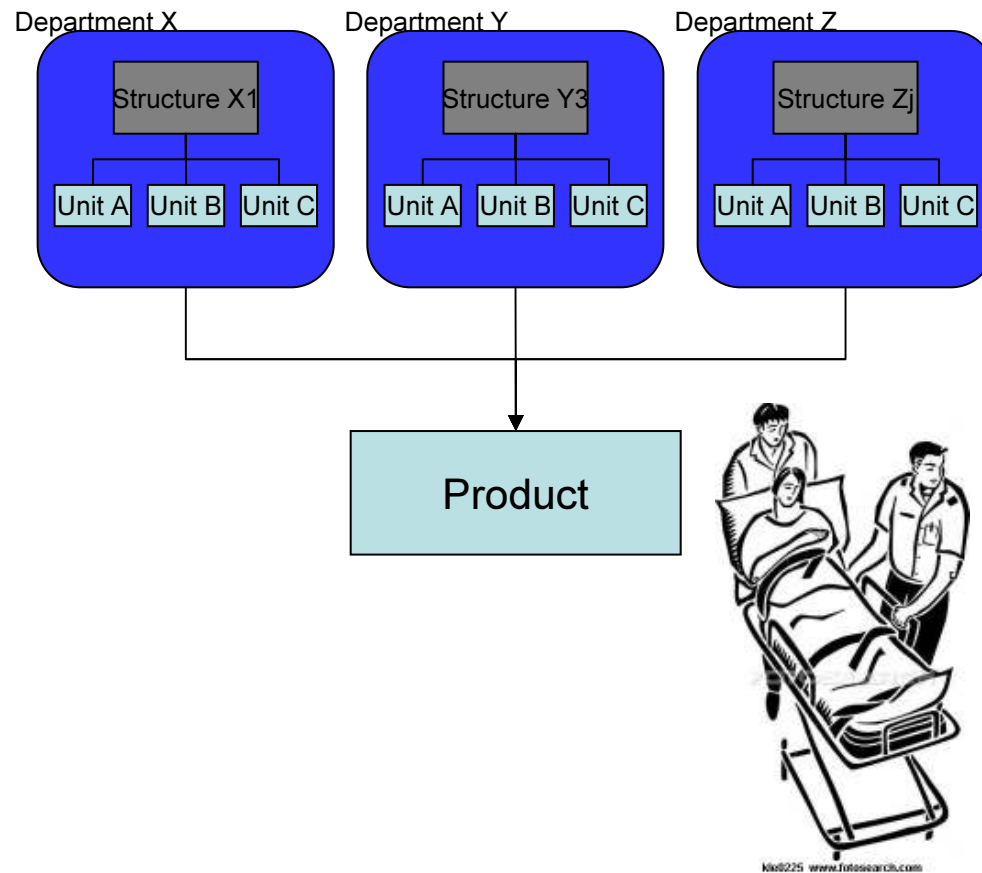
Processes



An organization generates VALUE through its processes and products, not through functions !

