M. Marengo

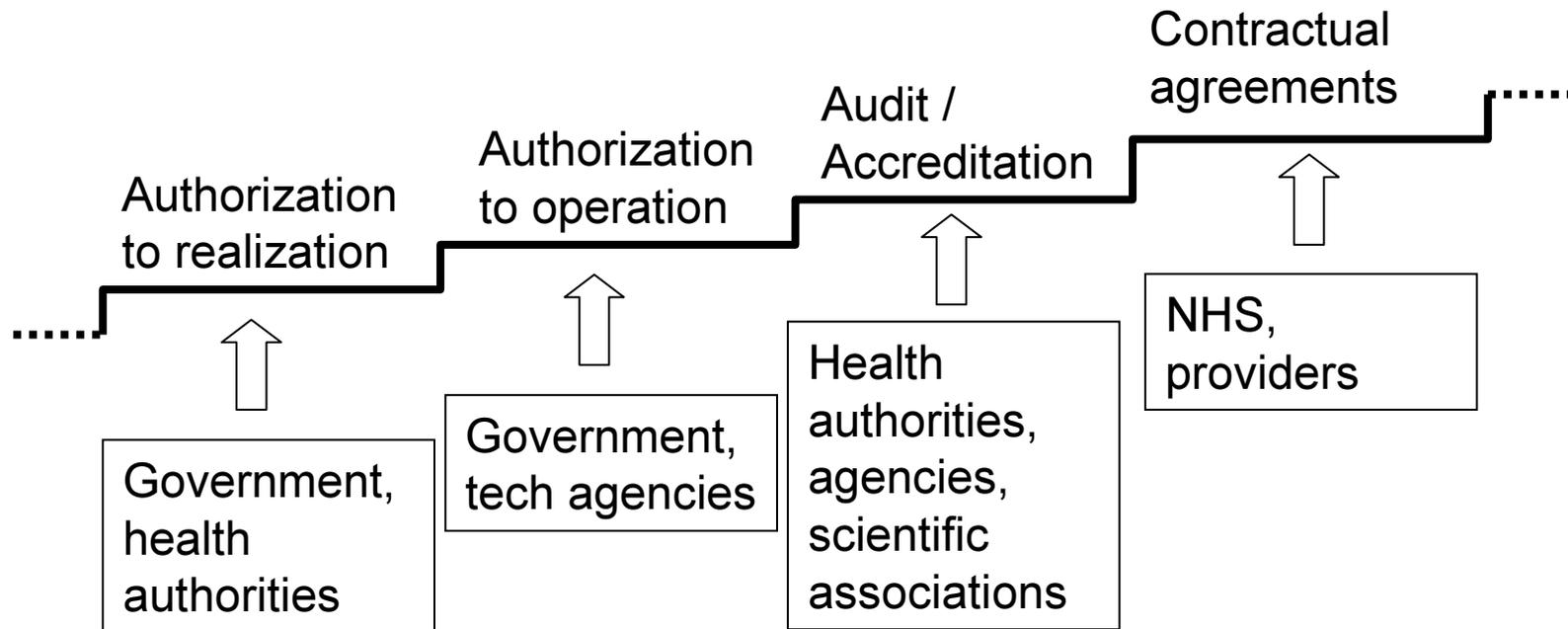# INTERNAL AND EXTERNAL AUDITS IN NUCLEAR MEDICINE

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Authorization, Accreditation, Audit
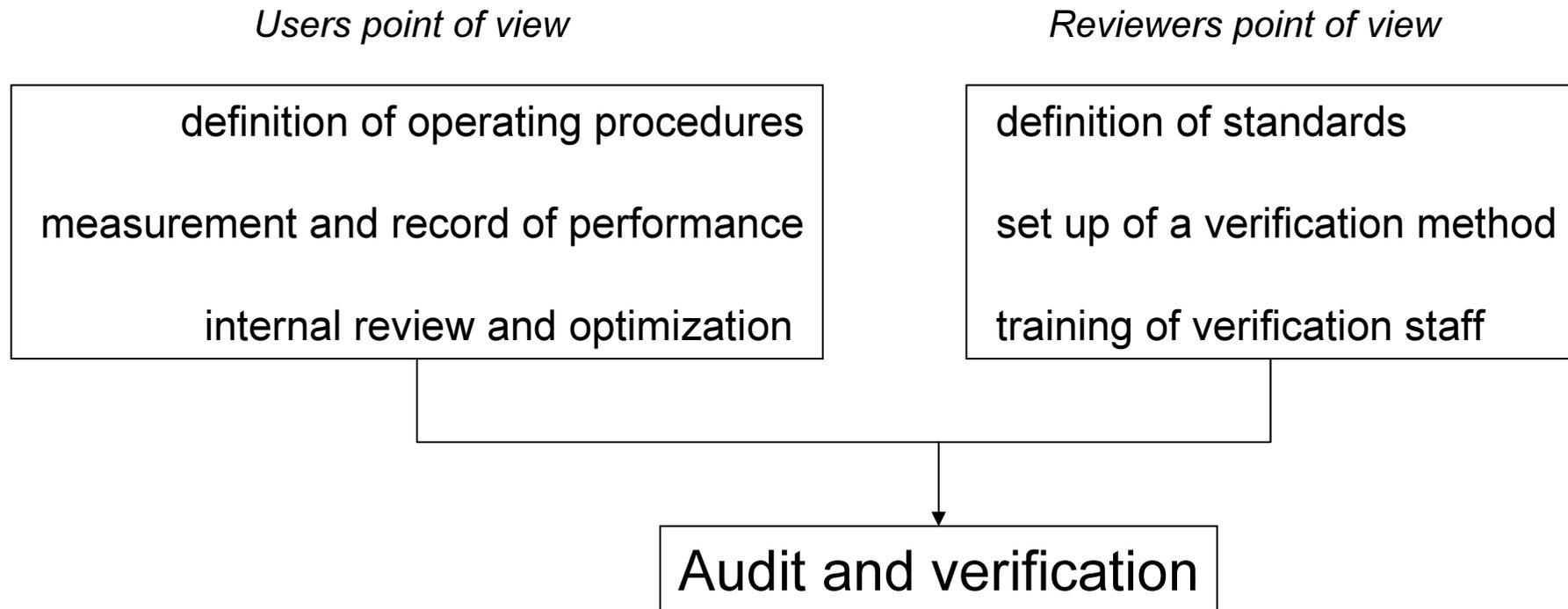# A multi step development

