Quality Assurance



IN NUCLEAR MEDICINE

OBJECTIVE

To become familiar with the concepts of Quality Assurance in nuclear medicine and procedures for reviewing and assessing the overall effectiveness of the practice



WHAT IS QUALITY?

The quality of a practice is to fulfil the expectations and demands from:

- Patient
- Clinician
- Yourself

QUALITY as a goal

"The totality of features or characteristics that bear on our ability to satisfy the stated or implied goal of effective patient care"

Comprehensive QA for radiation Oncology AAPM TG 40, 1994

To insure the goal is reached requires a fully implemented Quality Assurance program throughout the facility.

QUALITY ASSURANCE



What is Quality Assurance?

"All those planned and systematic actions necessary to provide confidence that a product or service will satisfy given requirements for quality."

ISO 9000



BSS

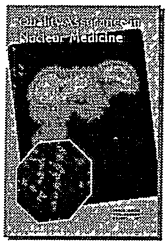
2.29. Quality assurance programmes shall be established that provide, as appropriate:

a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and

b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety.

QA-PROGRAMME OBJECTIVES

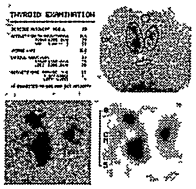
* Improvement in the quality of the diagnostic information.
* Use of minimum amount of radionuclide activity to ensure the production of the desired diagnostic information.
* Effective use of available resources



QUALITY
DEFINE OBJECTIVES

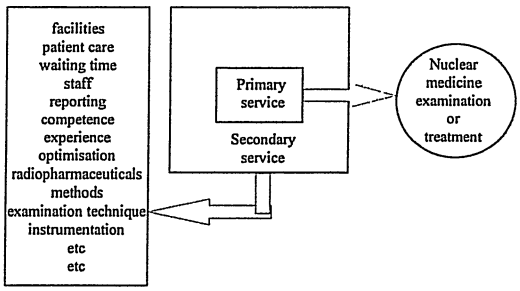


How many times should the nurse be allowed to drop the child?

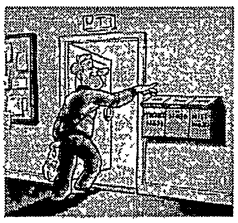


What is an acceptable sensitivity and specificity?

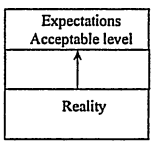
NUCLEAR MEDICINE SERVICE



QUALITY ASSESSMENT
(primary service)



Communication with the client (patient, clinician).



QUALITY ASSESSMENT
(primary service)

The final judge of any nuclear medicine practice is a clinical audit:

the correctness and impact of the decisions made with respect to any method and process.

QUALITY ASSESSMENT (secondary service)

Internal audit

Inspections

- **Health authority**
- **Regulatory authority**

QUALITY ASSURANCE PROGRAMME

•**Procedure** (i.e patient history and signs, diagnostic question,appropriateness of investigation, contraindications)
•**Planning of procedure** (i.e reliable administrative procedures, patient information, patient preparation)
•**Clinical procedure** (i.e approved suppliers and materials, storage,preparation, clinical environment, patient handling and preparation, equipment performance, acquisition protocols, waste disposal)
•**Data analysis** (i.e processing protocol, equipment performance, data accuracy and integrity)

QUALITY ASSURANCE PROGRAMME

•**Report** (i.e. data, image review, results and further advice)
•**Training and experience** of nuclear medicine specialists, physicists and technologists and others involved
•**General outcomes** (i.e clinical outcome, medical exposure, patient satisfaction, referring physician satisfaction)
•**Audit**

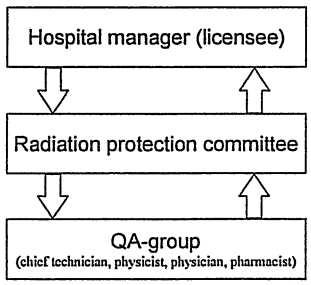
Quality Assurance

Organization

ORGANIZATIONS

International bodies
Recommendations.
Interlaboratory comparison programmes.
Education and training.
National organizations
National guidelines, codes of practice etc.
Interlaboratory comparison programmes.
Education and training.
Industry
Assistance in acceptance tests.
Documentation.
Training.
Maintenance.
Professional associations
Supporting QA-programmes
Establishing working groups
Education and training

LOCAL ORGANIZATION



Quality Assurance

Administrative routines

REQUEST

It is the responsibility of the nuclear medicine specialist that the study requested by the referring physician is justified. Special attention must be paid to studies requested for children and pregnant women. Are there alternative methods e.g. ultrasound, MRI etc.?