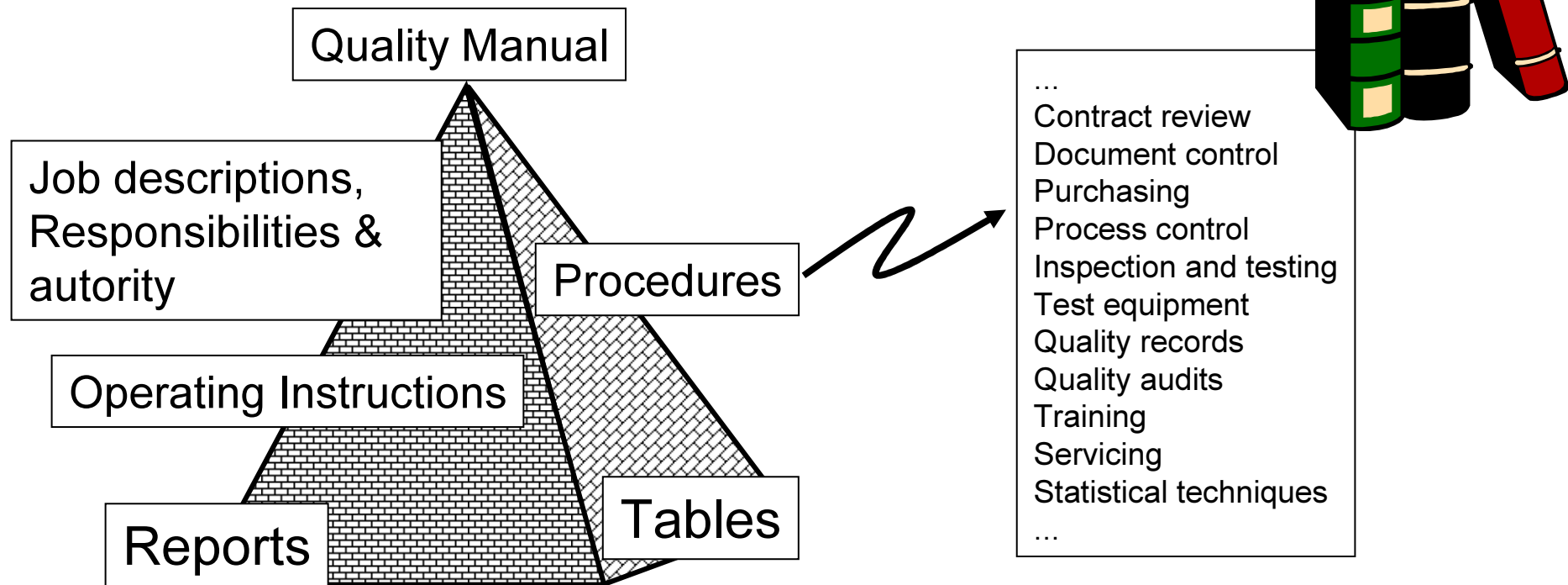
Processes

The customer do not perceives the results of activities of a single department or function, but of the concatenation of the efforts of the whole organization



Documental system

- Hierarchical organized series of document describing the whole Quality System
- Covers all the 20 points of the ISO Standard
- To be maintained “under control”
- Operating Instructions are only a part of the whole system



... the heaviest and most time consuming task in the construction and running of a Quality System.

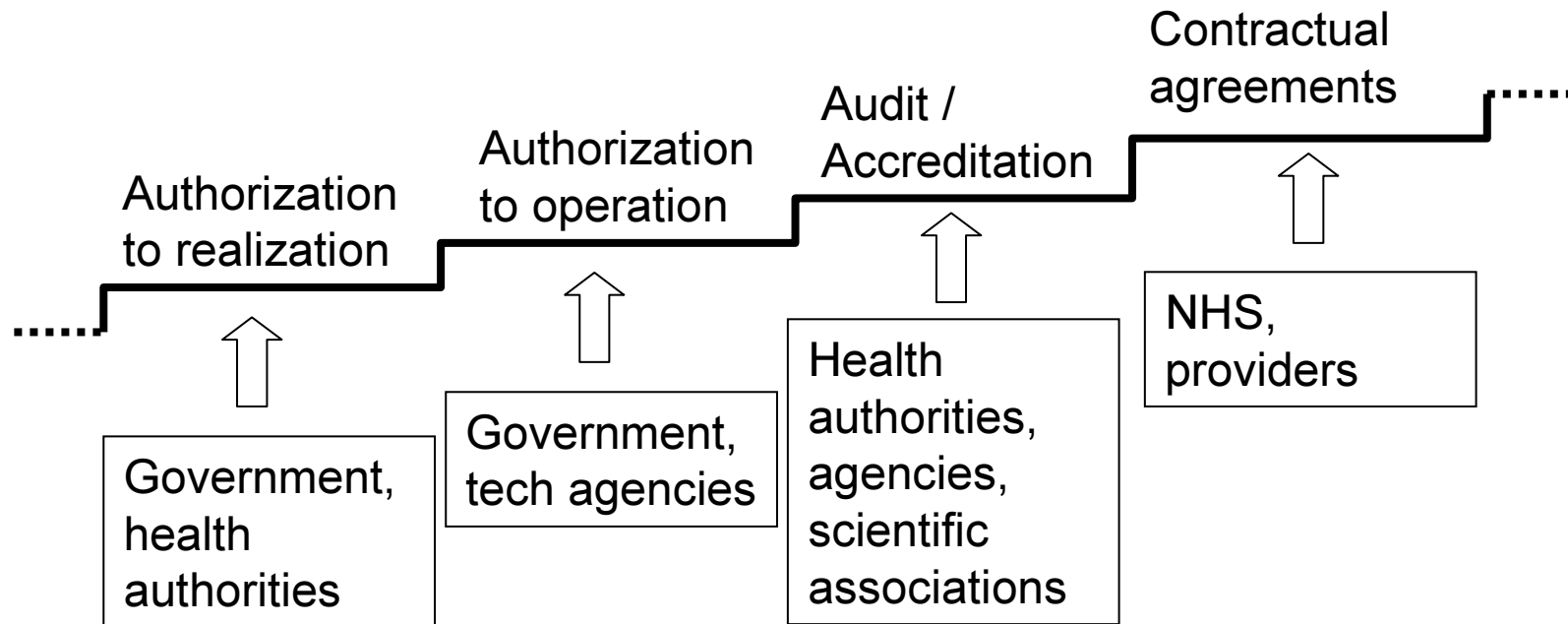
Procedure

A written description of what operations are to be performed to carry out a particular process.