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

Users point of view

Reviewers point of view

definition of operating procedures	definition of standards
measurement and record of performance	set up of a verification method
internal review and optimization	training of verification staff

Audit and verification

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

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

IAEA and audit in Nuclear Medicine

The IAEA, through its Technical Cooperation programme, has received numerous requests from developing countries to perform quality audits of their nuclear medicine services.

Several African countries have already participated in nuclear medicine audits.

The IAEA audits normally take place at a national level; however, routine audits of individual institutions are essential.

The IAEA recommends that nuclear medicine departments use its Publication "QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE PRACTICES" as a tool to carry out self-reviews with the intention of applying good clinical practices by identifying those improvements which can be implemented using their own resources.

The publication is freely availbale for download from the IAEA publications we site

Comprehensive audits in Nuclear Medicine

The objective of quality audits is to evaluate the quality of all components related to the nuclear medicine practice applied at an institution, including its professional competence, with a view for quality improvement.

The aim of a quality audit process in nuclear medicine is to assist nuclear medicine departments/laboratories in maintaining or improving the quality of service for their patients.
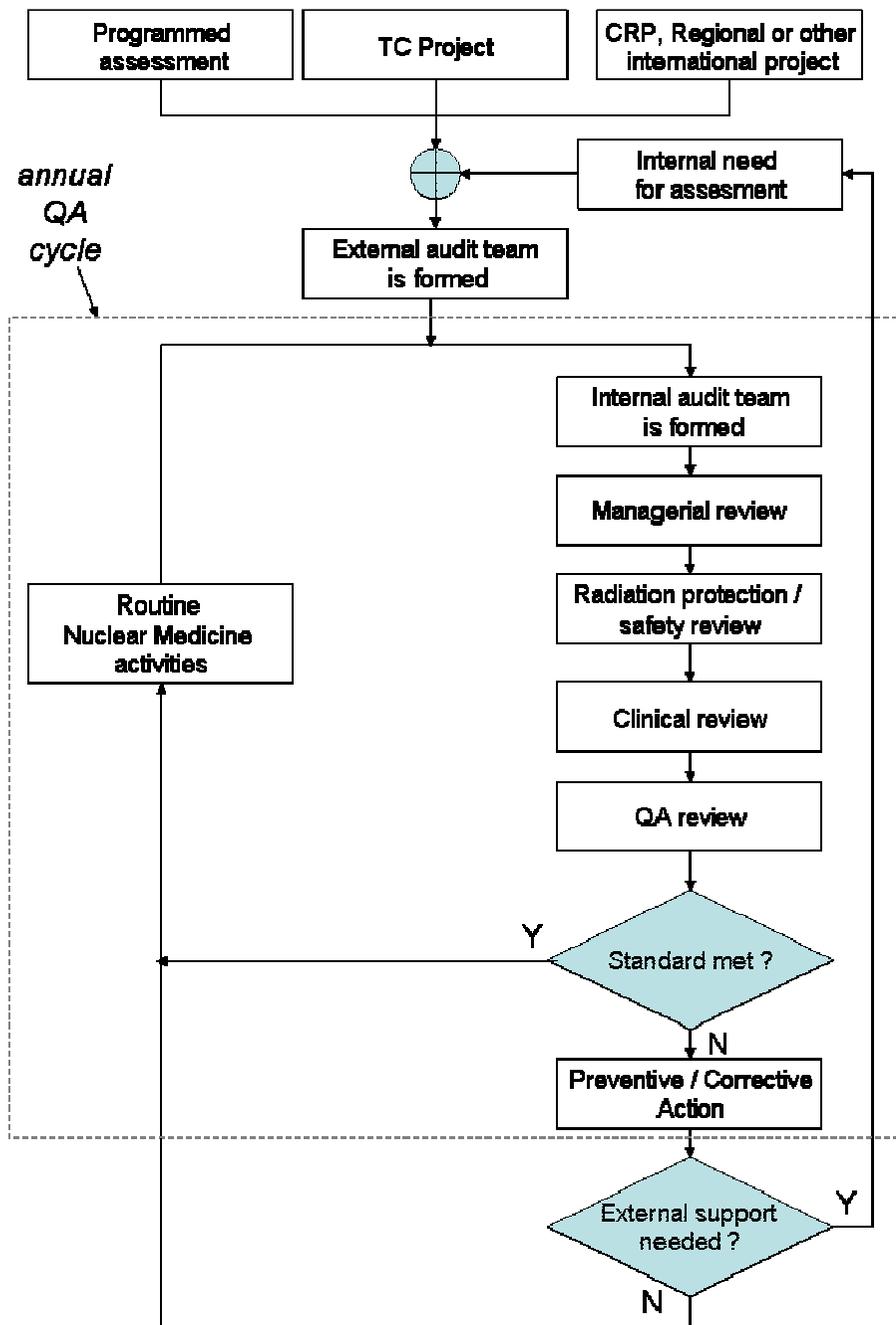
The audit should review and evaluate the quality of all elements involved, including staff, equipment and procedures, patient protection and safety, the overall performance of the nuclear medicine department as well as its interaction with external service providers.

