



# Comprehensive Auditing in Nuclear Medicine Through the International Atomic Energy Agency Quality Management Audits in Nuclear Medicine (QUANUM) Program. Part 1: the QUANUM Program and Methodology

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An effective management system that integrates quality management is essential for a modern nuclear medicine practice. The Nuclear Medicine and Diagnostic Imaging Section of the International Atomic Energy Agency (IAEA) has the mission of supporting nuclear medicine practice in low- and middle-income countries and of helping them introduce it in their health-care system, when not yet present. The experience gathered over several years has shown diversified levels of development and varying degrees of quality of practice, among others because of limited professional networking and limited or no opportunities for exchange of experiences. Those findings triggered the development of a program named Quality Management Audits in Nuclear Medicine (QUANUM), aimed at improving the standards of NM practice in low- and middle-income countries to internationally accepted standards through the introduction of a culture of quality management and systematic auditing programs. QUANUM takes into account the diversity of nuclear medicine services around the world and multidisciplinary contributions to the practice. Those contributions include clinical, technical, radiopharmaceutical, and medical physics procedures. Aspects of radiation safety and patient protection are also integral to the process. Such an approach ensures consistency in providing safe services of superior quality to patients. The level of conformance is assessed using standards based on publications of the IAEA and the International Commission on Radiological Protection, and guidelines from scientific societies such as Society of Nuclear Medicine and Molecular Imaging (SNMMI) and European Association of Nuclear Medicine (EANM). Following QUANUM guidelines and by means of a specific assessment tool developed by the IAEA, auditors, both internal and external, will be able to evaluate the level of conformance. Nonconformances will then be prioritized and recommendations will be provided during an exit briefing. The same tool could then be applied to assess any improvement after corrective actions are taken. This is the first comprehensive audit program in nuclear medicine that helps evaluate managerial aspects, safety of patients and workers, clinical practice, and radiopharmacy, and, above all, keeps them under control all together, with the intention of continuous improvement. Semin Nucl Med 47:680–686 © 2017 Published by Elsevier Inc.

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## Introduction

Evidence of the quality of clinical practices, their adherence to quality standards, to evidence-based medicine, and to directions provided by regulatory bodies are increasingly requested from regulators, national health systems, health-care insurers, and other third parties.<sup>1-3</sup> These aspects have a specific relevance in high-tech disciplines such as nuclear medicine. Indeed, an effective management system that integrates quality management (QM) is essential for a modern nuclear medicine practice.

The International Atomic Energy Agency (IAEA),<sup>4</sup> a member of the United Nations family with a long history of promoting the safe, secure, and peaceful use of nuclear technologies in its member states (MS) and, among others, of providing assistance in the field of nuclear medicine, has published a variety of documents on management systems for all facilities. IAEA publications such as Safety Requirement (GS-R-3)<sup>5</sup> and a Safety Guide (GS-G-3.1)<sup>6</sup> address the application of an integrated management system approach that is applicable to nuclear medicine practices as well, but covers only parts of the whole nuclear medicine practice, which is, by its inherent nature, a multidisciplinary medical specialty. Clinical audits of Nuclear Medicine (NM) services should be organized as a comprehensive peer review of all components of service delivery against predetermined standards and thus aim at continuous improvement of all aspects and services of the department. This includes focus on patients and clinical effectiveness and requires commitment of the various professional groups active in nuclear medicine.

The IAEA's Human Health program includes the Nuclear Medicine and Diagnostic Imaging (NMDI) subprogram, which takes care of numerous initiatives aimed at fostering the integration of nuclear medicine practice into MS's health-care systems.<sup>7</sup> In 2006, NMDI launched an initiative to design a program to help its constituency in MS to self-assess the standard of their NM clinical practices and, if necessary, improve them to accepted international standards. The output of that initiative has been a program called Quality Management Audits in Nuclear Medicine (QUANUM), based on comprehensive auditing missions of multidisciplinary teams fielded by the IAEA through its Technical Cooperation Program<sup>8</sup> and technically supported by NMDI.

