ABSTRACT
Audit is an ongoing review of all processes involving a particular service to ensure that each process is developed systematically and in accordance with specific regulations. The IAEA developed an internal audit process named QUANUM - Quality Management Audits in Nuclear Medicine and available in their website. This tool offers support to management quality audits, assisting teams in the evaluation of quality management system. QUANUM tool was developed based on the European Community guidelines and international recommendations. In order to be better applied in a country, national regulations should be followed not to generate non-conformities. Based on the current legal framework a review was performed under light of the normative items from national regulators which should be in compliance with the international recommendations. Also, national requirements not addressed by international recommendations were considered. Therefore, a single model was designed to meet both requirements, national and international standards and regulations. An Internal Audit model was elaborated helping to quantify risk levels concerned to the process as a whole demonstrating that national regulations meet 0,63 % of the international QUANUM requirements This tool systematizes and improves the quality management policy and, at last, be able to attend the Regulatory Audit, minimizing non-conformities.

Keywords: Internal Audit, Nuclear Medicine, QUANUM.
1. INTRODUCTION

Brazil has two regulatory bodies for NM: National Nuclear Energy Commission (CNEN) and National Sanitary Surveillance Agency (ANVISA). CNEN establishes the CNEN-NN-3.01 [3] standard to establish requirements for radioprotection for all installations that use ionizing radiation, and CNEN-NN-3.05 [4] to specify requirements for the licensing and control of NM facilities [5]. Furthermore, ANVISA establishes sanitary requirements in Resolutions of the Collegiate Board, or RDC. For specific NM control and regulation ANVISA published RDC-38 on June 4, 2008, providing design and operation conditions for in vivo Nuclear Medicine services [5].

However, none of the regulatory agencies has a published methodology to verify compliance with specifically applicable requirements or conformities assessed by documentation or on-site inspections. This self-assessment, or internal audit, is required to comply with the QA process and ensure satisfactory performance.

2. MATERIALS AND METHODS

Brazilian standards and regulations and international recommendations was analyzed and compared to requirement introduced by QUANUM tool. Within the worksheet, a new tab was created to identify Brazilian normative items. Therefore, a single model was designed to meet both requirements, national and international standards and regulations. The process should contain the quality assessment of all components related to the practice, including professional education and training needs to be continuously evaluated [7, 8]. In the new model developed the risk assessment will be implemented according to the non-conformity in the evaluated items, these risks will be graded according to the priority of the MNS. Then, a National Internal Audit model was developed to be capable of showing the real level of competence of a service.
3. RESULTS AND DISCUSSIONS

Currently in Brazil, there are 460 nuclear medicine services, of which only 39 are registered in the IAEA NumDAB system (Nuclear Medicine Database). The registration of a service in the system is voluntary but is important to inform the level of assistance and the real competence is in place.

Analyzing national regulations, the quality control tests (QC) of the equipment are established without any minimum performance parameter. Therefore, it is necessary to elaborate minimum performance values to be implemented, based on international and manufacturer recommendations for good equipment performance and tests reliability [3]. The Regulatory Authorities also do not establish minimum requirements for professional training as doctors, pharmacists, physicists, nursing technicians, radiology technicians, among others. The adapted QUANUM tool is demonstrated in figure 1, where it could be observed international (blue) and nationals (red) requirements to each evaluated item.

**Figure 1.** QUANUM tool with international and national data.

<table>
<thead>
<tr>
<th>CHECKLIST 6</th>
<th>PATIENT RADIATION PROTECTION</th>
<th>QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>N°</td>
<td>COMPONENT</td>
<td>CONFORMANCE LEVEL</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>5.1</td>
<td>Are there standard operating procedures (SOPs) available to ensure correct identification of the patient prior to administration of the radiopharmaceutical?</td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td>Are there SOPs and appropriate signage for identifying females-patients of chest-baring age to request any potential pregnancy or breast-feeding?</td>
<td></td>
</tr>
</tbody>
</table>

Accordiing to the quantitative primary verification, national regulations and standards meet 63.63% of the international QUANUM.

4. CONCLUSION
An easy tool to evaluate quality of the health system applied to Nuclear Medicine Services in Brazil was developed based in QUANUM process proposed for IAEA. The proposed Internal Audit (IA) model will attend national regulations and can help to quantify risk levels concerned to the process as a whole. This tool systematizes and improves the quality management policy in this field and, at last, be able to attend the Regulatory Audit (RA) minimizing non-conformities.

As a next step in this project, we will systematize this auditing model to make its use more dynamic and afterwards, we will test the applicability of a nuclear medicine service in our country.

REFERENCES

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