The auditing team

A multidisciplinary team comprising experienced nuclear medicine physicians, a medical physicist, a radiopharmacist and a senior administrator should carry out both internal and external audits.

In some instances, a laboratory service specialist in radioimmunoassay or a radiographer may be needed to provide additional support for the audit team. Such an audit team can carry out internal and/or external audits.

The final composition and size of the audit team should be pre-stated before the actual audit. A similar team may also be required for follow-up.

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┌─────────────────┐   ┌─────────────────┐   ┌─────────────────────┐
│   Programmed    │   │   TC Project    │   │ CRP, Regional or other│
│   assessment    │   │                 │   │ international project │
└─────────────────┘   └─────────────────┘   └─────────────────────┘
          │                    │                        │
          └──────────┬─────────┴────────────────────────┘
                     │                                   ┌──────────────────┐
  annual           ( ● )◄──────────────────────────────│  Internal need   │◄───┐
  QA                 │                                   │ for assessment   │    │
  cycle              ▼                                   └──────────────────┘    │
                ┌─────────────────┐                                             │
                │ External audit team│                                          │
                │   is formed     │                                             │
                └─────────────────┘                                             │
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      ┌──────────────┴──────────────────────┐                                  │
      │                                      ▼                                  │
      │                            ┌──────────────────┐                        │
      │                            │ Internal audit team│                      │
      │                            │   is formed      │                        │
      │                            └──────────────────┘                        │
      │                                      │                                 │
      │                            ┌──────────────────┐                        │
      │                            │ Managerial review │                       │
      │                            └──────────────────┘                        │
      │                                      │                                 │
      │                            ┌──────────────────┐                        │
      │                            │ Radiation protection /│                   │
      │                            │  safety review   │                        │
      │                            └──────────────────┘                        │
      │                                      │                                 │
   ┌──────────────┐                ┌──────────────────┐                        │
   │   Routine    │                │ Clinical review  │                        │
   │ Nuclear Medicine│             └──────────────────┘                        │
   │  activities  │                         │                                 │
   └──────────────┘                ┌──────────────────┐                        │
      ▲                            │    QA review     │                        │
      │                            └──────────────────┘                        │
      │                                      │                                 │
      │                    Y          ◇ Standard met ? ◇                       │
      └───────────────────────────────                                        │
                                            │ N                                │
                                  ┌──────────────────┐                        │
                                  │ Preventive / Corrective│                  │
                                  │     Action       │                        │
                                  └──────────────────┘                        │
                                            │                                 │
                                    ◇ External support ◇  Y                   │
                                    ◇   needed ?     ◇─────────────────────────┘
                                            │ N
                                            │
      └─────────────────────────────────────┘
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Internal audits

Are they really useful ?

-

• an internal audit can rise problems you cannot solve with you own forces

• a problem that you cannot solve immediately can be presented as a weakness and as a demonstration of lack of usefulness of the auditing

• performing an internal audit means the attribution of some control and criticism capacity to operators different from the Dept. Management

+

• performing an internal audit will increase self consciousness of the staff

• even if you cannot always solve completely a problem, you can address it in a positive way and do something in the aim of improvement

• the capacity of promoting and performing an internal audit shows the strength of the management

Audit & Review

Review: a formal, documented and systematic examination of the organization and its quality system, aimed to evaluate the system requirements, the capability of the system to meet the requirements and to identify problems and propose solutions.

Audit: a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements. The audit also determines whether these arrangements are implemented effectively and are suitable to achieve objectives

Audit & Review

Example:

A Department has a variety of objectives and goals planned for each year.
In example:

- productivity: number of examinations per year
- budget: obtain a reduction of 5 % of the expenses of radiopharmaceuticals compared to last year
- quality: improve the time for booking critical examinations (let say bone scintigraphy for in-patients) and the time for completion of reporting of these studies, in order to decrease hospitalization time of an Internal Medicine Dept.
- quality: improve your procedure for QC of 99mTc generators

The Department management prepare plans to achieve these goals, sets indicators, then, in the Reviewing process, periodically verifies how the Dept. is performing in reaching the objectives
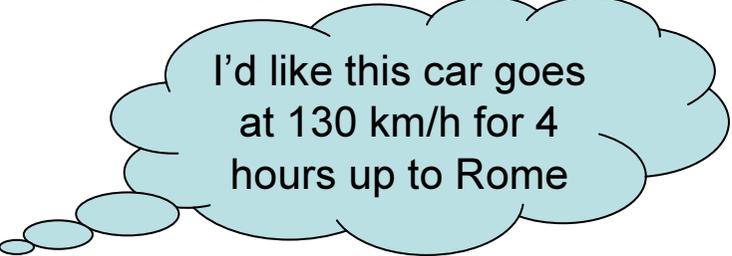
I'd like this car goes at 130 km/h for 4 hours up to Rome