The aim of the QUANUM program is threefold: first, to encourage the introduction of a routine process of conducting annual systematic audits in the clinical arena; second, to encourage the adoption of a culture of regular analyses and reviews of internal processes, both of them essential for positive growth in medical services; and third and even more important, to introduce a quality audit process that is patient oriented, systematic, and outcome based.<sup>9,10</sup>

This paper aimed to provide detailed information on the QUANUM program and its methodology.

## Materials and Methods

The IAEA convened at its headquarters in Vienna a working group of international experts, covering the fields of clinical

practice of NM: radiopharmacy and medical physics. Two working groups met in Vienna at IAEA Headquarters in January and December 2006, with the aims of

- 1) designing the audit methodology;
- 2) identifying references to international standards such as those published by IAEA, EANM, and SNMMI, among others;
- 3) drafting a document for subsequent publication and distribution to IAEA MS;
- 4) creating a tool to ensure homogeneity, consistency, and adequate coverage of all concerned areas;
- 5) establishing guidelines for external peer-review audits and follow-up mechanisms, including the composition of the audit teams; and
- 6) identifying modalities of training for auditors.

After several iterations among the members of the two working groups, the final document was published in 2008.<sup>11</sup> The document was developed with the aim of providing nuclear medicine practitioners in IAEA MS with a tool to assess their compliance with internationally accepted standards. The underpinning concept was that the audit should be multidisciplinary and comprehensive, and not an inspection but rather a peer-review process. International experts would spend a week working with their local peers, look at their practice from a different perspective, identify any possible gaps, and give advice on remedial actions.

Based on the initial experience from 2008 to 2012, and in adherence to the culture of continuous improvement embedded in the principles of quality, a revision was carried out in 2012 and 2013 resulting in the QUANUM v2.<sup>12</sup> The main changes from v1 to v2 have been (1) the introduction of more detailed analysis of clinical practices; (2) the introduction of a five-step scoring of the assessment, in terms of conformance or nonconformance, as explained in the Results section; and (3) the introduction of graphic tools (radar plots, see later) for immediate visual representation of overall results. The introduction of the five-step scoring is particularly relevant at the level on internal audits, as well as for external auditors, because it allows a more precise assessment and quantitation of changes or improvement in comparison to a baseline evaluation, for instance, when previously partially implemented requirements were fully implemented (from levels 3 to 4) or implementation of previously absent requirements was planned or initiated (from levels 0 to 1 or 2).

## Results

Outputs from the previously mentioned meetings have been

- 1) identification of standards;
- 2) fully designed QUANUM audit methodology;
- 3) finalization of a tool used to run both the self-assessment and the peer-review process, and preparation of the final report; this tool is an Excel spreadsheet which has also been reviewed and slightly modified when the original QUANUM v1 program was revised; and

- 4) publication of manuals, where the methodology is explained and which contain the Excel spreadsheet.

## Identification of Standards

Conformance requirements are based on IAEA recommendations, such as Basic Safety Standards and documents from the NMDI section; documents of the International Commission on Radiological Protection and guidelines from the relevant societies, which contribute to Evidence Based Medicine.<sup>13-30</sup> All these documents are freely accessible at the IAEA's Human Health Campus (HHC).<sup>31</sup>

## QUANUM Audit Methodology

The QUANUM audit methodology is based on a two-step approach. The first step is an internal audit, where the institution to be audited will form an internal team and carry out a self-assessment. Internal audits are particularly encouraged, as they are considered the best and the financially most affordable stimulus to improve the quality standards of the services. After a voluntary request submitted to the IAEA through the competent national authority, which serves as liaison, an external audit can be run by IAEA experts. The flowchart in Figure 1 summarizes the decisional process.

Audits are structured in such a way that all components of nuclear medicine practice are covered. The external auditing teams therefore will include at least one physician, one

radiopharmacist, one medical physicist, and one technologist, chosen among a pool of qualified professionals already trained in the QUANUM methodology.

## The Excel Spreadsheet

The auditing process, both internal and external, is based on the use of the specific tool<sup>32</sup> that the NMDI has developed, that is, a spreadsheet, freely available at the HHC<sup>31</sup> and tested for compatibility in a variety of operating systems and software platforms. The current spreadsheet is structured into 17 different sections (Table 1), covering all aspects of nuclear medicine practice, from strategies and policies to clinical practice. Each section is laid out as a series of questions related to specific components of the nuclear medicine service, for a total of 263 requirements.

