



Comprehensive Auditing in Nuclear Medicine Through the International Atomic Energy Agency Quality Management Audits in Nuclear Medicine Program. Part 2: Analysis of Results

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The International Atomic Energy Agency has developed a program, named Quality Management Audits in Nuclear Medicine (QUANUM), to help its Member States to check the status of their nuclear medicine practices and their adherence to international reference standards, covering all aspects of nuclear medicine, including quality assurance/quality control of instrumentation, radiopharmacy (further subdivided into levels 1, 2, and 3, according to complexity of work), radiation safety, clinical applications, as well as managerial aspects. The QUANUM program is based on both internal and external audits and, with specifically developed Excel spreadsheets, it helps assess the level of conformance (LoC) to those previously defined quality standards. According to their level of implementation, the level of conformance to requested standards; 0 (absent) up to 4 (full conformance). Items scored 0, 1, and 2 are considered non-conformance; items scored 3 and 4 are considered conformance. To assess results of the audit missions performed worldwide over the last 8 years, a retrospective analysis has been run on reports from a total of 42 audit missions in 39 centers, three of which had been re-audited. The analysis of all audit reports has shown an overall LoC of $73.9 \pm 8.3\%$ (mean \pm standard deviation), ranging between 56.6% and 87.9%. The highest LoC has been found in the area of clinical services (83.7% for imaging and 87.9% for therapy), whereas the lowest levels have been found for Radiopharmacy Level 2 (56.6%); Computer Systems and Data Handling (66.6%); and Evaluation of the Quality Management System (67.6%). Prioritization of non-conformances produced a total of 1687 recommendations in the final audit report. Depending on the impact on safety and daily clinical activities, they were further classified as critical (requiring immediate action; $n = 276$; 16% of the total); major (requiring action in relatively short time, typically from 3 to 6 months; $n = 604$; 36%); whereas the remaining 807 (48%) were classified as minor, that is, to be addressed whenever possible. The greatest proportion of recommendations has been found in the category "Managerial, Organization and Documentation" (26%); "Staff Radiation Protection and Safety" (17.3%); "Radiopharmaceuticals Preparation, Dispensing and Handling" (15.8%); and "Quality Assurance/Quality Control" and "Management of Equipment and Software" (11.4%). The lowest level of recommendations belongs to the item "Human Resources" (4%). The QUANUM program proved applicable to a wide variety of institutions, from small practices to larger centers with PET/CT and cyclotrons. Clinical services rendered to patients showed a good compliance with international standards, whereas issues

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related to radiation protection of both staff and patients will require a higher degree of attention. This is a relevant feedback for the International Atomic Energy Agency with regard to the effective translation of safety recommendations into routine practice. Training on drafting and application of standard operating procedures should also be considered a priority.

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Introduction

The International Atomic Energy Agency (IAEA),¹ set up in 1957 as the world's center for cooperation in the nuclear field, works with its Member States and multiple partners worldwide to promote the safe, secure, and peaceful use of nuclear technologies in various fields, including human health. For this purpose, among other initiatives, the Division of Human Health of the IAEA has developed quality management programs, which cover the medical fields where the Division of Human Health² supports its Member States, namely radiation oncology, nuclear medicine, and radiology.

With regard to nuclear medicine, the Nuclear Medicine and Diagnostic Imaging Section, aiming to raise the quality of nuclear medicine practices in low-middle income countries up to internationally recognized minimum standards, has developed a program on Quality Management Audits in Nuclear Medicine (QUANUM),³ based on a combination of both internal and external audits. The internal audit processes are felt as essential to instil a culture of quality in the practice, followed when requested, by external auditing missions of multidisciplinary teams fielded by the IAEA through its Technical Cooperation Program and technically supported by the Nuclear Medicine and Diagnostic Imaging Section.^{4,5}

Between 2006 and 2007, the QUANUM program was designed as a result of two consultancy meetings involving experts in clinical nuclear medicine, radiopharmacy, and medical physics, and initially published in 2008.⁶ Based on initial feedback and experiences, the program was subsequently revised, and QUANUM v2 was published in 2014.⁷ The main changes included the introduction of a more detailed evaluation of clinical practices; a grading system for a more refined assessment of the level of conformance (LoC); and a specific checklist for level 3 Radiopharmacy practice, for those centers where cyclotrons are being operated. For immediate visual representation, a graphic tool (radar plot) was also introduced (Fig. 1).

