

Quality Management Audits in Nuclear Medicine practices.

The Essentials.

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– Clinical Audit, September 2008 Tampere, Finland



IAEA

International Atomic Energy Agency

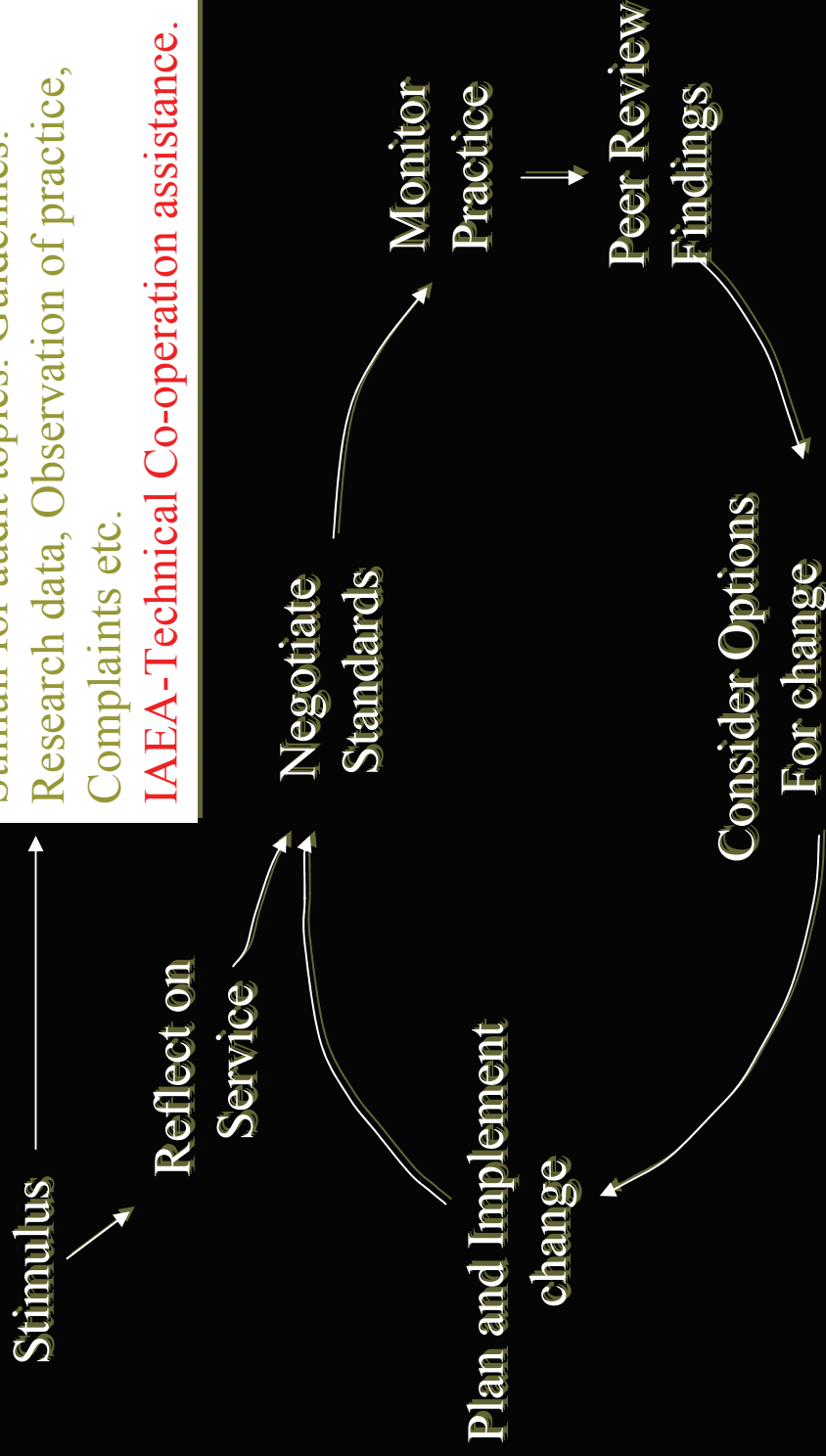
Atoms For Peace

The need for Quality management (QM) in Nuclear Medicine

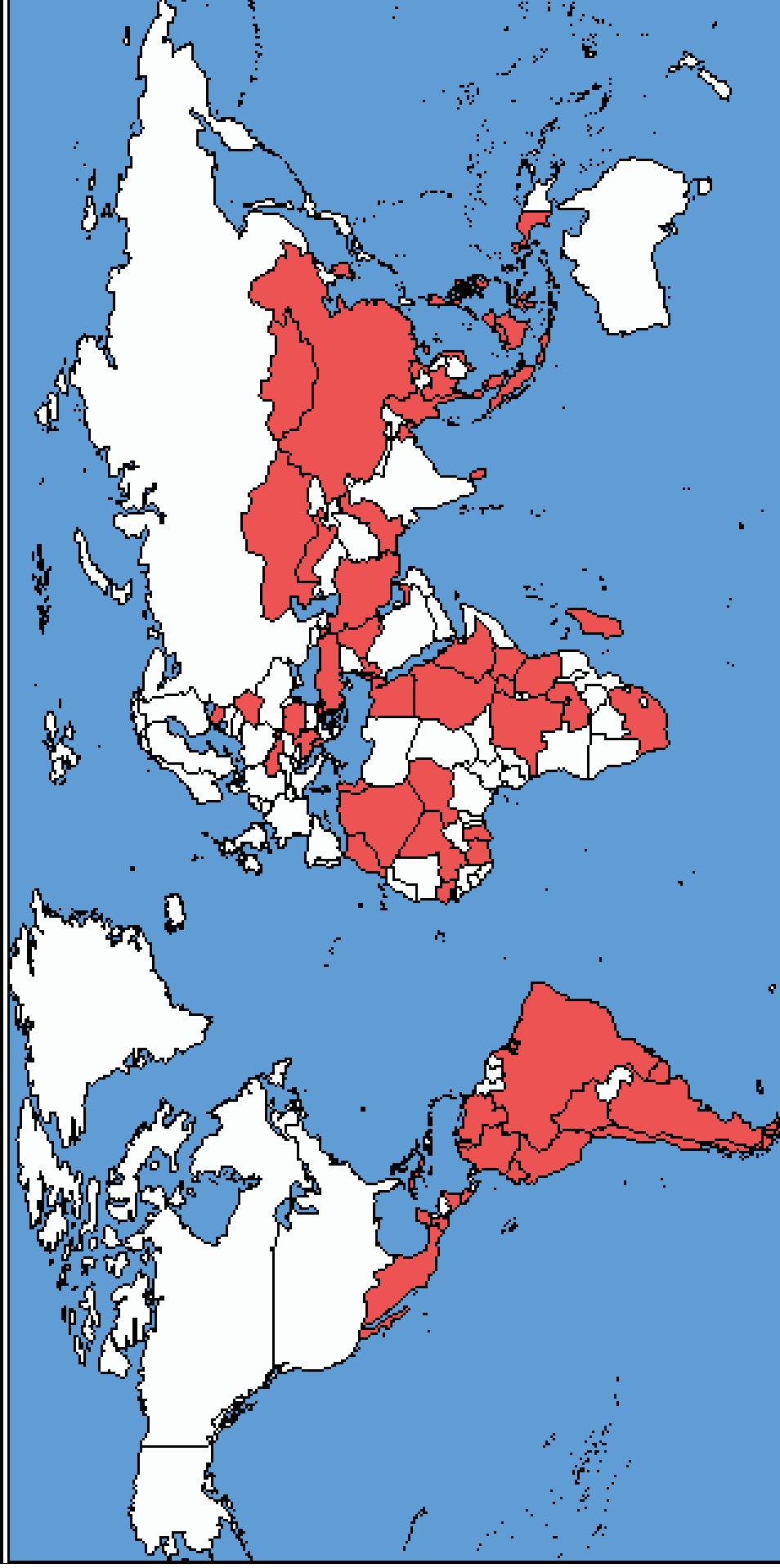
- QM is a means by which nuclear medicine facilities can demonstrate **the level of patient