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Implementation of Quality Systems in Nuclear Medicine: Why It Matters. An Outcome Analysis (Quality Management Audits in Nuclear Medicine Part III)

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The International Atomic Energy Agency (IAEA) developed a comprehensive program—Quality Management Audits in Nuclear Medicine (QUANUM). This program covers all aspects of nuclear medicine practices including, but not limited to, clinical practice, management, operations, and services. The QUANUM program, which includes quality standards detailed in relevant checklists, aims at introducing a culture of comprehensive quality audit processes that are patient oriented, systematic, and outcome based. This paper will focus on the impact of the implementation of QUANUM on daily routine practices in audited centers. Thirty-seven centers, which had been externally audited by experts under IAEA auspices at least 1 year earlier, were invited to run an internal audit using the QUANUM checklists. The external audits also served as training in quality management and the use of QUANUM for the local teams, which were responsible of conducting the internal audits. Twenty-five out of the 37 centers provided their internal audit report, which was compared with the previous external audit. The program requires that auditors score each requirement within the QUANUM checklists on a scale of 0-4, where 0-2 means nonconformance and 3-4 means conformance to international regulations and standards on which QUANUM is based. Our analysis covering both general and clinical areas assessed changes on the conformance status on a binary manner and the level of conformance scores. Statistical analysis was performed using nonparametric statistical tests. The evaluation of the general checklists showed a global improvement on both the status and the levels of conformances ($P < 0.01$). The evaluation of the requirements by checklist also showed a significant improvement in all, with the exception of Hormones and Tumor marker determinations, where changes were not significant. Of the 25 evaluated institutions, 88% (22 of 25) and 92% (23 of 25) improved their status and levels of conformance, respectively. Fifty-five requirements, on average, increased from nonconformance to conformance status. In 8 key areas, the number of improved requirements was well above the average: Administration & Management (checklist 2); Radiation Protection & Safety (checklist 4); General Quality Assurance system (checklist 6); Imaging Equipment Quality Assurance or Quality Control (checklist 7); General Diagnostic (checklist 9); General Therapeutic (checklist 12); Radiopharmacy Level 1 (checklist 14); and Radiopharmacy Level 2 (checklist 15). Analysis of results related to clinical activities showed an overall positive impact on both the status and the level of conformance to international standards. Similar results were obtained for the most frequently performed clinical imaging and therapeutic procedures. Our study shows that the implementation

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of a comprehensive quality management system through the IAEA QUANUM program has a positive impact on nuclear medicine practices.
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Introduction

In the last decades, the importance of providing the best possible medical services as well as the need for standardization has been increasingly recognized among health-care providers and patients.[1,2]

The International Atomic Energy Agency (IAEA) is a member of the United Nations system with the mission of fostering peaceful applications of nuclear techniques in several fields, including human health.[3] Through its Human Health Division,[4] the IAEA has developed a program on Quality Management Audits in Nuclear Medicine Practices (QUANUM),[5,6] to help its member states verify the status of their nuclear medicine practices and their adherence to international reference standards.[7-25]

The QUANUM program has been described in detail.[26] In summary, the program aims at promoting a culture of continuous improvement of quality management aspects of nuclear medicine practice as a whole, including thorough training on this matter, through implementation of internally managed self-audits. Unlike other approaches to quality improvement, the QUANUM program includes detailed checklists, very specific to nuclear medicine and covering all aspects of its practice, including clinical applications, radiopharmacy, general and radiation safety, and quality assurance (QA) or quality control (QC) of instruments. They also establish the minimal requirements to be conformant to internationally recognized quality standards for the covered areas. Before implementing any external audit, centers are requested to self-assess their practices by completing the checklists, and then a qualified team of external auditors is fielded to conduct an independent confirmatory audit working in close contact with local counterparts. External auditors will independently score each requirement of applicable checklists and at the end of the mission; the team provides recommendations that are discussed with local counterparts during the exit briefing. Based on those recommendations, an action plan including corrective actions and their implementation are agreed upon.