Communication, on a regular basis, between the referring clinician and the nuclear medicine specialist is very important.

PATIENT

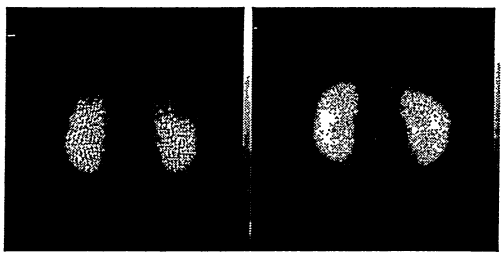
- Identification of the patient.
- Information about the examination including premedications.
- Waiting for the examination

A fully informed and motivated patient is the basis for a successful examination as well as a staff well educated in care of the patient.

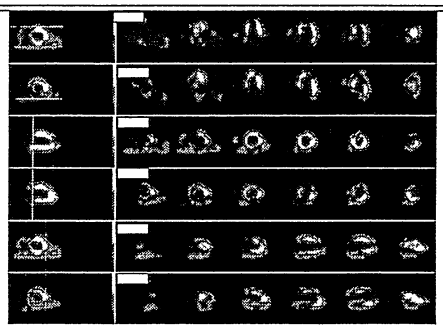




PATIENT MOVEMENT



PATIENT MOVEMENT



METHODS

A procedure manual should be available for each type of study. The manual should be reviewed annually. Methods should be in accordance with accepted practices

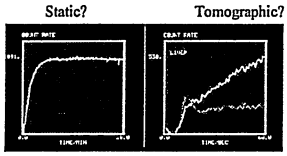
Study name:	Bone scan
Preparation of patient:	Empty bladder
Radiopharmaceutical:	Tc99m-MDP
Route of administration:	IV injection
Activity:	400 MBq
Type of examination:	Whole body scan
Views:	AP, PA
Scanning speed:	10 cm/minute
Collimator:	Scanning
Window setting:	140+/-20% keV
Positioning of patient:	Supine
Presentation of result:	Images in BW on film. Original and filtered.

METHODS



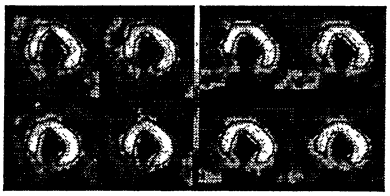


Static? Tomographic?



Dynamic?

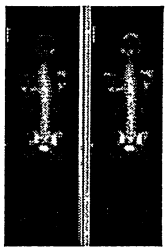
METHODS



Tl-201
25 mSv

Tc-99m
8 mSv

QUALITY ASSURANCE COMPUTER EVALUATION



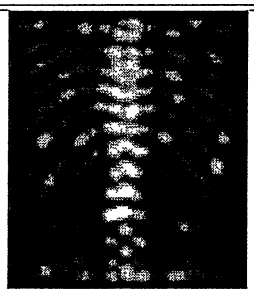
Efficient use of computers can increase the sensitivity and specificity of an examination.

- software based on published and clinically tested methods
- well documented algorithms
- user manuals
- training
- software phantoms

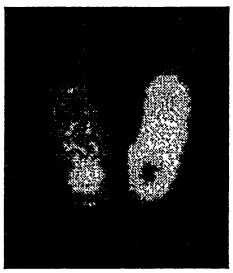
QC Application programmes

- **Analysis of the programme code**
- **Phantom studies**
- **Simulated examinations**
- **Referense data (normal material)**
- **Clinical evaluation**

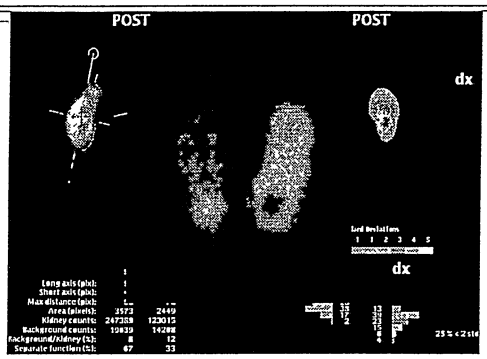
Bone scan phantom



Thyroid phantom



Thyroid phantom



DIAGNOSTIC REPORT

Patient identification
Date and type of study
Radiopharmaceutical and activity
Study results - e.g. a graph or a series of images
Objective description of findings
Diagnostic conclusion and recommendations

Avoid adjectives like 'possible', 'probable', 'likely' etc. They can never be interpretated by the referring physician. The diagnostic conclusion should be more quantitative e.g. by using a probability statement.