care they provide** by following a process of **self- and external evaluation**.
- It implies **a commitment to quality care** and should be seen as a continuous educational process.

Clinical Audit (The Audit Cycle)

Stimuli for audit topics: Guidelines.
Research data, Observation of practice,
Complaints etc.
IAEA-Technical Co-operation assistance.

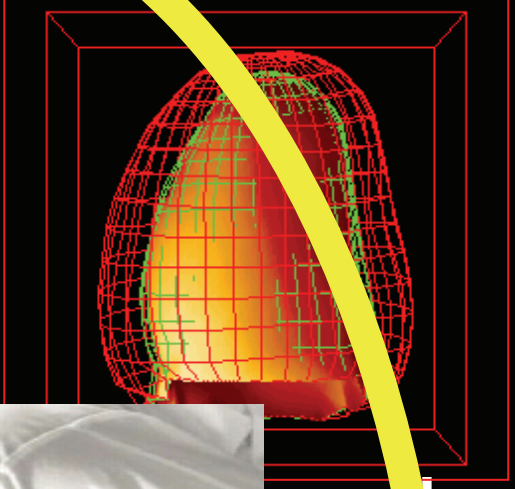
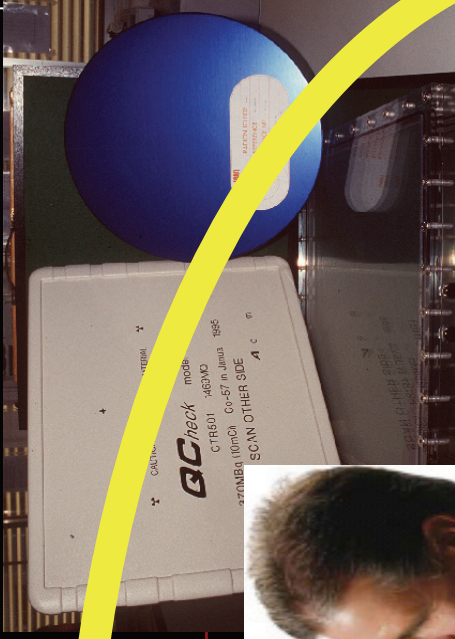
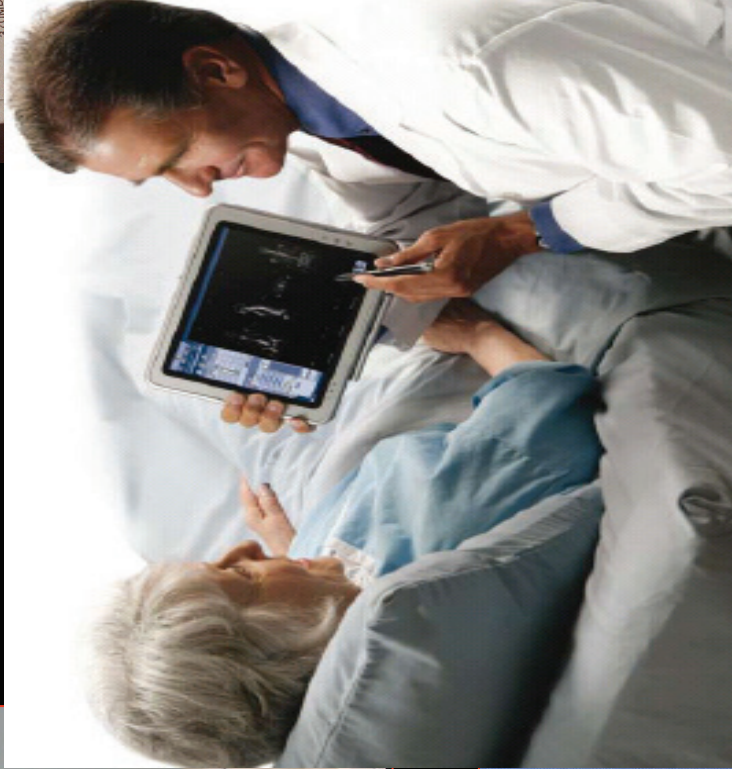