The program sets out a series of comprehensive criteria-based checklists⁸ covering 17 thematic areas and focused on international safety regulations and standards, clinical guidelines, and managerial strategies.^{9–26} Adherence to such criteria is considered a basic requirement for good patient care in nuclear medicine while reducing risks (radiation and other safety issues) inherent to health-care delivery processes.²⁷

In June 2016, the IAEA started an assessment of outcomes from those missions. The objective was, through the retrospective analysis of completed QUANUM mission reports, to review the experience gathered from the audits, and identify strengths and weaknesses of nuclear medicine practices

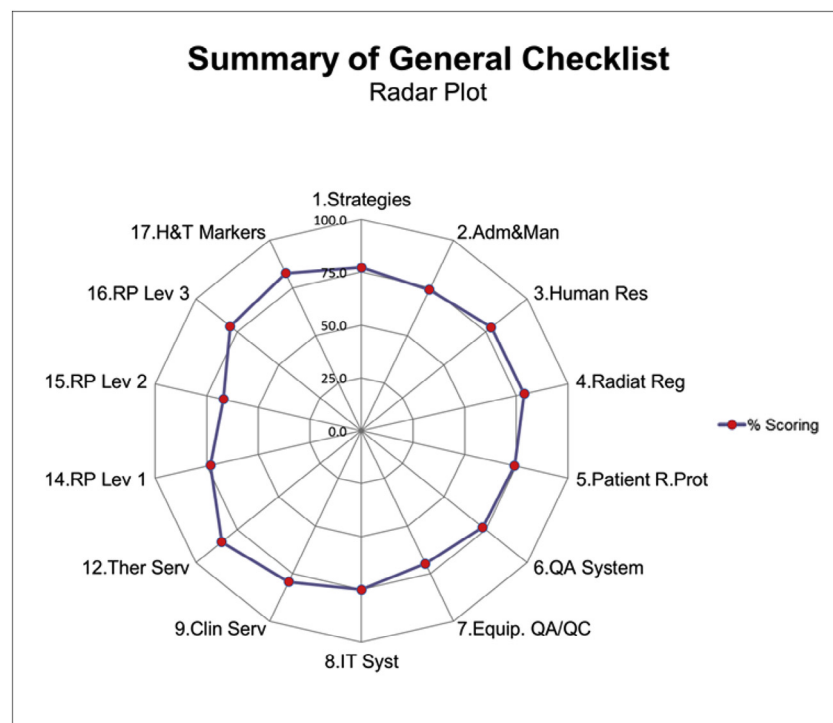


Figure 1 Example of a radar plot graphically representing results from one of the audits.