The rationale of the QUANUM program is based on the assumption that meeting the recommendations set out by the team of auditors and implementing the corrective actions defined during the first external audits would help the audited centers meet international quality standards and contribute to enhancing their clinical practice. Results and findings from a first batch of external audits have been published.[27]

However, to claim that a program of this kind is effective requires proving that its application has a positive impact on the audited centers. To this purpose, nuclear medicine centers that underwent an external audit through the QUANUM program for the first time at least 1 year before were requested to conduct an internal follow-up audit and provide results of this new self-assessment.

The current study aims at evaluating the impact of QUANUM implementation on the quality of nuclear medicine services based on change in adherence to previously set reference standards.

Materials and Methods

At the time of the beginning of this study, 37 centers qualified for re-evaluation. Those centers were invited to run an internal follow-up internal audit, which is a fundamental part of the QUANUM process. Twenty-five centers (67%) replied and provided their new self-assessment. Figure 1 represents their worldwide distribution.

Both internal and external audits are based on the QUANUM program checklists,[28] which require that, according to the level of implementation, each requirement is scored from 0 (absent) up to 4 (full conformance) or reported as not applicable. Scores 0, 1, and 2 of applicable items are considered nonconformance, whereas scores 3 and 4 are considered conformance. As explained elsewhere,[27,28] the overall results are graphically presented as radar plots built on the conformance level reached for each area. It should be noted that results related to general checklists (from 1 to 9, 12, and from 14 to 17) are presented independently from those related to clinical practice (from 10.1 to 10.5, from 11.1 to 11.3, and from 13.1 to 13.3).

For the outcome assessment, we compared how the nuclear medicine services met the QUANUM requirements during the follow-up audit with the results of the first mission, after addressing recommendations and implementing corrective actions. For each requirement, the pair of answers recorded from the first and follow-up audits were carefully checked and validated before comparison. For instance, requirements, which in the initial audit were graded as not applicable but became applicable in the follow-up self-assessment, or the other way around, were not considered. Eventually, the total number of validated pairs of requirements amounted to 6915, of which 4990 belonged to checklists 1-9, 12, and 14-17, covering general components (administration; policies; safety and radioprotection; physics, including aspects of dosimetry and quality assurance of equipment; radiopharmacy, including management, training, procedures, quality assurance; etc) whereas the remaining 1925 belonged to checklists 10.1-10.5, 11.1-11.3, and 13.1-13.3, covering the clinical components, including overall supervision of patient management and of all technical and QA aspects,[29,30] and a significant focus on standardization and quality of the final report.

This analysis was carried out on the 25 surveyed centers, focusing on 2 parameters:

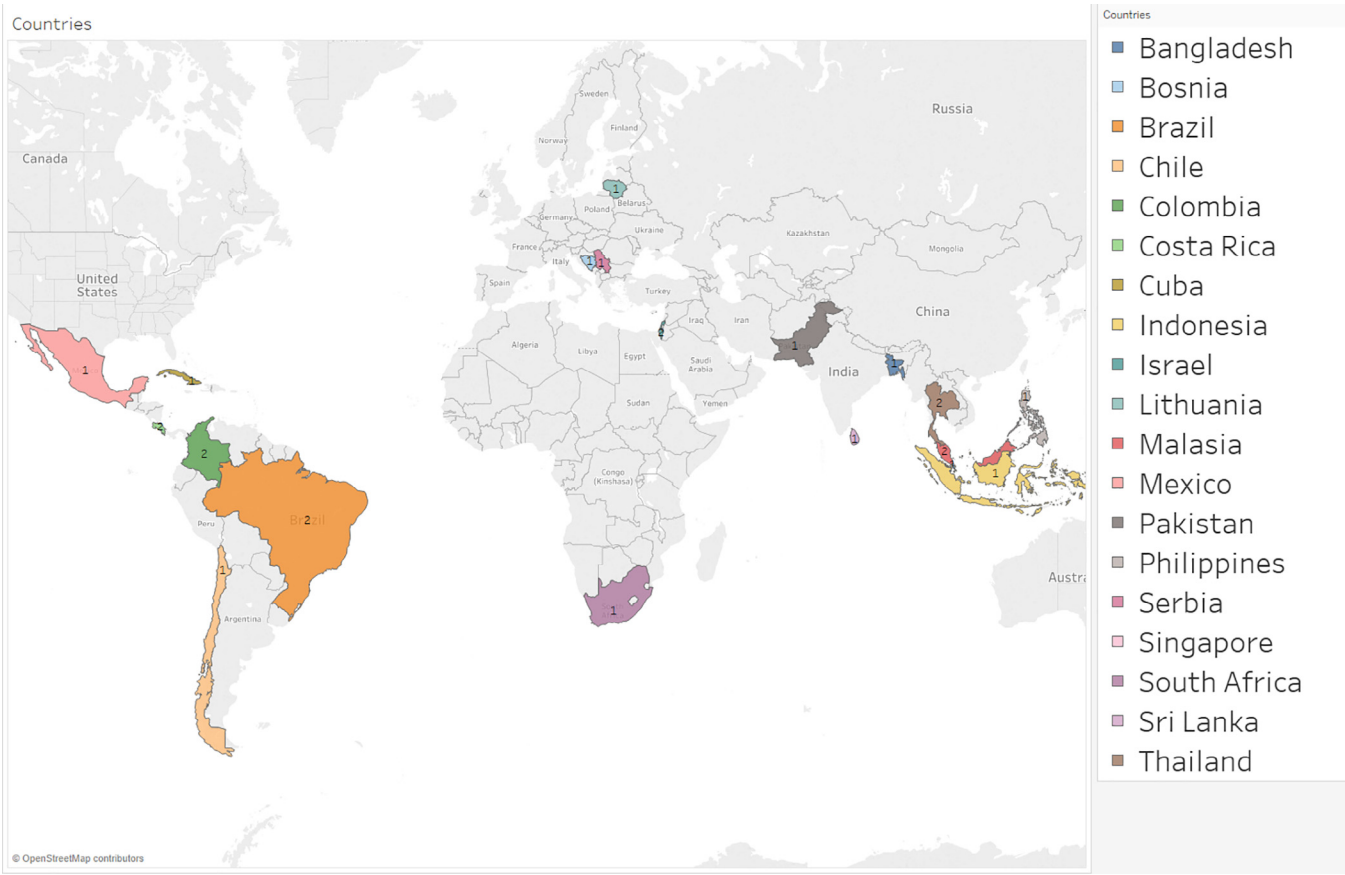

Figure 1 Worldwide distribution of audited centers (country level). Numbers are related to the number of audited centers within each country.

- changes of the *Status* of conformance, to verify how many requirements, previously classified as nonconformance, were up-scored to conformance, or vice versa. It was expected that most of the registered changes were in a positive direction from nonconformance to conformance.
- changes of *Level* of conformance of each requirement, that is, their ranking, as indicated by the overall scores reached using the previously described grading system 0-4.[3,4] This approach allows detecting any improvement or worsening of the quality systems even within the same conformance status. It was expected that it would change toward higher scores.

The implementation of the action plan defined at the end of the initial external audit was expected to increase not only the number of conformances but also their *levels*.

Statistical Analysis

Nonparametric statistical tests were used to assess changes in the status and levels of conformance of the requirements set out by the QUANUM program. This choice of test was based on the nature of the available data. The status of conformances was recorded on a dichotomous variable and the levels of conformance in ordinal values from 0 to 4. Moreover, some of the evaluated samples had a reduced size. Taking into account that the compared sets of data were collected from the same services at 2 different moments, they were considered paired or repeated observations. Therefore, the McNemar and the Wilcoxon signed rank tests were used for the statistical analysis of the changes in the status and levels of conformances, respectively.

The Wilcoxon signed rank test allowed considering the magnitude of the level of conformance changes for the evaluated pairs of requirements. Differences between the first and the follow-up audits were based on the following criteria: not significant if $P > 0.05$, significant if $P < 0.05$, and very significant if $P < 0.01$. For the analysis of results, the number of positive and negative changes, number of ties, number of ranks, and rank sums were used as complementary data. Two-tailed tests and 1-tailed tests were used according to the required data analysis for the evaluated hypothesis. Statistical analysis was performed using SPSS Statistics for Windows, version 22.0, released 2013 (IBM Corp, Armonk, NY).