- **Procedure guidelines** are a part of the process of evidence base medicine; they collect current opinions from relevant scientists and association and give us a definition of the “state of the art” in a certain matter. I.e. you may have a guideline on the use of FDG PET in oncology or on thyroid scintigraphy. Note that guidelines may be issued by different bodies / organizations and may have different level of recognition by law in different countries.
- The term “**protocol**” is used in several different contexts. One of the most frequent use is in research protocols or in multi centre trials. In this context it represents an agreement on how to perform a detailed series of operations. It has not necessarily any legal recognition and it is not a common base for the definition of the “state of the art”, but simply an agreed working program. Another use of “protocol” is in referring to the operating procedure that it is adopted inside a department to perform a given task, i.e. thyroid scintigraphy. In this sense, an internal protocol reflects only a convention inside a Department.
- A **Standard Operating Procedure** is a formal document, whose format, revision and distribution are maintained under control, as well as its contents. A SOP is used to define how a task or series of operations is performed inside an organization (a Department). In this sense, a SOP has (at least superficially) the same function as an “internal protocol”, as discussed previously. But a SOP is intended as a formal document and thus needs to be traceable to reference documents (i.e. guidelines from professional bodies) and in relation with the full set of SOPs dealing with other related subjects inside the organization.

Authorization, Accreditation, Audit

A multi step development



Types of Audit

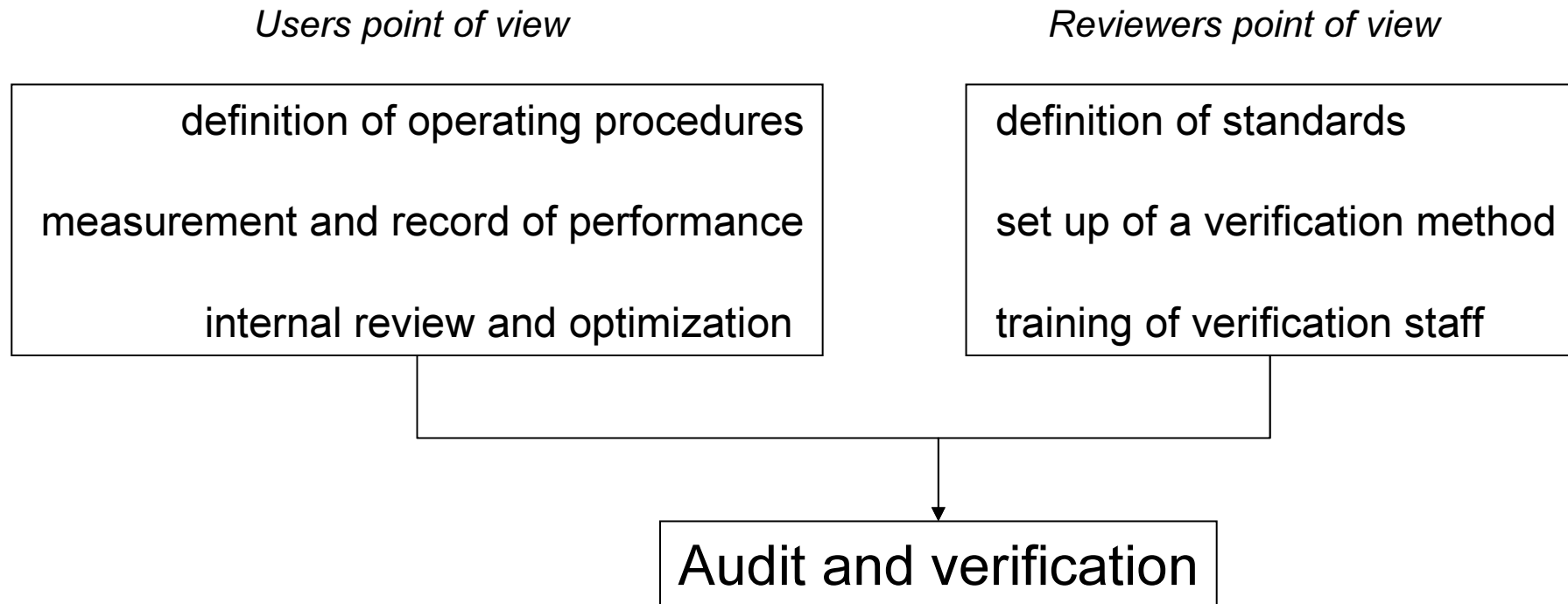
- Internal audit: members of the staff can be trained and qualified as Quality System evaluator; they can perform regular audit of the Quality System operation
- External (at the Dept.): by other members of the Hospital staff, or by peer review from professionals from other Institutions
- External: by evaluators form a Certifying Body

Internal audits should be encouraged, as a tool for developing consciousness and a self assessment attitude

Requisites for positive auditing

- local radiation protection authorization
 - government / health system authorization
 - adherence to the BSS
 - to set up all organizational and technical requirements for accreditation
 - to positively pass the audit and verification process
- These should mean that an adequate equipment is available*

Accreditation



... in great part a common job, with common goals ...

... needs a unitary vision and the construction of positive climate of relations