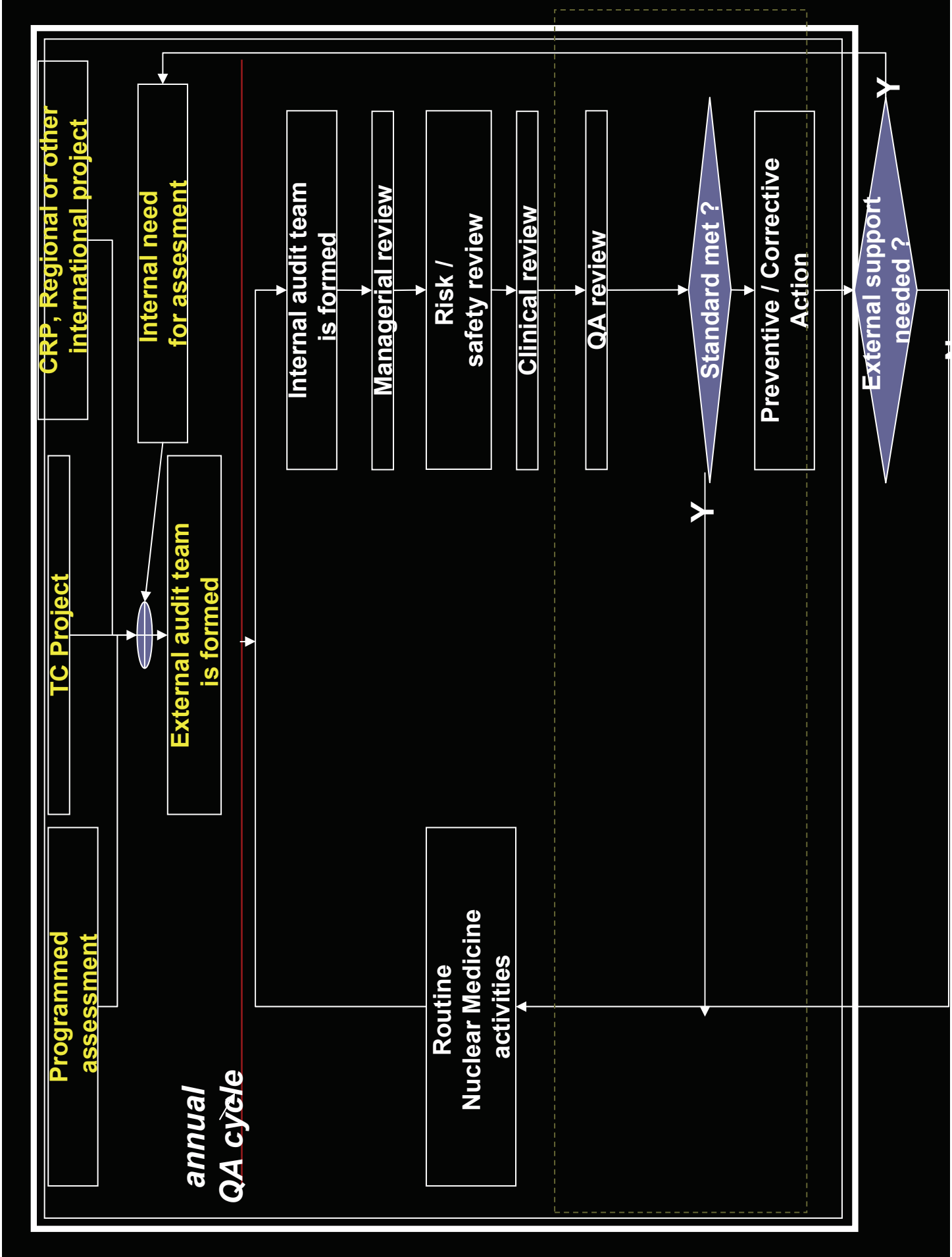
Nuclear Medicine Section Technical Co-operation Projects