Audit & Review

Example:

A Department has a variety of objectives and goals planned for each year.
In example:

• productivity: number of examinations per year
• budget: obtain a reduction of 5 % of the expenses of radiopharmaceuticals compared to last year
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• quality: improve your procedure for QC of 99mTc generators

The internal Audit team verifies in a comprehensive way how the quality system of the Department is performing. As regards yearly objectives, verifies if plans have been discussed and prepared, responsibilities attributed and resources allocated, if the indicators have been clearly set and if the monitoring procedure properly established.
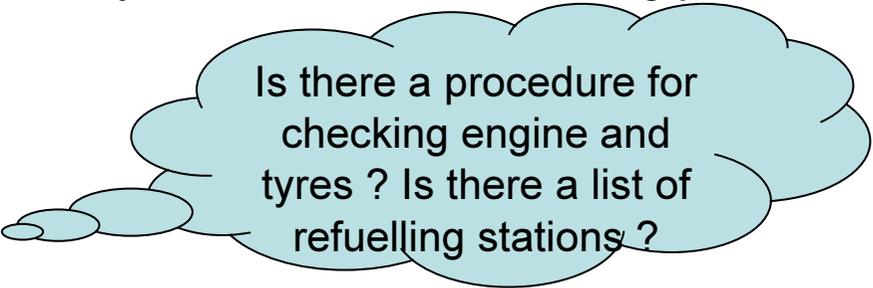
Is there a procedure for checking engine and tyres ? Is there a list of refuelling stations ?

Audit & Review

BOTH are tools in the hands of the management in order to verify and "tune" the performance of the organization !

Self referring

• the Nuclear Medicine physician is prescribing 80 % of the examinations performed in its own Department

• you submit papers only to a scientific journal in which you are an editor

• your procedure for treating hyperthyroidism with 131I is based on your own experience, and is quite different from the SNM guidelines

• I am the only referee in football games involving the Bologna FC

An independent evaluation is frequently necessary in order asses your performance against standards.
However, in some cases, a standard is not available, in the sense the term is used in metrology; the scientific community has developed the concept of "peer review" to deal with these situations. In particular, in Medicine the concept of Evidence Based care is used to formally define the "state of the art".

External Audits

Why are they necessary ?

-

• a more formal assessment

• the auditing team could be not completely aware of local issues

• all the disadvantages of internal audits

+

• all the advantages on internal audits

• independency of assessment

• the team is typically composed by experts with a valuable experience in the field

Rationale for QA/QC

Quality Control of equipment is fundamental in Nuclear Medicine:
• for regulatory reasons
• to optimize patient dose
• to maintain proper performance
• as a basis for quantitative procedures

But QC is not enough to reach this goals and maintain optimal performance, and it not only matter of experimental tests and measurements. Management issues as well should be properly addressed and an efficient **Quality System** should be introduced.

References:

IEC 1223-1 , 1993. Evaluation and routine testing in medical imaging departments.

ISO 9000 series. Quality management system.

ISO15189. Medical Laboratories. Particular requirements for quality and competence.

IEC 1223-1 flow chart for quality assurance of equipment

```
┌─────────────────────────┐                    ┌─────────────────────────┐
│ Equipment specification │                    │      Period of use      │◄──┐
└───────────┬─────────────┘                    └───────────┬─────────────┘   │
            │                                               │                 │
            ▼                                               ▼                 │
┌─────────────────────────┐                    ┌─────────────────────────┐   │
│     Acceptance tests    │                    │  Routine constancy test │   │
└───────────┬─────────────┘                    └───────────┬─────────────┘   │
            │                                               │                 │
            ▼                                               ▼                 │
┌─────────────────────────┐                    ┌─────────────────────────┐   │
│   Performance check     │                    │  Comparison of results  │   │
│      (status test)      │                    │   with reference values │   │
└───────────┬─────────────┘                    └───────────┬─────────────┘   │
            │                                               │                 │
            ▼                                               ▼                 │
┌─────────────────────────┐                         ◇ Are criteria ◇    YES  │
│  Initial constancy test │                         ◇   met ?      ◇─────────┘
└───────────┬─────────────┘                              │
            │                                            │ NO
            ▼                                            ▼
┌─────────────────────────┐                    ┌─────────────────────────┐
│    Reference values     │                    │    Corrective action    │
│   for constancy test    │                    └─────────────────────────┘
└─────────────────────────┘
```

Equipment specification → Acceptance tests → Performance check (status test) → Initial constancy test → Reference values for constancy test → Period of use → Routine constancy test → Comparison of results with reference values → Are criteria met ? — YES → Period of use; NO → Corrective action

Under control

QA is not merely the ability of performing test and measures …

… is not even a positive attitude of the staff towards quality …

… it is not something of immaterial …

… first of all a Quality Assurance system is made of paper !

… and the first step for setting up a Quality Assurance program and regularly maintaining it, is to write documents describing your working procedures, the action to be taken as a consequences of any specific event and regularly record your activities.

