

IAEA THA6042  
Improving Quality Management in Nuclear Medicine  
Workshop on Quality Management Audits in Nuclear Medicine  
Practices (QUANUM 2.0)

## QUANUM General Principles: An Overview

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## Background



- Expert group since 2006
- Aim: Encourage a routine of regular quality auditing (internal/external - full/partial) to insure a positive growth of nuclear medicine services,
- Establish a tool that is independent of size and resources of the service to be audited.



## Quality Audit Process

- Patient oriented
- Systematic
- Outcome based



## Objective

- To develop a means allowing nuclear medicine facilities to
  - Demonstrate their level of patient care by
  - Regular internal and external audits and
  - A constant commitment to quality



## Scope of QUANUM

- Develop a guide for auditing nuclear medicine services in their multidisciplinary aspects
- Quality over quantity



## Scope of QUANUM

- Key elements
  - Management
  - Human resources development
  - Safety aspects of patients, staff, public and environment
  - Equipment reliability and performance
  - Clinical services (diagnosis and therapy)
  - Hospital radiopharmacy and laboratories



## Structure of QUANUM

- General statements
- Auditing flow chart
- Audit team
- Check lists
- Prioritization
- Comprehensive audit report and action plan with timelines



## Management Commitment

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  - Communicating with the staff members of the NMS on the importance of meeting customer's needs as well as statutory and regulatory requirements;
  - Planning and properly managing resources;
  - Conducting management reviews



## QMS in Nuclear Medicine

- Design and implementation influenced by
  - Various needs and constraints
  - Particular objectives
  - Nature of services provided
  - Processes employed
  - Size and structure of the Nuclear Medicine Service



## QMS in Nuclear Medicine

A Nuclear medicine Service should

- implement
- document
- maintain

a Quality Management System



## QMS in Nuclear Medicine

- The effectiveness of the QMS should be continuously improved in accordance with the requirements of
  - Professional
  - Regulatory
  - Standardization
  - Accrediting bodies



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  - External/reference documents;



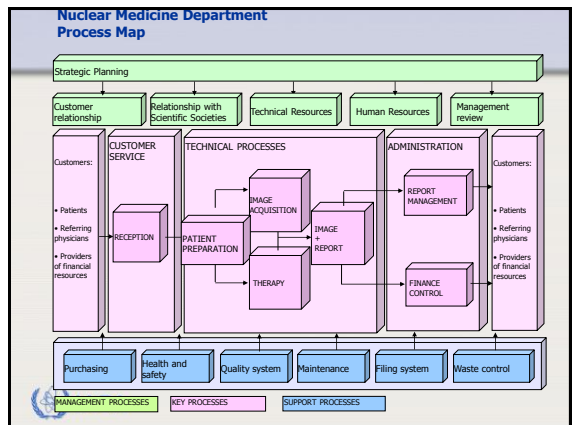
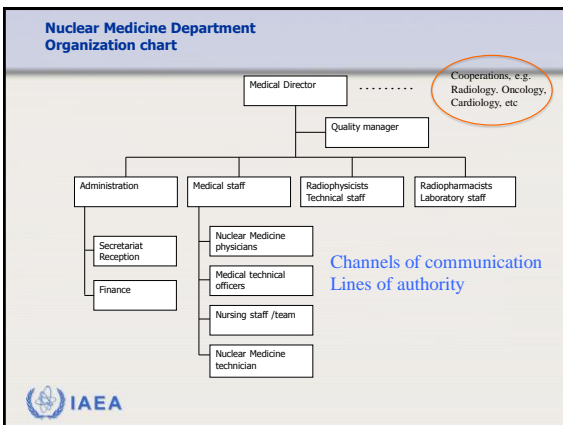
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  - A quality manual;
  - Written standard operating procedures (SOPs) for the primary (diagnosis and therapy), management and supporting processes
  - External/reference documents;
  - Records of indicators and parameters



### Quality Management System (QMS)

- Organisational structure
- Processes
- Procedures
- Resources


## Quality Management System (QMS)

### Procedures






## QM Procedures



- Develop standard operating procedures (SOP)
- defined as
  - detailed, written instructions to achieve uniformity of the performance of any specific function
- including also
  - Links
  - Conformity checks
  - Preventive and corrective actions



## Quality Management System (QMS)

### Resources


Human resources  
Equipment  
Finances







## Objective of QM Audit

- Review and evaluate the quality of all elements involved in the different processes




## Objective of QM Audit

- Elements to be evaluated
  - Staff
  - Equipment
  - Procedures
  - Patient protection and safety
  - Overall performance of the NMS
  - Interaction with external services




## Objective of QM Audit

- Review and evaluate the quality of all elements involved in the different processes
- Assist NMS in maintaining and improving the quality of service for
  - Patients
  - Referring physicians
  - Other stakeholders



### Audit Team


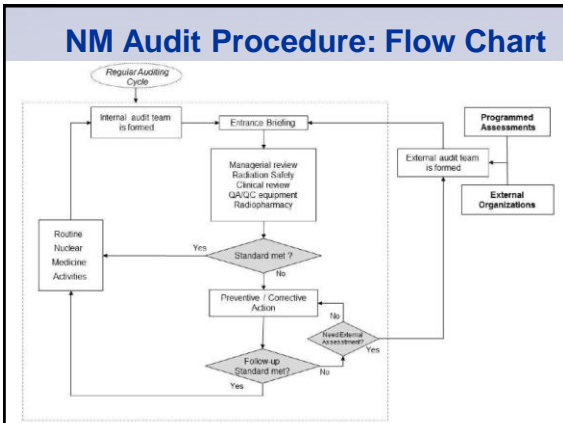
- Core Team
  - NM physician
  - Medical physicist
  - Radiopharmacist
  - NM Technologist



### Audit Team


- Other professionals
  - Quality experts
  - Administrators
  - Nurses
  - Laboratory specialist
  - .....

The final composition should be communicated to the staff in advance


### Nuclear Medicine Audit Procedure

- Regular (annual)
- Full or partial
- Written documentation is a priority
- Internal audit team to be formed including representative number of staff
- Completion followed by analysis of the checklists




### Nuclear Medicine Audit Procedure

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- When standards are met or corrective actions implemented, routine activity continues until next internal audit
- Periodic external independent audits as part of QMS



## Prioritization

- Critical
  - Major
  - Minor
- according to the degree of seriousness and risk to patient, staff or environment
- Shortcomings considered critical must be addressed rapidly (immediately)



## Limitations: General

- QUANUM not designed for
- Regulatory purposes
  - Investigation of accidents
  - Clinical research
  - Interdepartmental comparison



## Limitations: Checklists

- Comprehensive non-exhaustive tool
- To be used together with other updated IAEA documents and scientific literature
- Professional judgement to ensure adequate level of assessment



## Responsibility for Action

- Audit team discusses shortfalls
- NMS, if necessary in conjunction with the hospital and/or national authorities, is responsible for correcting identified deficiencies