## Assessment of the Level of Conformance (LoC)

The spreadsheet tool allows a graduation of the LoC of each requirement. It has also a specific column where standards are duly referenced. To assess the LoC to those previously defined standards, a scoring system has been designed. Each item is scored from 0 to 4 (Table 2), depending on the LoC. Requirements found to be "absent or inappropriate" are scored as 0; those found to be "planned or approximate" are scored as 1; and those found to be "partially conform or partially implemented" as 2. These all fall in the category of

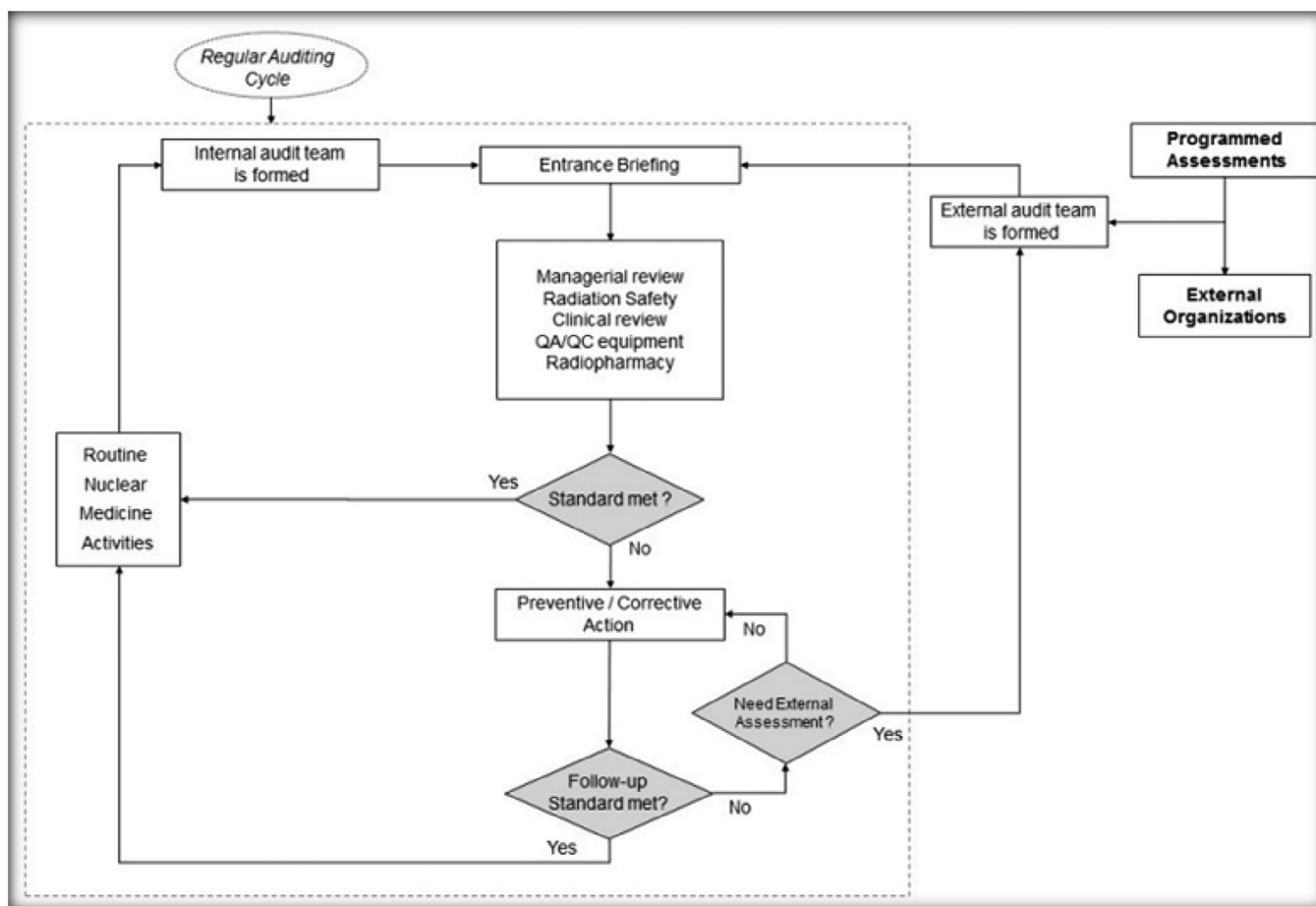


Figure 1 Flowchart of the QUANUM methodology.