For both general and clinical checklists, the overall evaluation covers the whole sample, where changes in all validated pairs of requirements are considered. This is followed by a stratification of the analysis at the level of institutions and for each independent checklist. Finally, to verify the impact of the program on clinical practice, samples of routine clinical studies are checked and a comparison of their level of conformance to international standards and regulations is also carried out.

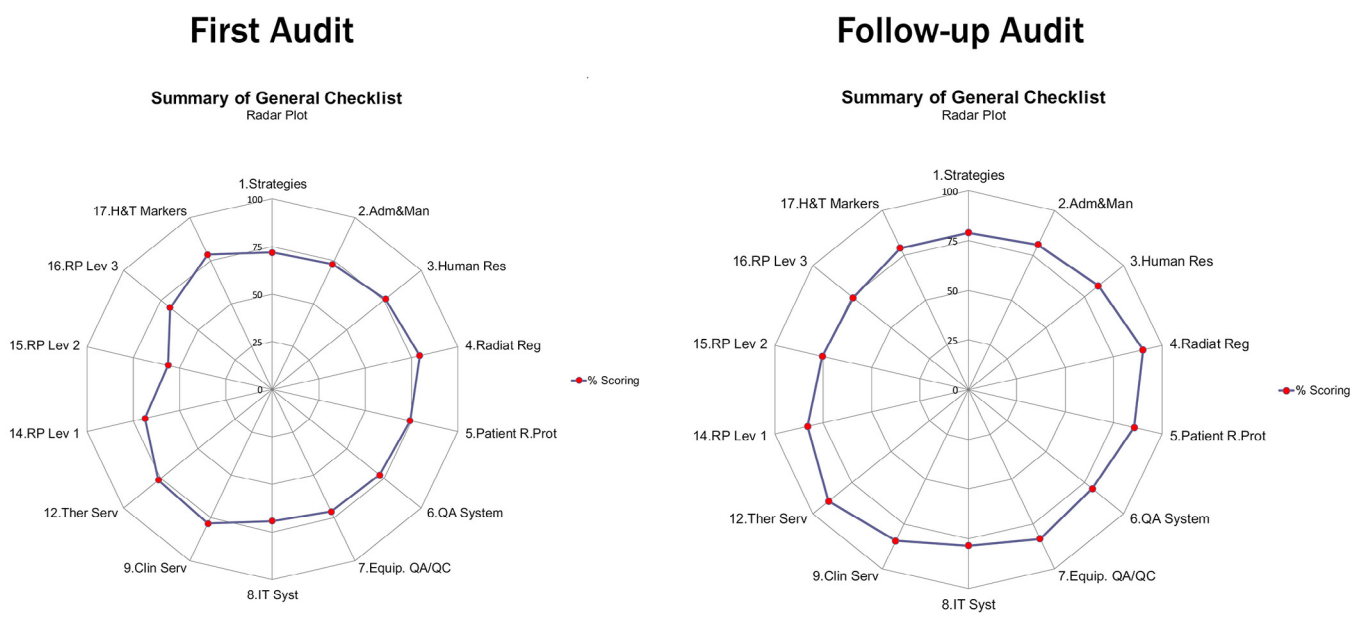

Figure 2 Radar plots computed from 25 institutions showing the general improvement on key areas from the first to the follow-up audit.

Results

Our analysis compares the validated pairs of results and their differences, if any, between the results of the follow-up audit run by teams of internal auditors and those from the first audit run by the teams of external auditors. For the purpose of our study, an analysis of general checklists was carried out at global and specific levels, as well as a specific analysis of clinical procedures.

Global Analysis of General Checklists

This analysis covers the requirements from the 14 general checklists collected from the 25 re-assessed institutions and is based on the global analysis of the changes of each pair of results. The average total score expressed as a percentage of the maximum achievable score improved from 73.2% to 83.2% ($P < 0.01$), as visually reflected by an increase of the area inside the radar plots built from the full statistic of the audit results[3] shown in Figure 2.