**National Projects = 98 , Regional = 26 , Interregional = 2
TOTAL Nos = 126**

Comprehensive audit





Requests

Entry level:

- Following internal self appraisal (copy provided)
- Complete NUMDAB – database
 - infrastructure & equipment
 - qualified staff & training
 - programmes
 - QA programme

Request for audit

National Atomic Commission

IAEA

Correct

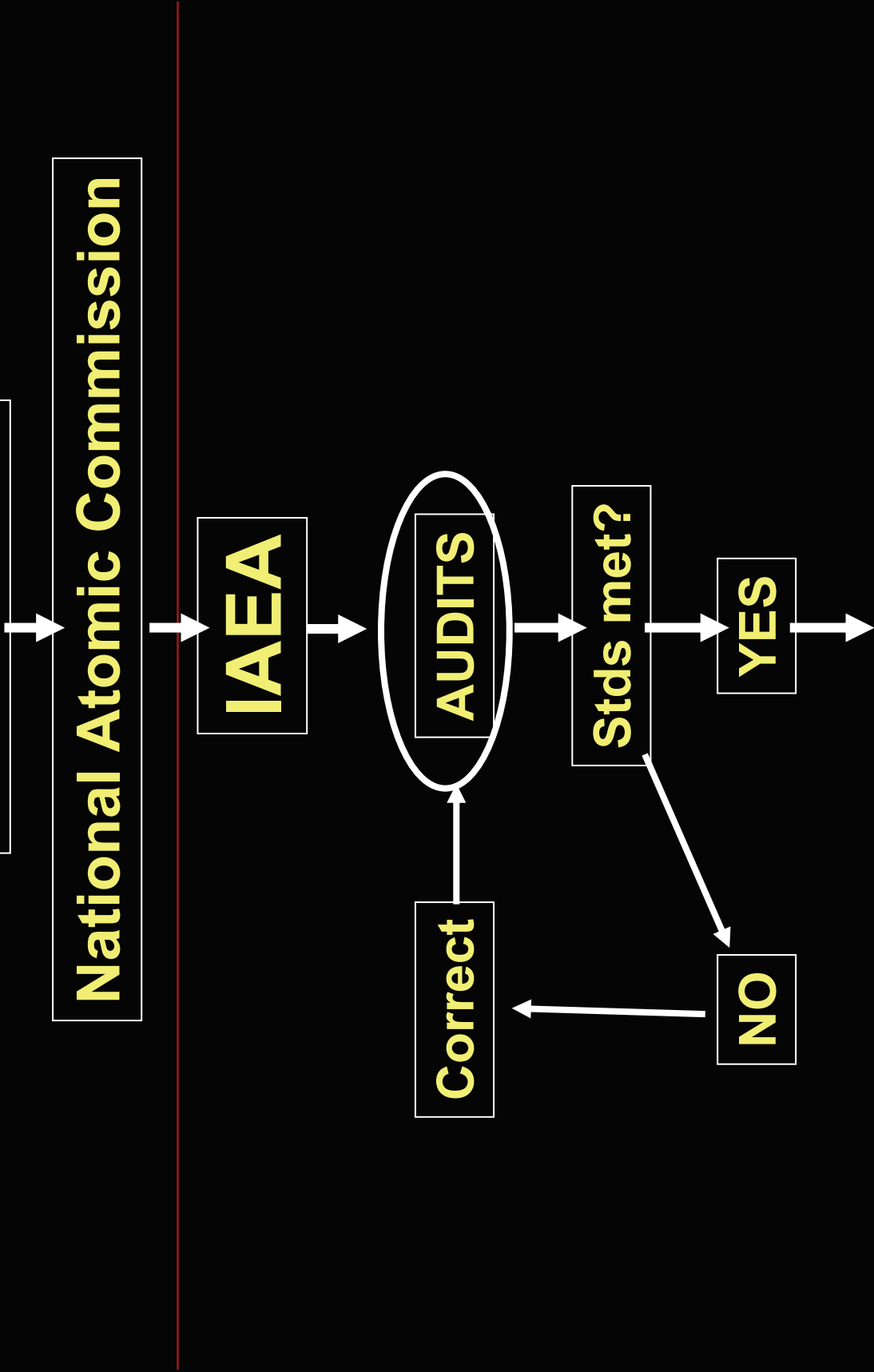
AUDITS

Stds met?