QUALITY ASSURANCE METHOD

Patient follow-up.

⇩

Correlation with other available surgical, pathological, clinical and anatomic information.

⇩

False positives?
False negatives?

RECORDS

- Authorization certificate and documentation supporting the corresponding application, and also any correspondence between the licensee and Regulatory Authority;
- Name of the person authorized and responsible for the RPP;
- Individual doses (current and prior work history);
- Results of area surveys;
- Equipment and instrument QC tests and calibration;
- Inventory of unsealed and sealed sources;
- Incident and accident investigation reports;
- Audits and reviews of the radiation safety programme;
- Installation, maintenance and repair work;
- Facility modification;

RECORDS (cont)

- Training provided (initial and continuing), including the following information:
  - Name of the person(s) who delivered the instruction or training;
  - Name of the person(s) who received the instruction or training;
  - Date and duration of the instruction or training;
  - List of the topics addressed; and
  - Copy of the certificates of training.
- Evidence of health surveillance of workers;
- Waste disposal;
- Transportation:
  - Package documentation;
  - Package surveys;
  - Transfer/receipt documents; and
  - Details of shipments dispatched
- Patient records; and
- Patient discharge surveys for patients receiving radionuclide therapy.

Quality Assurance

Occupational and medical exposure

BSS

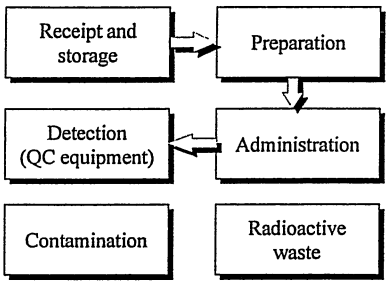
II.22. Registrants and licensees shall establish a comprehensive quality assurance programme for medical exposures with the participation of appropriate qualified experts in the relevant fields, such as radiophysics or radiopharmacy, taking into account the principles established by the WHO and the PAHO.

BSS

II.23. Quality assurance programmes for medical exposures shall include:

a) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter,
b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
c) written records of relevant procedures and results
d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and
e) as far as possible, regular and independent quality audit review of the quality assurance programme for radiotherapy procedures.

Factors affecting medical and occupational exposure



QA Medical exposure

- Choice of examination
- Determination of technical parameters
- Optimization of administered activity
- Methods of reducing the absorbed dose
- Quality control of equipment and radiopharmaceutical
- Quality assurance of methods
- Safe routines to avoid misadminstration

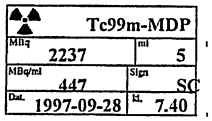
Patient

The patient shall always be confident that a nuclear medicine examination and therapy is performed correctly and with highest possible quality regarding both diagnostics/therapy and safety.



PREPARATION OF RADIOPHARMACEUTICALS

- Use a transparent vial shield
- Put the kit in the shield
- Add Tc99m and finish the preparation
- Measure the activity
- Write the label and put it on the vial shield
- Check the kit and the label on the vial shield. Same radiopharmaceutical?



The decision

Manufacturer 1
+ price
+ technical parameters
- service
- computer system



Manufacturer 2
+ price
- technical parameters
+ service
- computer system



We want that one!!

QUALITY CONTROL EQUIPMENT

Acceptance / reference testing.
Measurements to assess whether instrumentation comply with its specifications. Manual available.

Routine testing.
Performed to maintain high quality and standard of the equipment.

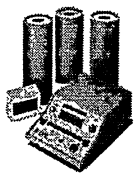
Analysis of results.
Is the observed result significantly different from the reference testing?
Is the observed result due to errors in the QC procedure?

Records.

ACTIVITY METER DOSE CALIBRATOR



CRC-15W
Item # 5130-3113



CRC®- 712M
Dose Calibrator
Item # 5130 - 3054

QUALITY CONTROL ACTIVITY METER

	Acceptance	Daily	Monthly	Yearly
High voltage/display	P	T	T	P
Zero adjust	P	T	T	P
Background	P	T	T	P
Accuracy	P			P
Precision	P		T	P
Relative responses	P		T	P
Subsidiary calibrations	P			
Linearity	P			P
Electrical safety	P			P
Leakage radiation	P			P

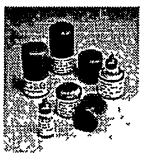
P: physicist
T: technician

The accuracy should be +/- 5%
Traceability to a national standard.
Interlaboratory comparisons.