Adherence to the international standards taken as reference from the QUANUM program,[4] and shown by the status of conformance, shows that out of the 4990 validated pairs of requirements, a total of 879 (17.6%) modified their conformance status. An overall very significant improvement in the status of conformance between the external and the internal follow-up audits ($P < 0.01$) was detected. Indeed, out of those 879 cases, which modified their status of conformance, in 770 (86%) there is an upstage from nonconformance to conformance, whereas the remaining 109 changes (12%) are in a negative direction, from conformance to nonconformance (Figure 3). The remaining 4111 requirements were ties, that is, did not show any modification. An overall very significant improvement in the status of conformance between the external and the internal follow-up audits ($P < 0.01$) was detected.

Specific Analysis of General Checklists

To assess which areas are more significantly affected by the QUANUM program, a detailed evaluation of general checklist was also carried out, with key areas 1-9, 12, 14, and 15 showing very significant improvements ($P < 0.01$) in their *Level* of conformance, as reflected by the score obtained, whereas checklist 16 (radiopharmacy level III) showed a significant improvement ($P < 0.05$). Only checklist 17, related to Hormones and Tumor markers determinations, did not show any significant change ($P = 0.816$).

As regards the changes of the *Status* of conformance, key areas 1-9, 12, and 14-16 present a significantly ($P < 0.05$) or very significantly ($P < 0.01$) higher number of conformances in the follow-up audit. As for the level of conformance, checklist 17, related to Hormones and Tumor markers, also showed a no significant difference ($P = 0.188$) between the

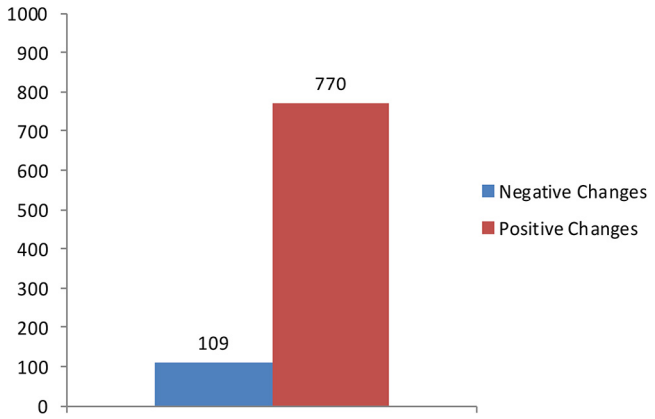

Figure 3 Global number of positive and negative changes of the status of conformance, for requirements of checklists 1-9, 12, and 14-17.

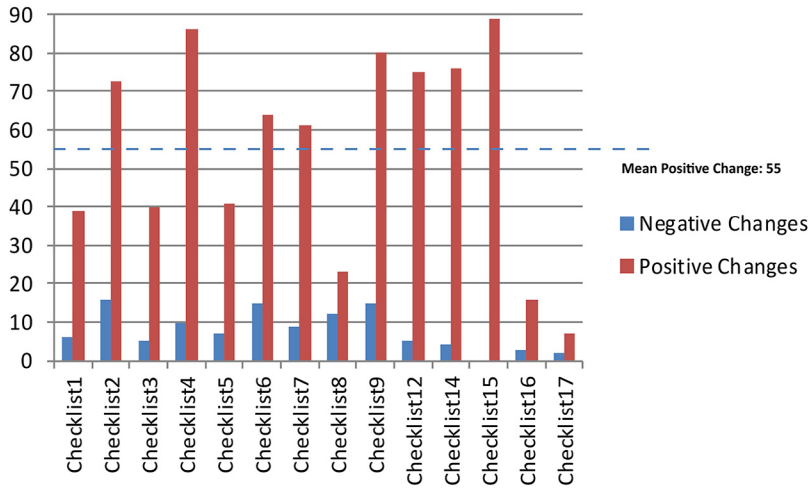

Figure 4 Changes of the conformance status for specific activity fields as reflected by checklists. Checklist 1: Strategies; Checklist 2: Administration & Management; Checklist 3: Human Resources; Checklist 4: Radiation Protection & Safety; Checklist 5: Patient Radiation Protection; Checklist 6: General QA system; Checklist 7: Imaging Equipment QA/QC; Checklist 8: IT Systems; Checklist 9: General Diagnostic; Checklist 12: General Therapeutic; Checklist 14: Radiopharmacy Level 1; Checklist 15: Radiopharmacy Level 2: Checklist 16: Radiopharmacy Level 3; and Checklist 17: Hormones and Tumor markers (H&T).