**Table 1** Structure of the Excel Spreadsheet

Nr	Section/Title	Description
1	Strategies and policies	A clear strategy and policy must be in place for an efficient management and is essential for the success of any undertaking.
2	Administration and management	Administration and management are central to an efficient and successful enterprise.
3	Human resources development	Human resources can be defined as the total knowledge, skills, creative abilities, talents, and aptitudes of the workforce.
4	Radiation regulations and safety	Compliance with all relevant regulations and good radiation practice in NM are of utmost importance.
5	Patient radiation protection	This includes all due considerations relating to radiation protection of patients.
6	Evaluation and assurance of quality system	The quality management system should be implemented and regularly reviewed to ensure compliance with standards.
7	QC of imaging equipment	A comprehensive system of QC for all imaging equipment is essential for optimal patient examinations in NM.
8	Computer system and data handling	Computers have been central to the practice of NM for many years, as the extraction of functional information commonly requires patient image analysis.
9	General clinical services	The conformance of general diagnostic clinical services requirements is essential to ensure the safety and efficacy of imaging and non-imaging procedures.
10	Assessment of imaging procedures	The auditing team has to assess up to five files of patients. Clinical information, technical aspects and procedures, patient preparation, traceability, reporting, and follow-up will be considered.
11	Assessment of nonimaging procedure	
12	General radionuclide therapy	Reviews essential aspects of the radionuclide therapy service.
13	Assessment of therapy	The auditing team has to assess up to three files of patients as per item 10.
14	Radiopharmacy operational level 1	See Reference 9 for level explanation.
15	Radiopharmacy operational level 2	See Reference 9 for level explanation.
16	Radiopharmacy operational level 3	See Reference 9 for level explanation.
17	Hormones and tumor markers	This audit section focuses on the clinical use of hormones and tumor markers for NMSs using radioimmunoassay.
	Audit report	
	Radar summary	

“nonconformance.” The elements “largely conform or largely implemented” are scored as 3 and “fully conform or fully implemented” are scored as 4. The last two elements are classified as “conformance.” Not all questions have to be addressed, only those relevant for the specific institution. Questions that are not relevant for the audited center are marked as N/A (not applicable) and are not included in the assessment of the final scores. The achieved final score is the sum of the individual scores and expressed as a percentage of the total possible score.

The tool is also used to build a radar plot to enable the reader to get an immediate visual representation of the overall

results. The radar plot is built from the full statistic of the audit results as a graphic illustration of the LoC achieved during the audit. The general radar plot (Fig. 2), however, will not include assessment of clinical practices, items 10 and 13, which instead have their own radar plots representing the average from the observation of five different imaging studies (Fig. 3A) and three therapeutic procedures (Fig. 3B).