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

Quality Manual

Job descriptions, Responsibilities & autority

Procedures

Operating Instructions

Tables

Reports

...
Contract review
Document control
Purchasing
Process control
Inspection and testing
Test equipment
Quality records
Quality audits
Training
Servicing
Statistical techniques
...
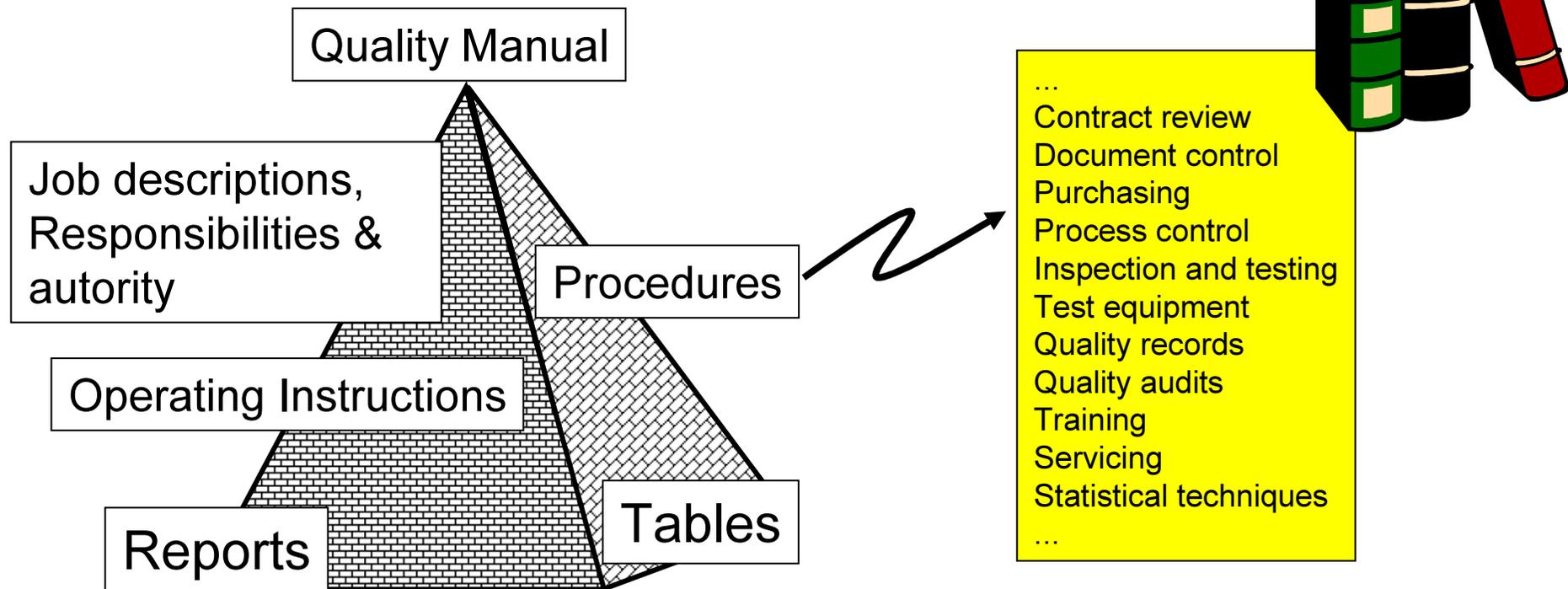
… the heaviest and most time consuming task in the construction and running of a Quality System.

Contract

A contract is an agreement between two or more parties to define mutual relations or obligations or for performing specific actions.

In terms of quality, a contract could be formal or informal.

Examples:

- a patient generally do not signs any contract with a diagnostic department, but the request of the referring physician is a formal document that can be considered a contract between the representative of the patient and the diagnostic service.

- the agreement between a Nuclear Medicine and a Medical Physics Departments can and informal agreement of co-operation (implicit contract, following the existence and scope of the two Depts.) or, better, can be a formal document, defining reciprocal duties and responsibilities).

See example docs

Example of procedure flow chart

Macrofase 1 : Esecuzione dei controlli di qualità apparecchiature di Radiologia, Radioterapia e Medicina Nucleare

Example of flow chart of Med. Nuc. equipment QC (part 1 of 4)

Documenti

| Macrofase 1 | Scadenza programmata o richiesta | Nota 1 |

IOS collegate a PS09.01

| Preparazione strumenti, sorgenti, fantocci, oggetti di test |
| Operatore Tecnico |

Annotazioni su Report

Nota 2

| Predisposizione acquisizione misure |
| Operatore tecnico |

Parametri ok ? — no

Registrazioni su Report

sì

| Acquisizione misure / Esecuzione cq |
| Operatore tecnico/TSRM |

Sez. 10 del MAQ

Registrazione su Report

| Elaborazione dati |
| Operatore tecnico/TSRM |

Risultati accettabili? — no — Macrofase 3

IOS collegate PS 09.01

Sez. 10 del MAQ

sì

Macrofase 2

Reference docs

Reporting anomalies

- A Quality System relies on measurable parameters of performance
- Every activity should be individually recorded
- Discrepancies form specifications should be reported and formally treated
- This applies both to organisational Non Conformities (e.g. a scheduled QC has not be performed) and to equipment failures or out of range performances
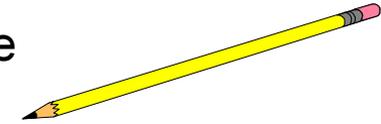
Example of Table of definition of Anomalies and related responsibilities & treatment.