2 audits. Figure 4 shows the magnitude of changes, both positive and negative, of the conformance status for checklists 1-9, 12, and 14-17. The number of positive changes ranged from as low as 7, for checklist 17 (Hormones and Tumor markers), and up to a maximum of 89 for checklist 15 (Radiopharmacy Level 2). The mean number of changes is 55, with 8 key areas above this value, namely Administration & Management (checklist 2); Radiation Protection & Safety (checklist 4); General QA system (checklist 6); Imaging Equipment QA or QC (checklist 7); General Diagnostic (checklist 9); General Therapeutic (checklist 12); Radiopharmacy Level 1 (checklist 14); and Radiopharmacy Level 2 (checklist 15).

Based on the changes in conformance levels in the 25 surveyed institutions, our study shows a very significant improvement ($P < 0.01$) in 23 (92%) between the 2 audits, together with a prevalence toward higher values. Only 2 institutions (number 6 and 22) maintained a similar performance without any significant difference ($P > 0.05$), (Fig. 5), with virtually no changes for institution 22 and a comparable number of positive and negative changes for institution 6.

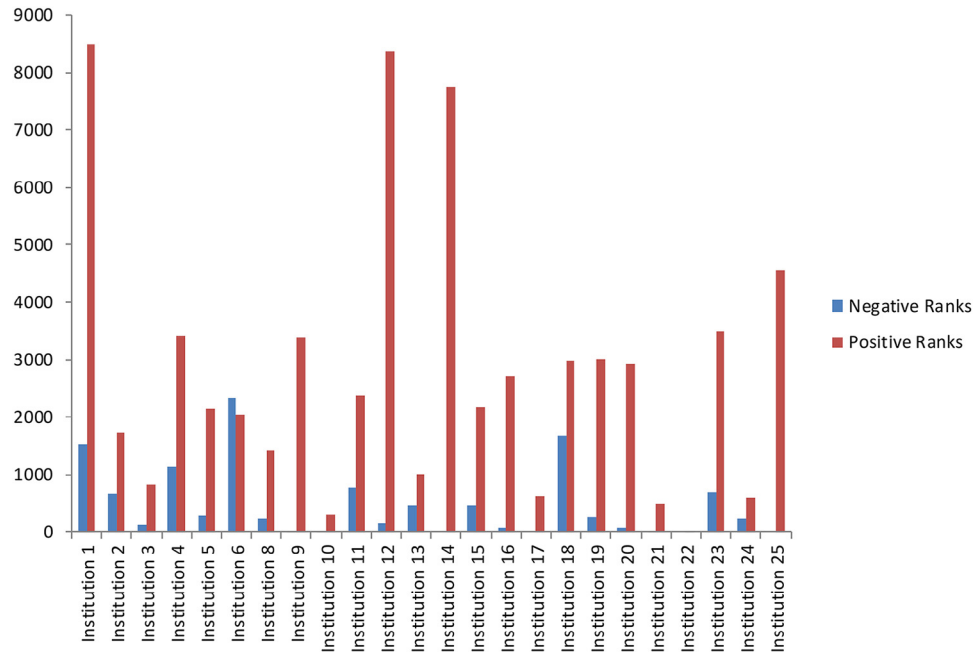

Figure 5 Magnitude of level of conformance changes between the first and the follow-up audits by institution as reflected by the sum of ranks.

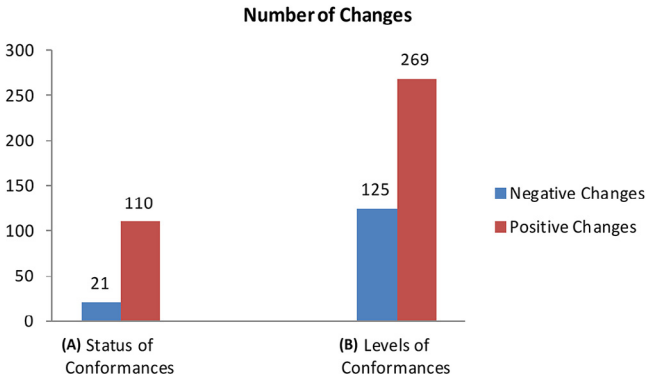

Figure 6 Changes of the conformance status (A) and of conformance levels (B) in clinical checklists.