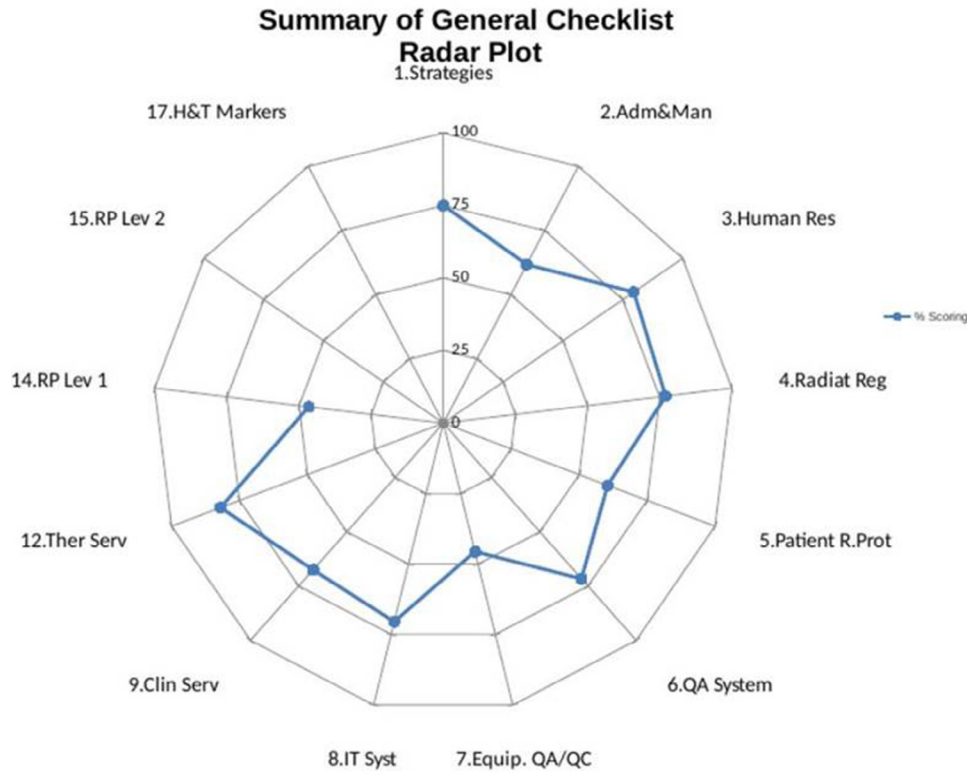
#### Prioritization of Nonconformances

Finally, an Excel spreadsheet, named Prioritization of Nonconformances, allows summarizing and prioritizing nonconformances. This is required by the QUANUM program

**Table 2** Scoring the Documental System

Score	Description	Level of Conformance	Example
NA	Not applicable	NA	When an activity is not performed (eg, therapeutic procedures)
0	Absent or inappropriate	Nonconformance	No documents available
1	Planned or approximate	Nonconformance	Documentation is planned or exists as an informal draft.
2	Partially conform or partially implemented	Nonconformance	A limited number of SOPs are complete or most SOPs exist but lack important parts.
3	Largely conform or largely implemented	Conformance	Most of the SOPs are complete but some information is missing (eg, reference to guidelines, dosimetry data, etc.) or documents are not regularly updated.
4	Fully conform or fully implemented	Conformance	All SOPs are complete, in use, and periodically reviewed.

SOPs, Standard Operating Procedures.



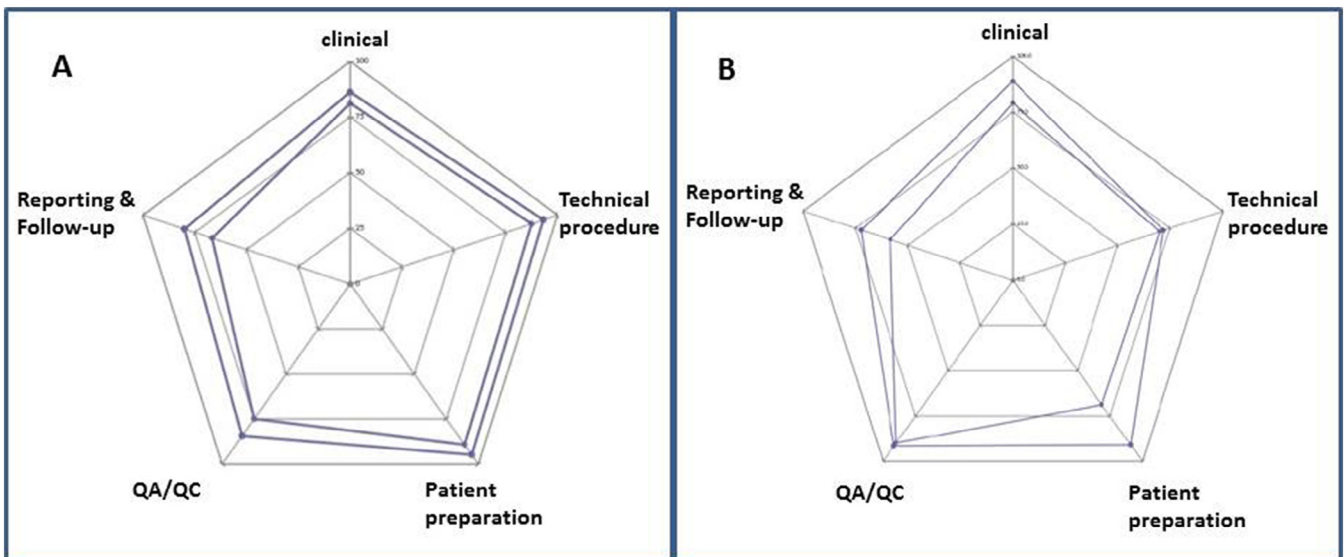
**Figure 2** Radar plot of overall quality system (example). Missing values for checklists 15 (radiopharmacy level 2) and 17 (no radioimmunoassay lab) are due to non-applicability of the two checklists for this particular center.