NO

YES

**Towards Centre of Competence
Recognised by National Authorities**



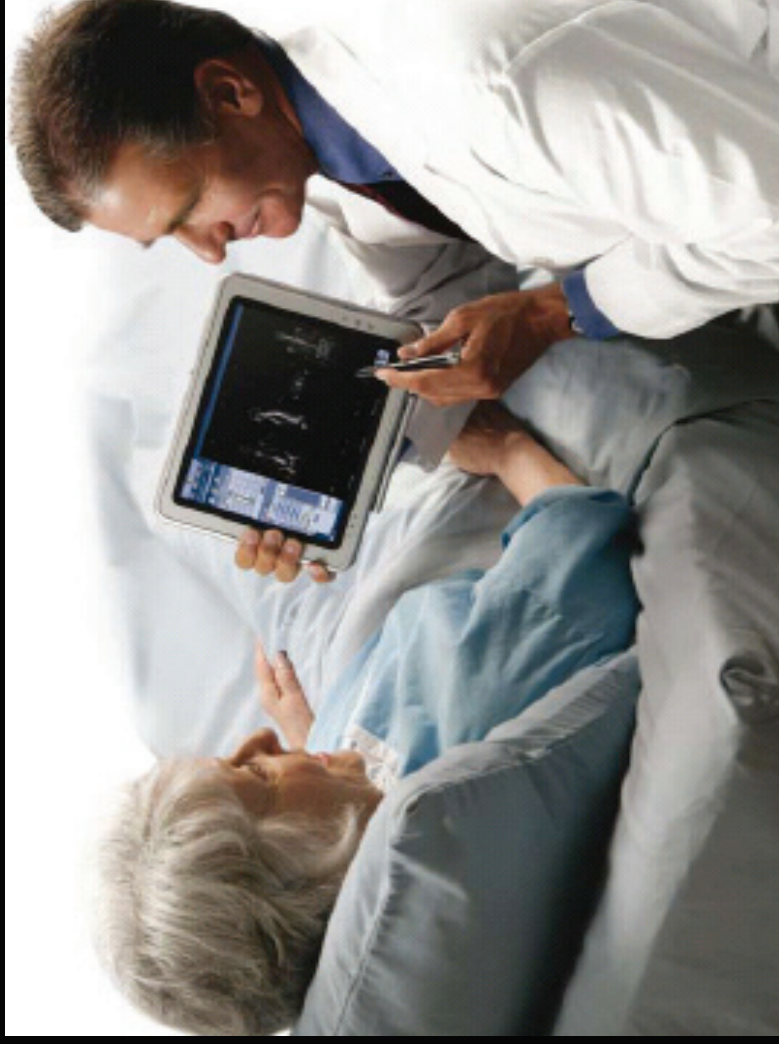
Technical approach of the audit

- Pre-visit questionnaire
- Verification details
 - ❖ Observations
 - ❖ References
 - ❖ non-conformance
- Remedial action & Follow-up

1. STRATEGY AND OBJECTIVES Components:

No	Component	Class	Verifiable – Manual, Reference Documentation, SOP, QC Data, Patient file etc.	Y / N	Comments/Planned Action	Date achieved.
5.2.1	Is the nuclear medicine service guided by specific objectives developed at the national level?	A			<i>IAEA Nuclear Medicine Resources Manual</i>	
5.2.2	Is the nuclear medicine service guided by specific objectives developed by the management of the service and is consistent with the overall stated aims of the nation or hospital?	A			<i>IAEA Nuclear Medicine Resources Manual</i>	
5.2.3	Does hospital management seek the participation of the nuclear medicine staff in decisions which will affect the Department's role and function?	B			<i>IAEA Nuclear Medicine Resources Manual</i>	
5.2.4	Is the range of specific nuclear medicine diagnostic imaging and therapeutic services appropriate to the size and scope of the hospital's clinical service?	B			<i>IAEA Nuclear Medicine Resources Manual</i>	
5.2.5	Do the objectives of the nuclear medicine service include the provision of services on urgent requests?	B				