Specific Analysis of Clinical Checklists (10.1-10.5; 11.1-11.3; 13.1-13.3)

Adherence of clinical practice to international standards was assessed, collecting detailed information on 5 randomly selected clinical procedures through specific checklists for a total of 1925 requirements. In comparison with baseline audits, change of conformance status was found in 131 cases. Out of those, 110 (83.9%) changed from nonconformance to conformance (Fig. 6A). These results reflected a very significant improvement ($P < 0.01$).

The evaluation of the changes of the conformance levels was also carried out on clinical checklists. Figure 6B shows an increase of the level of conformance in 269 items (positive changes) and a decrease in 125 (negative changes). Statistically, the improvement is also very significant ($P < 0.01$).

The impact of the implementation of the QUANUM program on clinical practices by field of activity, that is, imaging, nonimaging, and therapy, was also analyzed. A very significant ($P < 0.01$) improvement of the conformance status was found for the imaging and therapy fields (Fig. 7), whereas no significant modifications could be observed in the nonimaging field ($P = 0.125$).

During both the external and the follow-up audits, clinical practice is assessed by evaluating different types of diagnostic studies or therapeutic procedures, up to 5, in randomly selected patient files. For the present study, reports

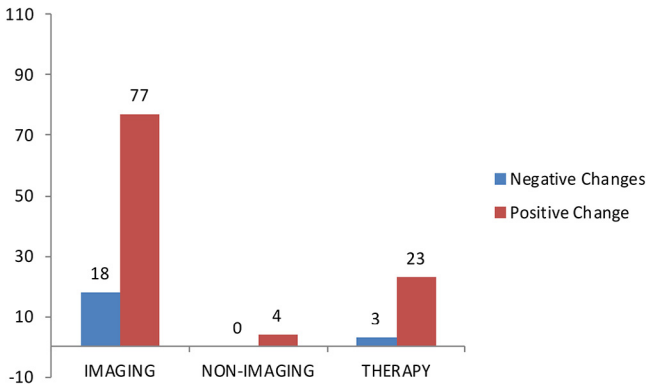

Figure 7 Number of positive and negative changes regarding the status of conformance by field of activities in the clinical areas.

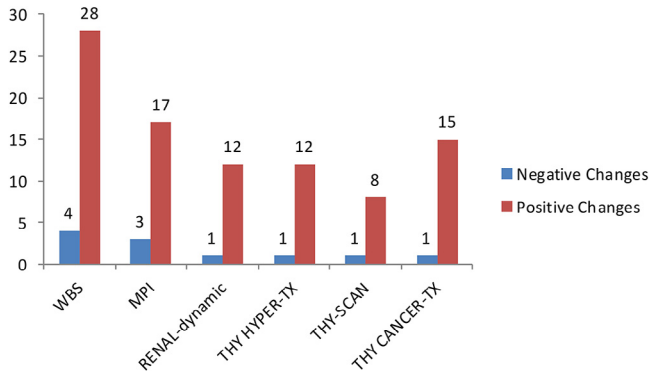

Figure 8 Types of studies showing a significant change in the conformance status. Hyper-Thy, treatment of benign thyroid conditions; MPI, myocardial perfusion imaging; RD, renal dynamic; Thy-Cancer-Tx, treatment of thyroid cancer; Thy-Scan, thyroid scanning; WBS, whole-body scan.

covered a total number of 20 different types of procedures. A significant improvement ($P < 0.05$) was detected for the more frequently performed diagnostic modalities, such as bone scans, renal dynamic studies, myocardial perfusion imaging, thyroid scans, and for treatment of both hyperthyroidism and thyroid cancer (Fig. 8).