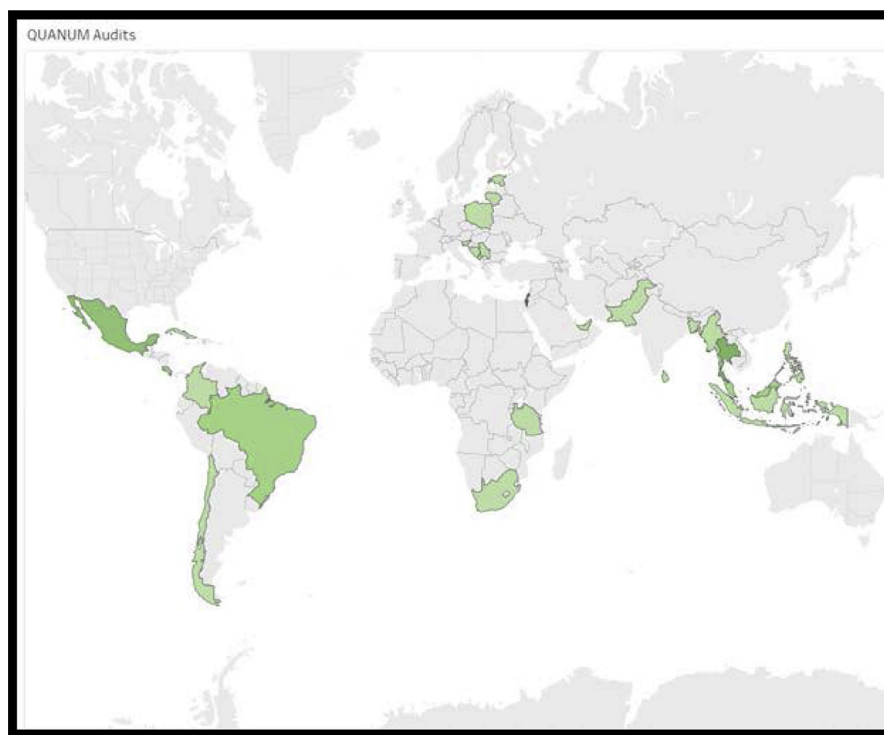


Figure 2 Geographical distribution of audited centers.

in emerging economies. This paper reports overall results from that analysis.

Materials and Methods

This retrospective analysis covered 42 QUANUM audit missions carried out in 39 centers, from 2008 to 2016. By geographical area, 6 centers were audited in Central Europe, 11 in Latin America, 19 in Asia, and 2 in Africa (Fig. 2). Three centers (two in Asia and one in Latin America) had a follow-up mission. Because in the latter cases only results from the second audit were considered, and out of the total of 42 missions one report could not be retrieved, eventually 38 reports were assessed.

As the original QUANUM program was revised within the period under investigation, out of the 38 reports, 16 have been prepared using version 1 of the QUANUM v1 checklists,⁶ and the remaining 22 using QUANUM v2.⁷ Because during the process of revising the QUANUM program the checklists were also slightly modified, for the purpose of this analysis, results from QUANUM v1 checklists have been carefully reorganized to be comparable with data from QUANUM v2.

Depending on the level of adherence to each required standard, checklists allow the grading of the LoC. Therefore, each item could be graded as not applicable (eg, when radioimmunoassay determinations are not carried out in the audited center); 0 (absent); 1 (planned or approximate); 2 (partially conform or partially implemented); 3 (largely conform or largely implemented); or 4 (full conformance). Items scored 0, 1, and 2 are considered non-conformance (NC); items scored 3 and 4 are considered conformance. For each audited center,

the level of adherence to standards (LoC) is assessed as the percentage of the total score received by the auditors toward the maximum achievable score, calculated as the number of applicable questions multiplied by 4, which is the maximum achievable score for each requirement. The program provides the score for each individual checklist, as well as the overall total score.

Almost all checklists were found to be applicable in all audited institutions, with the exception of the “Tumour and Hormones” checklists, applicable in only eight centers. Radionuclide therapy was not applicable in only two centers. The checklist for the assessment of Radiopharmacy Level 3 was introduced only with the QUANUM v2 spreadsheets and, because only few centers reached that high level of practice, data could be collected in only six of the 22 centers audited with QUANUM v2. Statistical analysis was run using the Mann-Whitney *U* test.

Results

Comparison of QUANUM v1 and v2 Checklists and Analysis of the Levels of Conformance

It was found that the mean LoC from QUANUM v1 was $73.0 \pm 25.1\%$ (range: 49.9%–92.0%), whereas the mean scoring of the QUANUM checklists v2 was $73.6 \pm 23.3\%$ (range: 61.6%–87.8%). The Mann-Whitney *U* test showed no statistically significant difference ($P = 0.26$).

After data from QUANUM v1 checklists were reorganized to be comparable with QUANUM v2 data, combined overall results were assessed. LoCs and level of NC per checklist, expressed as percentages, are reported in Figure 3.