as an important and final step of the audit report. Auditors will translate nonconformances into recommendations, according to three levels of prioritization as follows:

1) Critical priority: issues affecting the safety of patients, staff, caregivers, and environment that should be promptly addressed (within days or weeks)

2) Major priority: issues affecting the capacity of the Nuclear Medicine Services (NMS) to adequately perform its activities that should be addressed in a timely manner (eg, 3-6 months)

3) Minor priority: issues that are not urgent but may need to be improved within a defined time period and re-evaluated during the next audit.



**Figure 3** Examples of radar plots from clinical (A) and therapeutic (B) procedures.



Nonconformances are discussed during the exit briefing of the audit mission and are duly reported, along with defining possible corrective actions and a time frame for their implementation.

## Discussion

There are diversified levels of development of NM practice worldwide. This is particularly true in low- and middle-income countries (LMICs), where several factors, including, but not limited to, financial constraints, lack of training opportunities, limited professional networking, and limited, or no possibility at all, of exchange of experiences, may hamper access to scientific publications and other educational resources, including those related to safety and quality of practice. There are countries where only one NM center exists with just very few practitioners. Clinical guidelines are often applied to a limited extent only and the culture of QM as a tool to maintain the level of practice up to recognized and internationally accepted standards is often lacking.

To tackle those problems, the NMDI Section of the IAEA, in pursuing its mission of supporting NM practice in LMICs, has developed and continues to develop educational resources and initiatives, all accessible at its HHC. The QUANUM program represents one of those initiatives. This program has been developed keeping in mind that any successful approach to auditing in a complex, multidisciplinary field such as nuclear medicine should be comprehensive, that is, should include all aspects and components of the process.

Nuclear medicine has a long tradition in the development and application of advanced methodologies for quality assurance (QA) and quality control (QC) of the employed sophisticated imaging equipment, and of radiopharmaceuticals, all aimed at ensuring the safety and efficacy of the procedures. However, this was felt as still not completely sufficient if all the “system” variables were not included in the QM, and thus in the auditing process. For these reasons, the QUANUM program was designed to consider also administrative processes; the proper management of human resources, including training and clinical competence; QA/QC procedures not only for main imaging equipment but also for all relevant equipment; and the assessment of safety conditions (for patients and staff), not only in relation to the predominant issues of radiation exposure but also including other sources of risk, microbiological, mechanical, electrical, and so on.

Finally, a detailed analysis of the components related to patient management (booking, preparation, interviews, medications, and surveillance) is included, as well as a synthetic evaluation of the quality of reports.

In the QUANUM program, the concept of “quality” covers aspects that go far beyond the usual QA/QC of instrumentation. For the first time, to our knowledge, there is a comprehensive program that helps evaluate managerial aspects, safety of patients and workers, and clinical practice, and, most importantly, provide an overview to facilitate monitoring of all the aspects with the intent of continuous improvement.

## Conclusions

The QUANUM program provides a holistic approach and takes into account the diversity of nuclear medicine services around the world and multidisciplinary contributions. The QUANUM program has been conceived and developed to provide NM professionals in LMICs with a comprehensive tool where minimum acceptable requirements in all aspects of their clinical practice are set out, based on international regulations, clinical guidelines, and managerial strategies, and adherence to which should be considered a basic requirement for a successful practice of nuclear medicine. The QUANUM program aims to provide nuclear medicine practitioners in IAEA MS with a tool to assess their compliance with those standards. It is worth noting that the QUANUM program is freely available and can be applied autonomously, without requiring an external audit that could be called in case of need. In this case, the IAEA would be available to support the audit missions through its Technical Cooperation Program.

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