Central to on-site audit procedures



Patient investigations, reports, patient managements and outcomes

Auditors will also seek evidence for

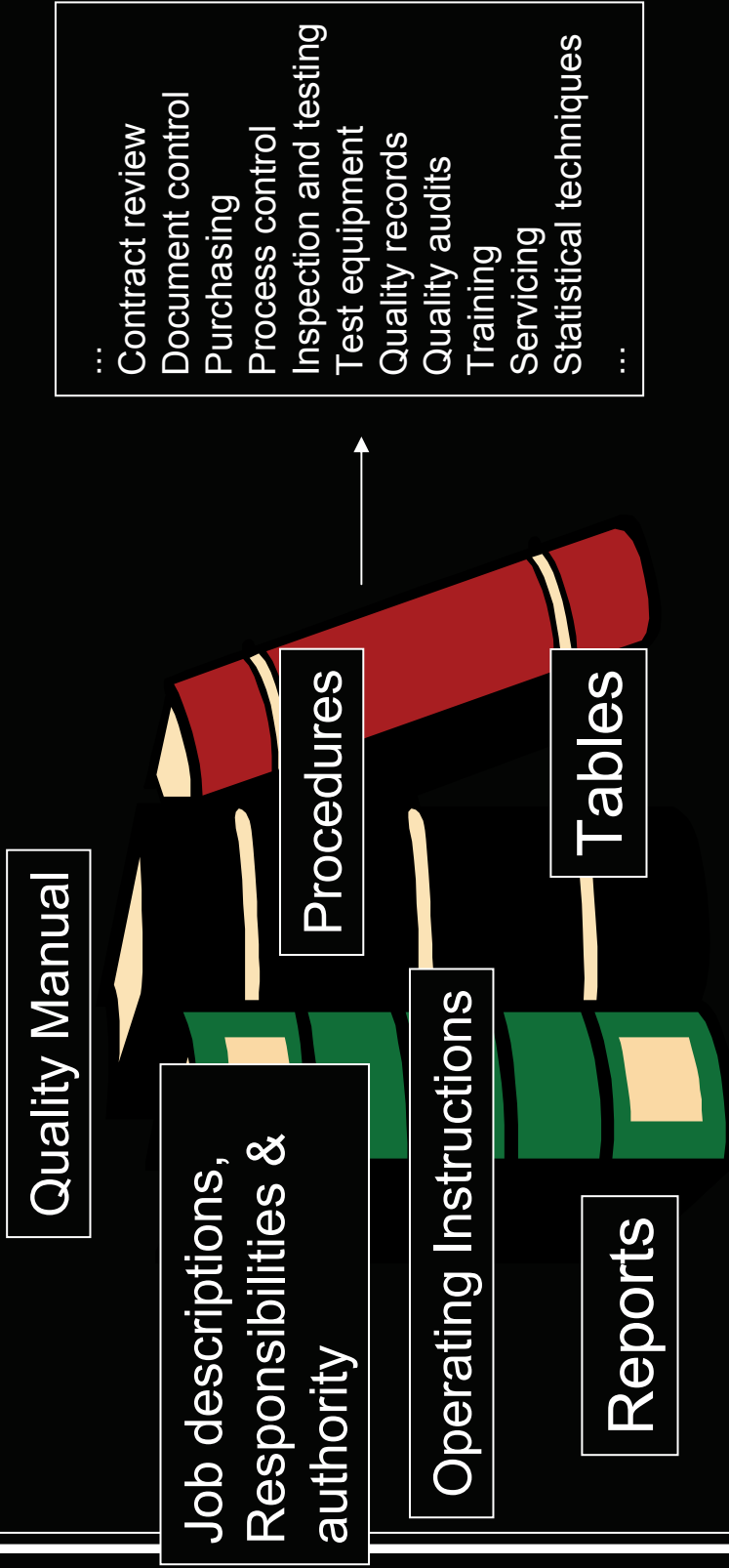
- Patient oriented organization
- Multi-disciplinary and integrated clinical practice
- Culture of cooperation between staff members
- QA system in place with the objectives of continuous quality improvement
- Openness to follow-up non-conformance
- Adaptation to change or newer practices, protocols and new technologies



1.IMAGING DIAGNOSTIC PROCEDURES Final summary table

Type of investigation	Type of study	Clinical problem	Patient preparation	Radio-pharmaceutical activity	Acquisition parameters	Processing parameters	Images	Final report	Recommendations
Planar	Thyroid								IAEA Nuclear Medicine Resources Manual. e.g. I/II/III
Planar Whole body	Bone								IAEA Nuclear Medicine Resources Manual
Dynamic	Renography								IAEA Nuclear Medicine Resources Manual
SPECT	e.g. bone								IAEA Nuclear Medicine Resources Manual
Cardiac SPECT	MPS								IAEA Nuclear Medicine Resources Manual

Comprehensive and well controlled documentation system



ASSESSMENT OF CLINICAL PROCEDURES

- Clinical procedures need to be assessed applying
 - the criteria of evidence based medicine,
 - according to internationally accepted standards,
 - as can be found in published guidelines and up-to-date literature.

ASSESSMENT OF CLINICAL PROCEDURES

Applying these standards, the studies should be evaluated and graded according to the following categories:

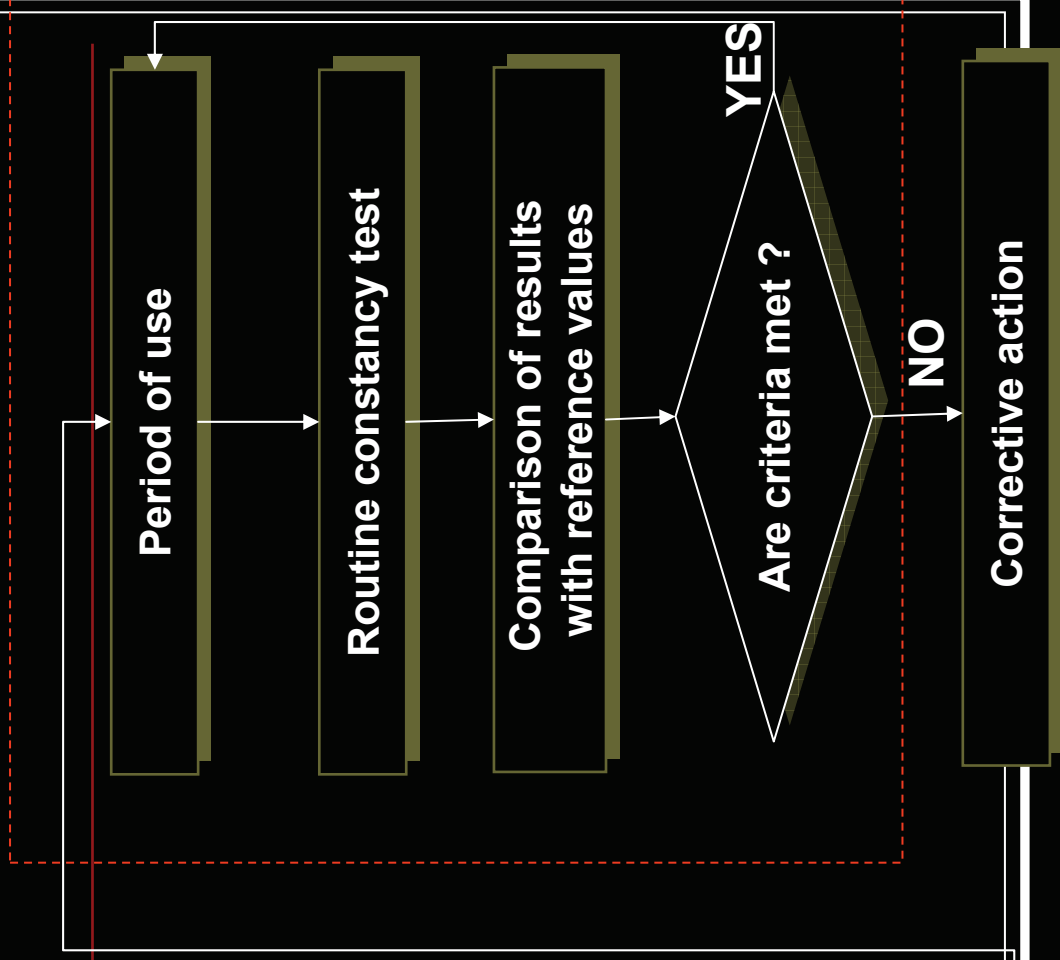
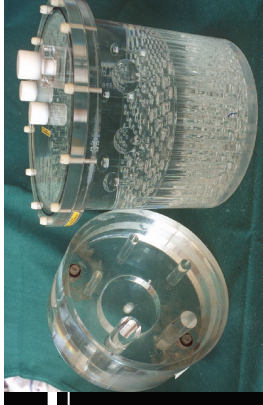
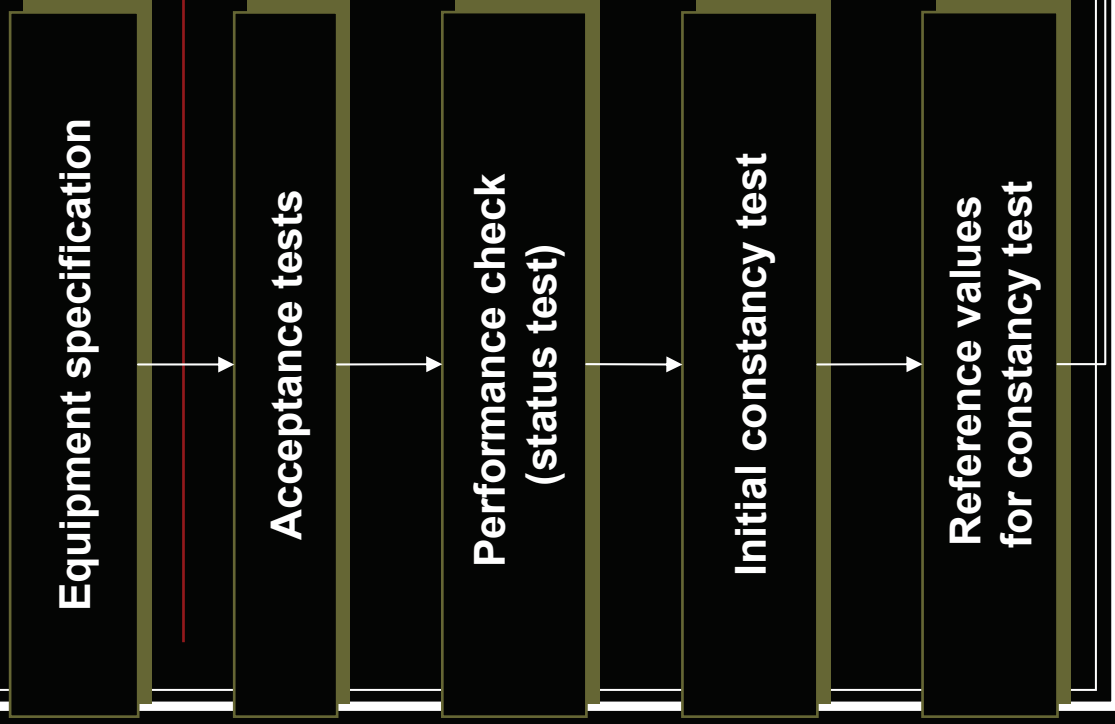
- I. **Conforming completely** to the published (national, international) guidelines
- II. Acceptable, but could be improved to the standard
- III. **Nonconforming to the criteria of good clinical practice**

Radiation risk



- Formal authorizations
- Radioactive test sources should be properly stored and periodically checked for leakage / contamination
- Test equipment and tools, reference sources, phantoms should be identified, catalogued and labelled
- They should be periodically assessed for accuracy, and results should be recorded and stored
- New equipment should be acquired by qualified suppliers

Flow chart for quality assurance of equipment



QA/QC elements

Gamma camera QC tests

- uniformity calibration
- centre of rotation calibration
- 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

IAEA-Operational Guide on Hospital Radiopharmacies.