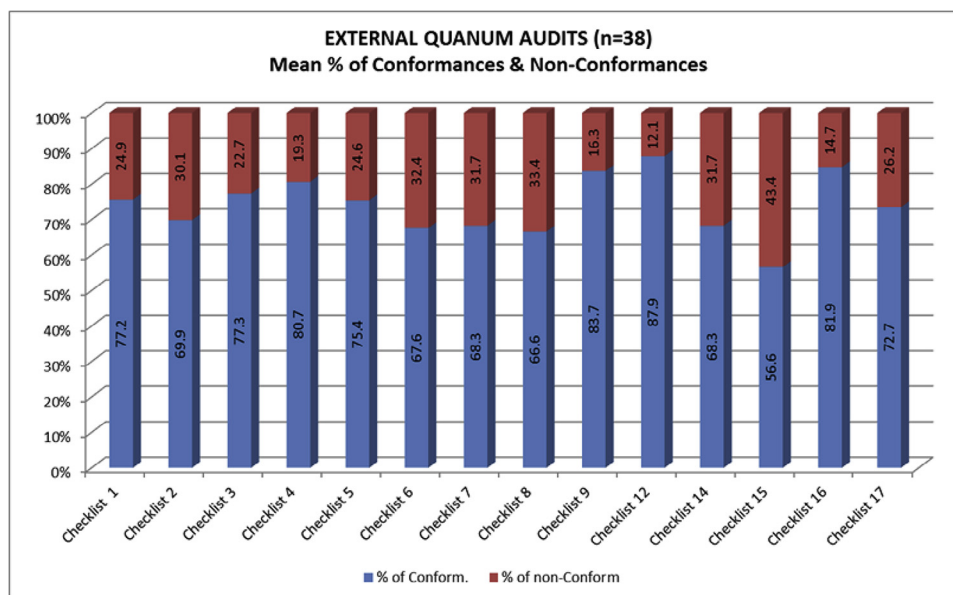


Figure 3 Average percentage of conformances and non-conformances per checklist.

Checklist 1: Strategies and policies; **Checklist 2:** Administration and management; **Checklist 3:** Human resources development; **Checklist 4:** Radiation regulations and safety compliance; **Checklist 5:** Radiation protection of patients; **Checklist 6:** evaluation of the quality management system; **Checklist 7:** Quality control for imaging equipment; **Checklist 8:** Computer systems and data handling; **Checklist 9:** General diagnostic clinical services; **Checklist 12:** General radionuclide therapy; **Checklist 14:** Radiopharmacy operational level 1; **Checklist 15:** Radiopharmacy operational level 2; **Checklist 16:** Radiopharmacy operational level 3; **Checklist 17:** Hormone and tumor markers

Note: Checklists 10, 11, and 13, related to clinical practice, do not appear here as they were introduced with QUANUM v2 and are treated separately.

Overall, audited centers showed a good LoC, $73.4 \pm 23.3\%$ (mean ± 1 standard deviation [SD]), ranging between 56.6% and 87.9%. We considered a level of 70% or more as good level of practice.

The checklists on clinical requirements related to diagnostic procedures as well as therapeutic procedures showed the highest LoC, respectively, as high as 83.7% and 87.9%. Radiopharmacy level 3 had an average conformance value of 81.9%. On the other hand, Radiopharmacy Level 2 (checklist #15), Computer Systems and Data Handling (checklist #8), and Quality Assurance Systems (checklist #7) showed the lowest values of conformances (56.6%, 66.6%, and 67.6%, respectively). The standard deviation for each independent checklist ranged between 10.6% and 34.3%, showing a great variability among the audited centers. The checklist related to information technology and computer systems showed the highest data dispersion.

Prioritization of Non-conformances

The QUANUM methodology requires that auditors, when preparing the final report, prioritize NCs, depending on the impact they may have on safety and daily practice. They are therefore converted into priorities, which are classified as (1) critical, when they pose a major threat to patients, to staff, or to the environment itself, and should be addressed immediately; (2) major, when corrective actions should be implemented in 3-6 months; and (3) minor, when they could be addressed in the medium term.