Cod.	Tipo	Trattamento	Resp. Rilevazione	Resp. Trattamento	Resp. Registrazione
01	Non acquisisce	Verifica se testata alimentata. Prova spegnimento - riaccensione. Verifica connessione cavi. Se non recupera, chiamata Ass.Tec.	TSRM	Fisico o TSRM	Fisico
02	Movimento bloccato o non regolare	Verifica se c'è ostacolo o collisione. Controllo indicazione delle coordinate di posizione gantry/lettino. Prova spegnimento - riaccensione. Controllo switch collimatore. Controllo tastierina di comando. Controllo cavi ECT o binario scorrimento. Se non recupera, chiamata Ass.Tec.	TSRM	Fisico o TSRM	Fisico
03	Falsa segnalazione di collisione	Controllo switch e montaggio collimatore ; eventuale pulizia o regolazione viti di fissaggio. Prova smontaggio/rimontaggio collimatore. Se non recupera, chiamata Ass.Tec.	TSRM	Fisico o TSRM	Fisico
04	Fuori picco	Autocalibrazione (se disponibile) ; ripristino mappe di correzione. Se non recupera, programmare nuova calibrazione.	TSRM o Fisico	Fisico o TSRM	Fisico
11	Sistema di riproduzione non funzionante	Controllo messaggi di errore ; controllo accensione dispositivo. Verifica se carta/lastre presenti ; verifica se inchiostro/toner/liquidi presenti. Verifica configurazione software. Rimozione dati bloccati da coda di stampa. Ripetere stampa. Se non recupera, chiamata Ass.Tec.	TSRM	Fisico o TSRM	Fisico
17	Prova di uniformità fuori range	Controllo acquisizione ed eventuale ripetizione. a)Verifica se fuori picco. Se si , vai a trattamento fuori picco. b) Controllo condizioni ambientali (temperatura condizionamento) ; autocalibrazione ; ripristino mappe di correzione. Se non recupera : se problema mappe energia/unif. programmare nuova calibrazione ; se problema di linearità o elettronica, chiamata Ass.Tec.	Fisico o TSRM	Fisico	Fisico

Keeping test equipment under control

• Test equipment and tools, reference sources, phantoms should be identified, catalogued and labelled
• They should be periodically checked, and results should be recorded and stored
• New equipment should be acquired by qualified suppliers

Example: for water filling phantoms can be defined
  • characteristic of the filling solution (carrier, bacteriostatic agents ecc.)
  • maximum time between replacement of the solution
  • periodical inspections and maintenance of O-rings

Example: radioactive test sources should be properly stored and periodicaaly checked for leakage / contamination

Suppliers control

Suppliers should be catalogued and qualified based on:

- type of products, quality marks and certifications, traceability to standards
- organisation (staff, laboratories, service)
- Quality System and certifications
- previous data

Monitoring of suppliers performance:

- check that specifications are meet
- check that time of product delivery is respected
- in case of discrepancies or products not suitable a Non Conformity
  should be reported
- after repeated non recoverable N.C., a supplier should be disqualified
  and not considered for further orders until new qualification

Note: applies to the supply of equipment and services

Customer satisfaction. Management of complains

- Unsatisfied users and customers should have the possibility of complain
- A procedure for collection and answer to complaints should be activated
- Questionnaires can be used for periodical surveys of customer satisfaction
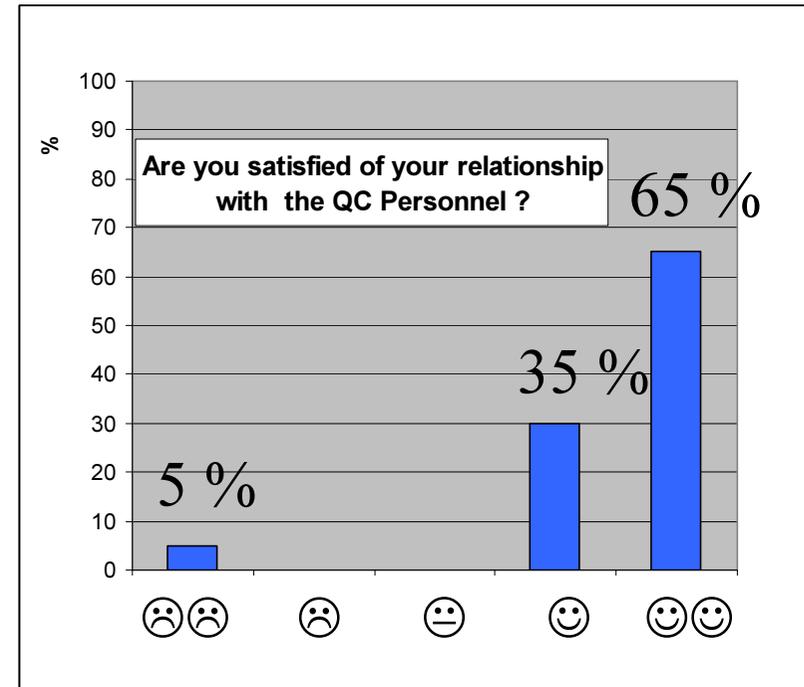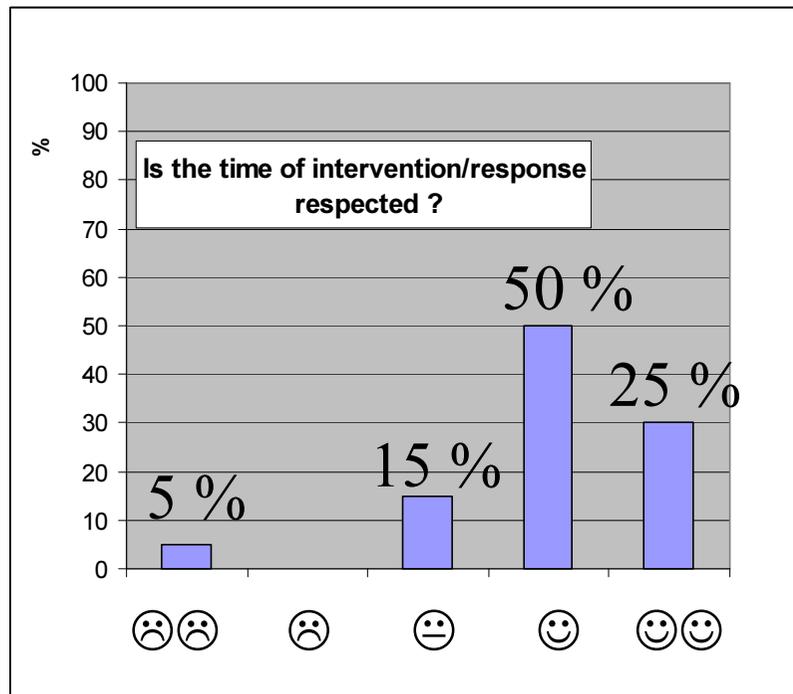
Review and statistical recording