Discussion

This work presents a quantitative assessment of the outcomes of the systematic application of an IAEA comprehensive program of quality assurance in nuclear medicine called QUANUM. This evaluation is based on 2 parameters: (1) change of the *Status* of conformance or nonconformance of each requirement to previously set standards, and (2) the relative change in the score used to grade the *Level* of conformance. Indeed the 2 parameters are strictly connected, as there cannot be improvement in status of conformance without improvement in the level of conformance (ie, its score). However, there might be an increase of the conformance level from 0 to 2, for example, which is still considered nonconformance despite the improvement. Therefore, assessing changes in the level of conformance provides a more detailed vision.

Overall we have seen a very significant improvement in both the levels and the status of conformance for the general checklists as shown in Figures 2 and 3. In our opinion, this is evidence that through the QUANUM program the auditors efficiently identified the main areas of weakness and that the corrective action plans that were agreed upon at the end of the audits were effectively implemented with very positive impact on many key areas.

The highest impact of the implementation of action plans is found in the field of radiopharmacy services, both levels 1 and 2, which had the lowest conformance levels during the initial external audit. This could be considered as a contribution of the QUANUM to a worldwide ongoing process of rising of the standards of quality in the production and use of radiopharmaceuticals, following the full recognition of these

products as pharmaceuticals in several countries or international regulatory agencies.

The area of radiation protection and safety (checklist 4) also showed a sharp increase on the status of conformance at follow-up that is particularly relevant considering the importance of radiation protection issues for staff, patients, and public. Furthermore, radiation safety aspects are heavily regulated by national and international regulatory agencies, and compliance to the principles of optimization and practical implementation of the ALARA, that is, as low as reasonably possible, methodology, is mandatory.[31-34] In audited centers, the QUANUM has triggered a process of improvement and better application of already existing safety standards, making the working place safer for the staff and procedures safer for patients.

Other key areas such as general aspects of clinical imaging and therapeutic procedures, administration and management, as well as quality management systems implementation and QA or QC of imaging equipment showed significant improvements well above the mean number of positive changes, as shown in Figure 4. Some of these key areas have already been reported[28] as showing major deficiencies and as sources of many recommendations related to lack of standard operating procedures, structured records of QA or QC, and evidence of traceability of the whole quality management system. These findings emphasize the importance of preparing and maintaining an appropriate documentation system as a way to comply with international reference standards.

Almost all surveyed institutions improved their adherence to reference standards as shown by the increased number of conformances (Figure 4).

As concerns overall results on clinical practice, we have also found global improvements in both status and level of conformance related to the different types of audited procedures. When those procedures were grouped into 3 main fields of activities, namely, (1) imaging, (2) nonimaging, and (3) therapy (Figure 7), it was seen that imaging and therapy showed a significant improvement, whereas nonimaging procedures did not show a significant change, most likely because such procedures, except for sentinel node localization with probes, are rarely performed nowadays, and the size of the collected sample was too small.

Further detailed analysis of diagnostic (1) and therapeutic (3) procedures showed a significant improvement for the most commonly performed modalities (Fig. 8), whereas less frequently performed procedures showed no significant change, related with limited sample size.

The comment above, however, does not apply to positron emission tomography studies where no significant changes were revealed at the follow-up audit despite an adequate sample size. This finding might well be linked to the higher awareness of the need of a good quality management system in place when introducing complex and costly installations such as positron emission tomography-computed tomography and especially cyclotrons with their corresponding radiopharmacy laboratories. For this reason, the initial audit already showed high conformance levels.

Conclusions

The QUANUM program is the first example of a global approach to the implementation of quality management into the daily practice of nuclear medicine, with extensive coverage of the clinical aspects and related components of medical physics and radiopharmacy. To the best of our knowledge, there are no data published on such an experimental approach, and in many cases the outcomes of Quality Management Systems implementation are assumed or expected, but not directly observed and measured.

The present outcome-based study confirms the usefulness of the QUANUM program as a practical tool to implement a quality management system and raise the conformance to international guidelines, regulations, and standards, by implementing the recommendations given by experts at the end of the external audits.

These results speak in favor of introducing regular quality audit programs, including both internal and external periodic assessments, to improve adherence to national and international standards of quality, improving the quality of nuclear medicine practice and consequently meeting the requirements of accreditation bodies, regulatory authorities, and patient advocate organizations, therefore.

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