As several NCs observed in different checklists may have a single root cause, for the purpose of this analysis, the derived recommendations expressed as critical and major priorities have been reclassified into nine main topics. For example, all documentation issues, such as lack of standard operating procedures (SOPs), were grouped into category 1 (managerial, organization, and documentation), as seen in Table 1, which is a summary of the nine main topics and their distribution. Out of a total of 1687 recommendations, 880 (52%) were classified either as critical (276; 16%) or major (604; 36%) priorities. The average number of critical findings per audit was 7.3 (range 1-25), and of major findings was 15.9 (range 0-40). It is clear that the number of nonconformities per site varied significantly.

Evaluation of Clinical Services

The QUANUM v2 checklist allows collecting detailed information on specific imaging and therapeutic procedures from each audited nuclear medicine service (Fig. 4A and 4B). This is done analyzing up to five cases and their reports, randomly selected, and assesses them against (1) clinical information collected at referral; (2) technical procedure; (3) patient preparation; (4) quality assurance/quality control (QA/QC) of both radiopharmaceutical and instrumentation; and (5) reporting and follow-up. The mean scoring estimated from the imaging procedures checklists was 81.0% (SD $\pm 22.3\%$), with a minimum value of 25.5% and a maximum of 100%. Patient preparation requirements have

Table 1 Itemization of the Main Recommendations (Critical and Major) and Their Distribution

Nr	Item	Critical and Major Priorities	(%)
1	Managerial, organization, and documentation	229	26.0%
2	Education and training	42	4.8%
3	Patient radiation protection and safety	78	8.9%
4	Staff radiation protection and safety	152	17.3%
5	QA/QC and management of equipment and SW	100	11.4%
6	Human resources	32	3.7%
7	Radiopharmaceutical preparation, dispensing, and handling	139	15.8%
8	Clinical procedures (diagnostic and therapeutic)	35	4.0%
9	Facility design	73	8.3%
	Critical (total)	276	
	Major (total)	604	
	Overall (total)	880	
	No. of audits	38	
	Average no. of critical and major priorities notified per center	~23	

been found to have the highest average of conformances (85.3%), whereas numerous opportunities for improvements were identified in the area of QA/QC procedures of both instrumentation and radiopharmaceutical preparations (76.1%).

As concerns radionuclide therapy, it reached an average of 82.8% (SD \pm 22.2%) of conformances, with a minimum value of 37.5% and a maximum of 100%. Patient preparation also showed the highest score of the clinical activities, whereas the reporting and follow-up activities presented the highest opportunities for improvement.

Discussion

The analysis of QUANUM audit reports has shown interesting aspects related to quality management in nuclear medicine practices in IAEA Member States. It appears that the QUANUM program can be applied in a wide variety of nuclear medicine practices, irrespective of geographical area and of socioeconomic conditions. There was a great variability in the size and level of the audited institutions, from relatively small centers equipped with only one SPECT system and performing limited diagnostic imaging procedures, to large institutions with SPECT/CT, PET/CT, cyclotron and radiopharmacy, radioimmunoassay laboratories, and large radionuclide therapy services.

Prioritization of NCs produced 880 critical and major recommendations, as well as 807 minor ones. Overall, the highest percentage (26.0%) of critical and major recommendations were found in item #1, that is, managerial, organization, and documentation (Table 1). This is partially owing to the decision to classify all nonconformities generically because of inadequate development of quality systems, that is, written procedures, record-keeping, follow-up of deviations and complaints, training, qualification and validation, SOPs, records etc., into one single category, namely category #1. SOPs are in general lacking or, when present, not easily available to staff, not updated in accordance with international standards, or not applied in daily routine practice. Procedures are

often carried out based on “word of mouth” instructions. This clearly does not ensure a standardized practice and contradicts the requirements of a quality management system (QMS).