Data from workload, Non Conformities, complaints, failures, service etc. should be reviewed periodically (e.g. twice a year) to check productivity, performance and "tune" the Quality System, organisational aspects and management.

Riepilogo annuale 1997 anomalie apparecchiature

Legend: p3000 3, sp6, 209, p20004, p20005, spx4 1

Axes: Codice anomalia (y), Numero casi (x)

Tempo di fermo macchina annuale in funzione del tempo di lavoro programmato

% tempo inattivo — γ1, γ2, γ3, γ4, γ5, γ6

Controlli di Qualità in Medicina Nucleare
Statistica annuale parametri fisici misurati

Cq Mn, Calib Mn, Cq Rf — 1998, 1999
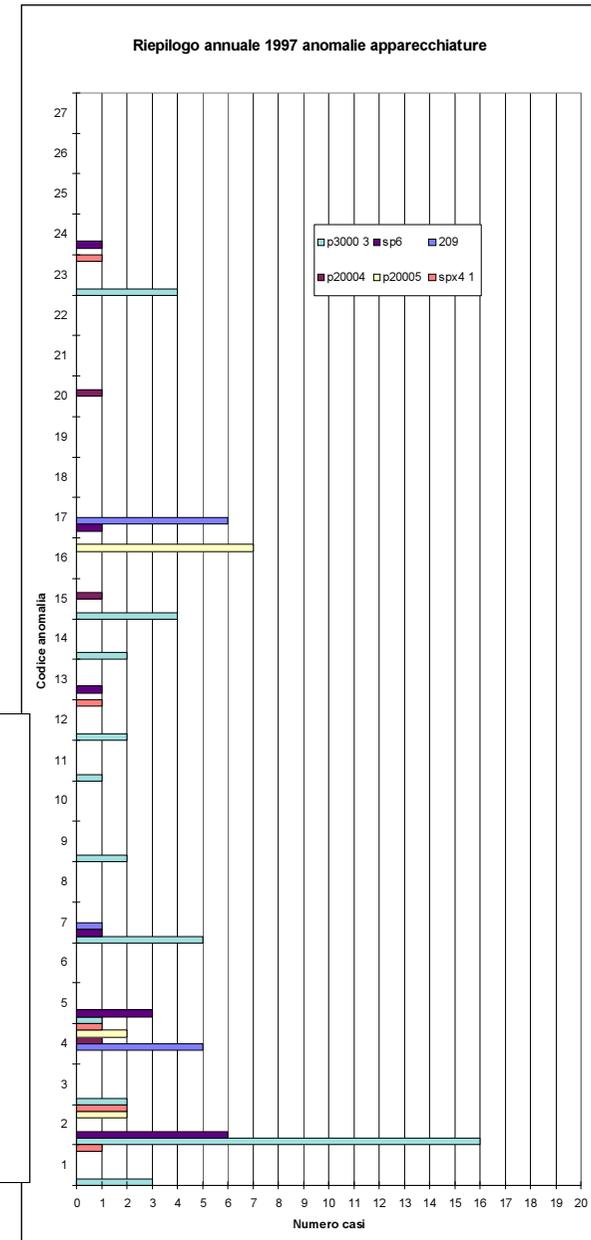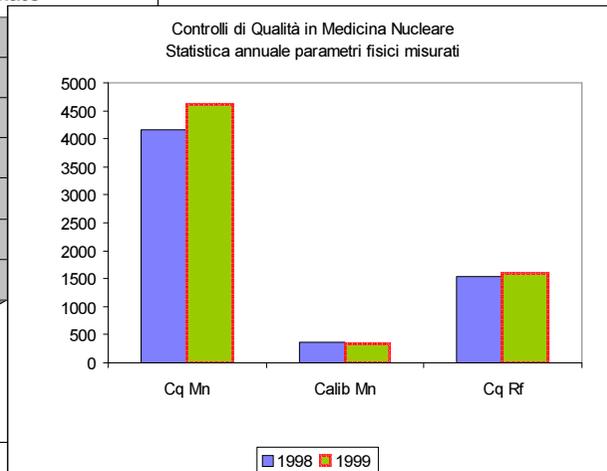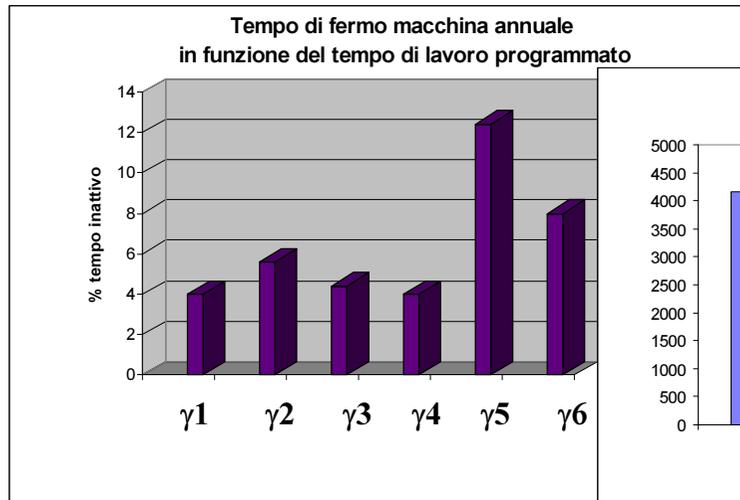
QA/QC elements