Operation level 1a – Ready to use

Operation level 1b -Radioiodine

Operation level 2a- App. kits and generator

Operation level 2b- Radiolabelled WBC

Operation level 3a-in-house/compounding

Operation level 3b - in-house-therapeutic

Operation level 3c - in-house-cyclotron/PET

Accurate and traceability of actual records of patient dose

QC - dose calibrators

- constancy test
- linearity
- accuracy
- For each of different isotopes used
- Closer look behind the lead shield!



Trend analysis

- Organisational aspects and management performance
- “tune” the Quality System
- Periodically review statistical recording
- Data from workload
- Service records
- Non Conformities
- Complaints
- Failures.

Overview of summary sheets

- CRITICAL PRIORITY LIST

- MAJOR PRIORITY LIST

- MINOR PRIORITY LIST

- Others

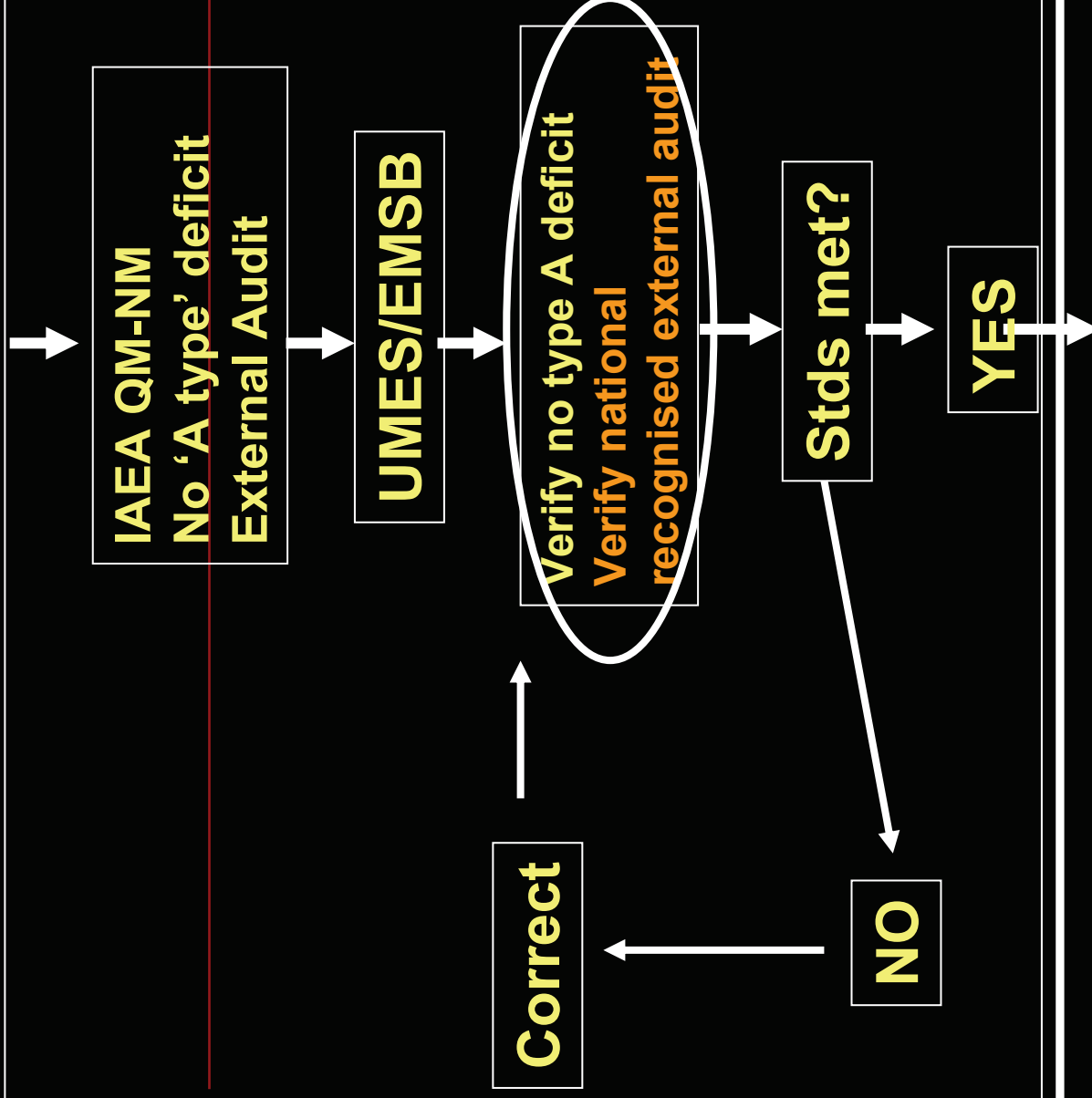
Audit Concerns

- Existing of a Large scale of differences between countries
- National regulation is not always present
- Medical physics support is not widespread
- Rare number of radiopharmacists
- Regular maintenance is not sure in many country

Follow-up

What is next!

Alternative Route to accreditation as Centre for competence in NM centre



Rec. accredited Centre of Competence

Future

- Link IAEA support with objective assessment and audit
- Overall targets and individual targets for self-reliance and sustained development.
- Annual Regional meeting should review audits in the regions