Checklist 3 (human resources) produced 22.7% of non-conformities, but only 3.6% of recommendations related to it (item # 6; Table 1). The high LoC (77.3%) in this category, however, is mainly owing to an adequate staffing of physicians and technologists. However, the structure of the checklist does not allow fully representing the frequent complaint of understaffing of qualified radiopharmacists and medical physicists, despite having been reported in 44% and 28% of audited institutions, respectively.

This fact raises a major concern as the consequences of a lack of qualified personnel in medical physics and radiopharmacy are reflected by the relatively higher number of NCs in two related fields.

One of those two fields is “radiation regulation and safety,” with 19.3% of NCs, as medical physicists are usually responsible for radiation protection. The second area of concern is related to “radiopharmaceuticals preparation, dispensing, and handling” (item # 7; Fig. 3). In this field, recommendations are rated as high as 15.8%, and certainly the absence of a qualified radiopharmacist has an impact on these activities. The same considerations apply to the finding that, out of the 73 nonconformities concerning facility design; the majority were related to radiopharmacy layout and patient waiting areas.

When safety and radiation protection in general are considered, interesting observations arise when we compare NCs with recommendations arising from their prioritization (Table 2).

Although the level of NCs recorded by the auditors averaged 25.5% of the requisites of checklist #5 “radiation protection of the patient,” this produced only 8.9% of the recommendations (item #3, Fig. 4). This implies that the observed NCs were of minimal impact and probably could be solved with a simple optimization of the procedures. The same does not apply to checklist #4 “radiation regulations and safety compliance” (Fig. 4); here, the level of NCs averages 19.3%, and the corresponding rate of recommendations was as high as 17.3% (item #4; Fig. 4), representing in this case the

Table 2 Translation of NCs Into Critical and Major Priorities and Recommendations

Item	% of Non-Conformances	% of Recommendations
Checklist 3: Human resources development	22.7%	3.7%
Checklist 4: Radiation regulations and safety compliance	19.3%	17.3%
Checklist 5: Radiation protection of patients	24.6%	8.9%

observation of severe deviations from standards and were flagged as such by the audit team.

If we furthermore consider that recommendations regarding clinical services (item #9; Fig. 4) are 8.3% of the total, it appears that slightly more than one third of the recommendations are linked to missing or inadequate procedures related to safety and radiation protection in general (poor area classification; lack of supervision for staff monitoring or lack of dosimeters for the extremities; lack of proper monitoring of workplace contamination, etc.).

As regard radiopharmacy, it should be noted that at operational level 1, all the NCs were related to the lack of SOPs and the specific training in the field, as well as to a lack of QA/QC procedures. At operational level 2, the number of NCs tends to increase, because NCs related to this operational level, such as lack of specific equipment (eg, laminar airflow cabinets) are added to those of operational level 1, which still apply. However; when a radiopharmacy reaches operational level 3, the number of NCs decreases: at this level SOPs, training and equipment are typically in place, and the number of NCs is the lowest of all the checklists. This shows that centers with complex and high-level radiopharmacy activities are adequately funded, and the corresponding equipment and necessary human resources are generally available.

On the other hand, checklists related to clinical activities, both diagnostic and therapeutic, showed a high LoC. Although the average percentages of conformances for each of the 14 general checklists showed a mean value of $73.4 \pm 23.3\%$ (mean \pm 1 SD), audits of diagnostic and therapeutic procedures found the highest LoCs and homogeneity, with values

of 83.7% and 87.9%, respectively. It might well be that medical practitioners, who usually also have managerial responsibilities, tend to focus more on clinical activities, including staffing, while putting less priority on nonclinical areas, as they are felt as having a limited impact on patient care. Another possible explanation could be the reluctance of administrators to fund additional academic personnel perceived as less essential.

It might also be that the structure of the audit process of clinical activities, limited to a few observations and a short period when everybody is aware of the audit, does not investigate in sufficient depth. The technique to evaluate this specific category may have to be reviewed and extended to include more aspects related to clinical practice. Indeed, clinical and therapeutic parameters measured in the appropriate checklists are relatively basic and restricted to the formal processes. Purely medical aspects such as the diagnostic quality of reports, the relationship with referring physicians or the role of nuclear medicine representatives in multidisciplinary conferences are not evaluated, as this kind of assessments would go far beyond the role and authority of the auditing team.