dose calibrators
- constancy test
- linearity
- accuracy

gamma camera good order & calibration
- maintaining system in good order
- data archiving
- uniformity calibration
- centre of rotation calibration

gamma camera QC tests
- system peak centering
- uniformity
- bar phantom linearity / resolution
- video reproduction
- printing system performance
- centre of rotation
- SPECT performance

PET scanners tests
- daily blank scan or equivalent QC
- normalization
- well counter / calibration factors
- spatial resolution
- PET-CT alignment

Improvement & Corrective actions

In the case of Non Conformities, problems or when the opportunity for an improvement is detected, a procedure should be in place in order to:
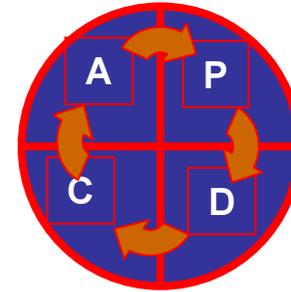
- Investigate the cause of the NC and identify what process needs to be improved so that further occurrence is prevented.

- Analyze processes, work operations, quality records, service reports and customer complaints to detect and eliminate potential causes of NCs

- Prevent potential problems that are understood and detected in advance of their practical occurrence

- Make sure that proper corrective / preventive actions are undertaken

- Record changes to procedures that result from corrective and preventive actions.

See example docs

Radiation protection issues: authorization

• a Nuclear Medicine Department shall be authorized according to local laws and rules

• authorization can be at different levels, according to the level of risk associated:
  • registration, for low to moderate risk activities, or
  • licensing, for moderate to high risk installations

• in the authorization file, responsible person shall be clearly identified

• qualification of professionals shall be adequate and documented

• the authorization file shall include:
  • a description of the activity to be carried out
  • an evaluation of the exposures in routine operation
  • an assessment of magnitude and likelihood of potential exposures

Problem: the IAEA Basic Safety Standards provide guidance and should be at the basis of every national legislation, but they are not always completely understood and applied in practice, taking into account local variations.
Should we accept any kind of local authorization ? Or should we suggest for improvement ?

Radiation protection issues: remember the principles

- Justification: are practices <u>really</u> justified ? Are alternatives to the use of ionizing radiations available ? Take into account local situation.

- Optimization: easy to say, but difficult to apply, particularly in developing countries. But, if not stimulated, it is very unlikely to start … key points:
    - *Basic QC of equipment as regards patients radiation protection*
    - *Training and written procedures as regards staff radiation protection*

- Limitation: do they have a personal dosimetry system ? Is it qualified ?

Radiation protection issues: technical

- are siting, location, design, construction adequate ?
    - *availability of adequate contractors for building / plants realization*
    - *quality of materials*

- sources safety:
    - *Is delivery safe ?*
    - *Is there a system of prevention against theft ?*
    - *Misuse or in adverted damage by unauthorized personnel ?*
    - *is there a system of catalog or inventory of sources*

- availability of radiation protection tools
    - *equipment*
    - *accessories*
    - *particularly in hot labs / radiopharmacies*

Radiation protection issues: management

- Is there an assessment system of radiation protection ?

- Is an RSO / Qualified Experts available in routine operation ?

- Is there a monitoring system ?

- Are exposures recorded ?

Radiation protection issues: training

- are staff members properly trained for all the aspects of routine operation ?

- is training reviewed and updated periodically ?

- has been a safety culture established ?