Sealed sources for calibration of activity meters

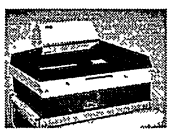
- Long half-life
- Range of photon energies
- Range of activities
- Calibrated within 5%

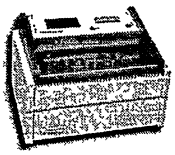
Co57, Ba133, Cs137, Co60



Sample counters

Gamma counter
Liquid scintillation counter







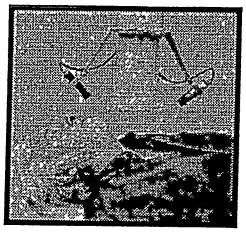
QUALITY CONTROL (Gamma counter)

- Scaler/timer/ratemeter function
- Energy calibration
- Energy resolution
- Sensitivity
- Counting precision
- Count rate losses
- Linearity of energy response
- Background
- Linearity of activity response
- Geometrical response
- Preset analyser facilities

QUALITY CONTROL (beta-counter)

- Scaler/timer function
- Energy calibration and energy window
- Sensitivity
- Counting precision
- Background
- Linearity of activity response
- Count rate losses
- Quench correction methods
- Geometrical response
- Preset analyser facilities

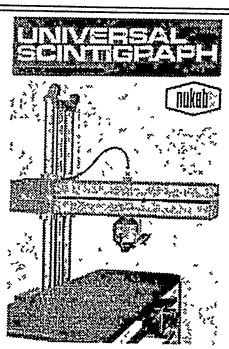
PROBE



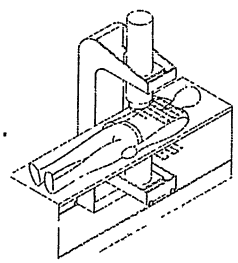
QUALITY CONTROL (probe)

- Scaler/timer/ratemeter function
- Energy calibration
- Energy resolution
- Sensitivity
- Counting precision
- Count rate losses
- Linearity of energy response
- Background
- Linearity of activity response
- Geometrical response
- Preset analyser facilities

RECTILINEAR SCANNER



Used to measure the spatial distnbution of a radiopharmaceutical



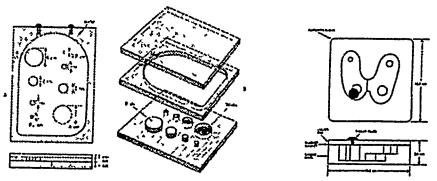
Rollo 1977

SCANNER QUALITY CONTROL

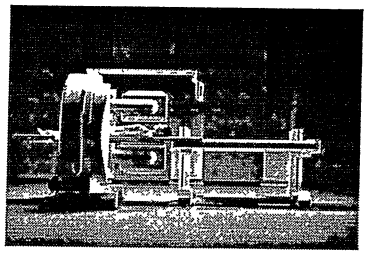
	Acceptance	Daily	Weekly	Yearly
Energy window	P	T	T	P
Energy resolution	P			P
Sensitivity	P		T	P
Counting precision	P			P
Linearity of energy response	P			P
Test of integral background	P		T	P
Test of preset analyzer facilities	P			P
System linearity	P		T	P
Background subtraction	P			P
Contrast enhancement	P			P
Scanner drive	P			P
Total performance	P		T	P

P: physicist T:technician

TOTAL PERFORMANCE PHANTOM



Gamma camera



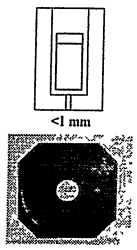
Used to measure the spatial and temporal distribution of a radiopharmaceutical

QC GAMMACAMERA

	Acceptance	Daily	Weekly	Yearly
Uniformity	P	T	T	P
Uniformity, tomography	P			P
Spectrum display	P	T	T	P
Energy resolution	P			P
Sensitivity	P		T	P
Pixel size	P		T	P
Center of rotation	P		T	P
Linearity	P			P
Resolution	P			P
Count losses	P			P
Multiple window pos	P			P
Total performance phantom	P			P