Conclusions

For any nuclear medicine service, the adoption of a QMS should be a strategic decision taken with the aim of improving the standard of care provided. The design and implementation of a QMS is influenced by various needs and

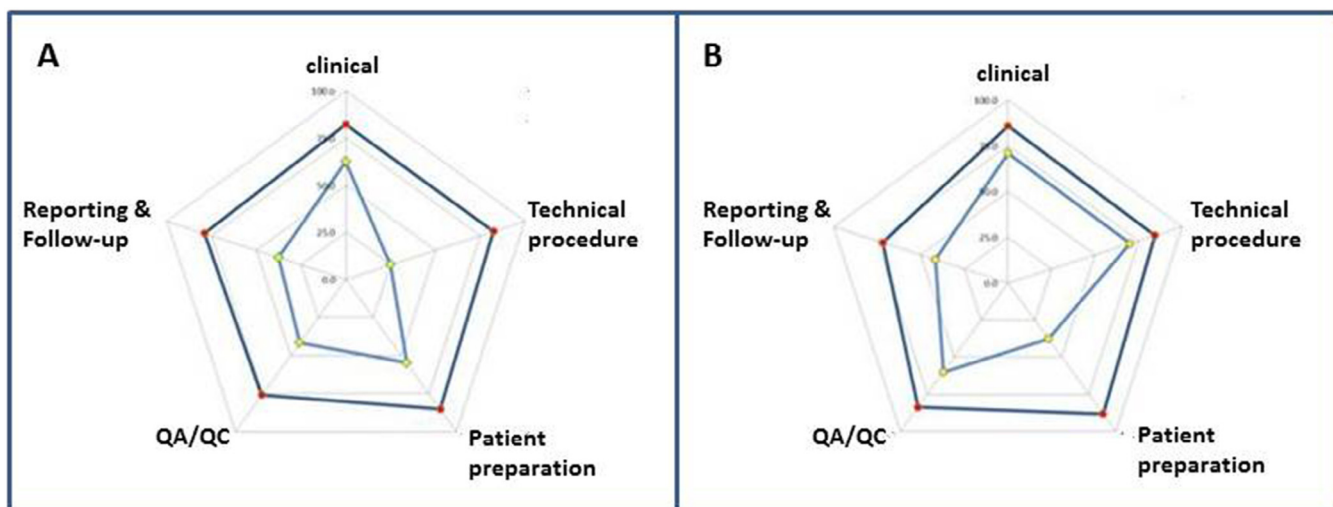


Figure 4 Radar plots representing the summary of imaging (A) and therapy procedures (B). Red dots represent the average score; yellow dots the lowest score.

constraints, particular objectives, the nature of services provided, the processes employed, and the size and structure of the nuclear medicine facility. QMSs should be implemented, documented, and duly maintained; effectiveness should be continuously improved in accordance with the requirements of professional, regulatory, and accrediting bodies.

From the experience gathered through the IAEA QUANUM program, the area of clinical services rendered to patients is the one with the highest degree of compliance with required standards, whereas issues related to radiation protection of both staff and patients require more attention. This should be considered as important feedback to the IAEA as regard the effective translation of Basic Safety Standards²⁷ recommendations into routine practice.

More specific training on preparing SOPs should be provided, and stricter adherence to them should be encouraged when they are available. If not available, they should be created to ensure smoother and standardized daily activities. Implementing a practice of periodical internal audits and, when needed, follow-up external audits will most likely also improve radiation protection issues without need for major investments.

Because of the inherent nature of a self-assessment program, which is the first step of this audit program, QUANUM should also result in the introduction of a culture of periodic self-auditing and continuous improvement.

To assess the outcome of the program, in terms of improved compliance with stated standards, audited centers will be invited to run a new self-assessment through the Excel tool. This part of the project is underway and will be reported on shortly.

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