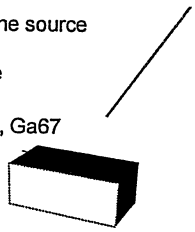
P: physicist T:technician

SOURCES FOR QC OF GAMMA-CAMERAS



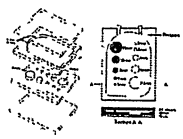
- Point source
- Collimated line source
- Line source
- Flood source

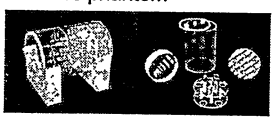
Tc99m, Co57, Ga67



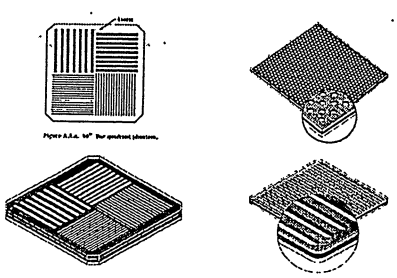
Phantoms for QC of gamma-cameras

- Bar phantom
- Slit phantom
- Orthogonal hole phantom
- Total performance phantom

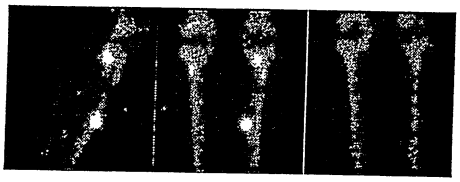




Phantoms for QC of gamma-cameras

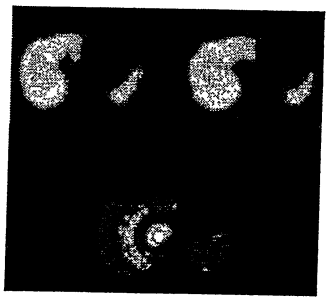


NON-UNIFORMITY

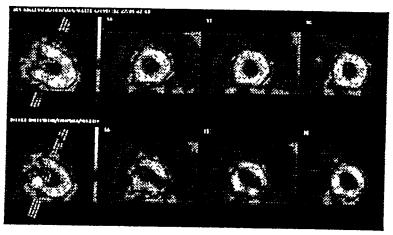


(Contamination of collimator)

NON UNIFORMITY RING ARTIFACTS

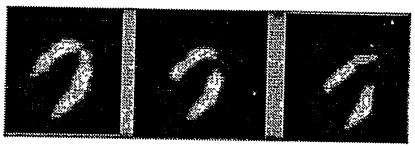


NON-UNIFORMITY



Defect collimator

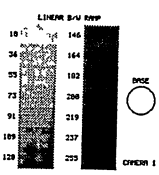
CENTER OF ROTATION



no offset offset: 1 pixel offset: 3 pixel

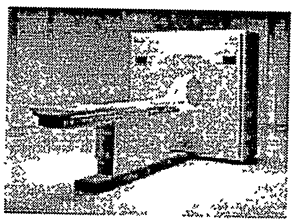
QUALITY CONTROL ANALOGUE IMAGES





Quality control of film processing: base & fog, sensitivity, contrast.

PET
Positron Emission Tomography



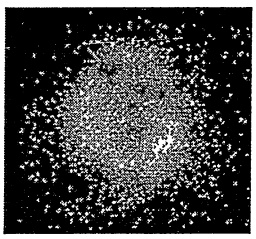
FACTORS AFFECTING IMAGE FORMATION

- Detector efficiency
  (the probability that the detector registers an event when a gamma ray path intersects the detector. Depends on detector size and material)
- System sensitivity
  (the number of events registered by the scanner per unit activity. Depends on detector efficiency and system geometry)
- Time resolution
  (the ability to accurately determine coincidence events.)
- Count-rate capability
  (the ability of the scanner to record events a high count rates. Depends on detector material and the properties of the electronic components)
- Spatial resolution
  (the ability to separate closely spaced objects. Depends on detector size, physics of positron decay, system geometry and detector material)

QUALITY CONTROL

- Calibration check
- Uniformity
- Spatial Resolution
- Scatter fraction
- Sensitivity
- Count rate losses and randoms
- Scanner cross calibration
- Drifts in coincidence timing
- Drifts in energy thresholds
- Mechanical movement of detector rings
- Removable septa positioning
- Laser alignment
- Attenuation correction accuracy
- Dead time correction accuracy
- Scatter correction accuracy
- Random coincidence correction accuracy

Finally, what is this?



Communication!

Where to Get More Information

Further readings

- IAEA Tecdoc 602
- Basic Safety Standards
- WHO publications
- ISO publications