BJRS

BRAZILIAN JOURNAL
OF
RADIATION SCIENCES
06-02-A (2018) 01-09

Adaptation of the QUANUM platform for internal audits in nuclear medicine in Brazil

V. M. de Paula[a]; L. V. de Sá[b]; M. A. Pinheiro[c]; G. I. O. A. de Lima[a]; E. R. de Andrade[a]; L. A. G. Magalhães[d]; M. C. Loureiro[d]

[a] *Instituto Militar de Engenharia (IME) - Seção de Engenharia Nuclear - SE/7, 21291-270, Rio de Janeiro, RJ, Brasil,*

[b] *Instituto de Radioproteção e Dosimetria (IRD) – Comissão Nacional de Energia Nuclear (CNEN), 22780-160,*

[c] *Hospital Universitário Clementino Fraga Filho (HUCFF) – Universidade Federal do Rio de Janeiro (UFRJ),*

[d] *Laboratório de Ciências Radiológicas (LCR) – Universidade do Estado do Rio de Janeiro (UERJ), 20550-900*

vitor_moura06@hotmail.com

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 being available at 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 which helps to quantify risk levels concerned to the process as a whole suggesting that Brazilian national regulations meet about 60 % of the international QUANUM requirements. After adaptation, a unified internal audit model was modeled where 32% are requirements from Brazilian standards, 27% from international recommendations and 41% for both Brazilian standards and international requirements. This tool systematizes and improves the quality management policy and, at last, be able to attend the Regulatory Audit, minimizing non-conformities with positive impacts on the services offered to the population.

Keywords: Internal Audits, Nuclear Medicine, QUANUM.

Acepted: 2018-05-15

1. INTRODUCTION

Nuclear Medicine (NM) is a medical specialty that uses safe, painless and mostly non-invasive methods providing information that other diagnostic exams couldn't. This technique uses non-sealed sources of radionuclides, called radiopharmaceuticals, which are administered to the patients orally, by inhalation or subcutaneously, presenting a specific distribution for each organ or cellular tissue [1].

Although the vast majority of procedures in Nuclear Medicine has a diagnostic purpose, therapeutic procedures have also been performed for many years. In these cases, the objective is using the deleterious action of the ionizing radiation from the radiopharmaceuticals in a tissue or organ of interest with the purpose of killing neoplastic cells. As examples of these procedures we can highlight the use of the radioiodinated iodine-131 in the form of sodium iodide for thyroid disorders treatments, and Samarium-157 in the form of Hydroxyapatite used in treatments for bone pain [1].

As a multidisciplinary field, NM involves several processes, ranging from the labeling of molecules in the preparation of the radiopharmaceutical, evaluation of the performance of diagnostic equipment, patient dosimetry, radiological protection, clinical analysis, among others. Thus, the effective control of the parameters which ensure quality of care for the population in diagnostic and therapeutic applications should be performed periodically, aiming to maintain a satisfactory level [1].

The Quality Control (QC) of the equipment is part of a larger Quality Assurance (QA) program. Not least, the training of the personel should also be evaluated during the implementation of the QA. This involves all efforts to ensure better results for the radiation detection process that will result in the best possible image, with a safety and optimized technique [1]. Therefore, the International Atomic Energy Agency (IAEA) has developed a tool called QUANUM - Quality Management Audits in Nuclear Medicine Practices, which supports the audit of quality management in NM practices, assisting audit teams in the evaluation of NM services [2].

Brazil has two regulatory bodies for NM: (a) National Nuclear Energy Commission (CNEN) and (b) National Sanitary Surveillance Agency (ANVISA). CNEN established the CNEN-NN-3.01 [3] standard towards to the requirements for radioprotection for all plants that use ionizing radiation, and CNEN-NN-3.05 [4] to specify requirements for security and radiological protection for nuclear medicine services [5]. Furthermore, ANVISA establishes sanitary requirements by means of the

resolutions of the collegiate board (RDC), which are norms for health establishments. For specific NM control and regulation, ANVISA published RDC-38 on June 4th, 2008, providing design and operation conditions for in vivo NM 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 ensuring satisfactory performance. For this internal audit to be adequate and best applied in a country, national regulations should be followed to avoid generating nonconformities, through an assessment process containing all the information of the steps that constitute a QA system should be established. The QUANUM tool was developed based on European Community guidelines and adapted to the reality of Brazilian NM services, using current legislation [2].

2. MATERIALS AND METHODS

In addition to the Brazilian standards and regulations, international recommendations were analyzed and compared to those requirements 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 which need to be continuously evaluated [7,8].

In the developed model a "risk level" has to be evaluated in relation to the level of compliance; risks was defined as level A, B and C. Level "A" was classified as high risk, where an immediate solution for noncompliance should be provided. Level "B" was considered moderate risk where nonconformity has to be solved in a period ranging from 1 to 3 months. Level "C" was considered a low risk and the nonconformity can be solved within 6 months or until the next internal audit. Therefore, a National Internal Audit model was developed aiming to suggest what is needed to be implemented to minimize risks.

This model takes into account the management, operational procedures, physical buildings, equipment, human resources, impact on operational practice and records. This audit system should be able to evaluate the whole process from the patient's entry to the medical report after solution.

3. RESULTS AND DISCUSSION

Currently in Brazil, there are 460 NM services, of which only 39 are registered in the IAEA NumDAB (Nuclear Medicine Database) system. The registration of a service in the system is voluntary but important to inform the level of assistance and the actual competence. Table 1 shows actual status of this practice in Brazil.

Table 1: Status of the Nuclear Medicine practice in Brazil, 2017.

Number of operating equipment	Planar and Single Photon Emission Tomography –SPECT	939
	Single Photon Emission Tomography/Computed Tomography – SPECT/CT	10
	Positron Emission Tomography/Computed Tomography – PET/CT	150
	Cyclotron for radionuclide production	18
Therapeutic rooms	For Radioiodine Therapy	100
Radionuclides in use	^{99m}Tc, ^{131}I, ^{123}I, ^{18}F, ^{11}C, ^{67}Ga, ^{68}Ga, ^{111}In, ^{153}Sm, ^{177}Lu, ^{90}Y,^{201}Tl, ^{223}Ra	

The number of Nuclear Medicine services in the country is growing fast. The complexity of the main procedures and controls makes necessary to better supervise and guarantee the safety of these facilities. Analyzing national regulations, the quality control tests (QC) for equipment are stablished without any minimum declared performance parameter. Therefore, it is necessary to elaborate those parameters, based on international and manufacturer recommendations for good equipment performance and tests reliability [3]. Furthermore, the Regulatory Authorities also do not establish minimum requirements for personel training. Figure 1 shows QUANUM tool with international and national data for checklist 5 (patient radiological protection), where it could be observed international (blue) and nationals (red) requirements to each evaluated item.

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

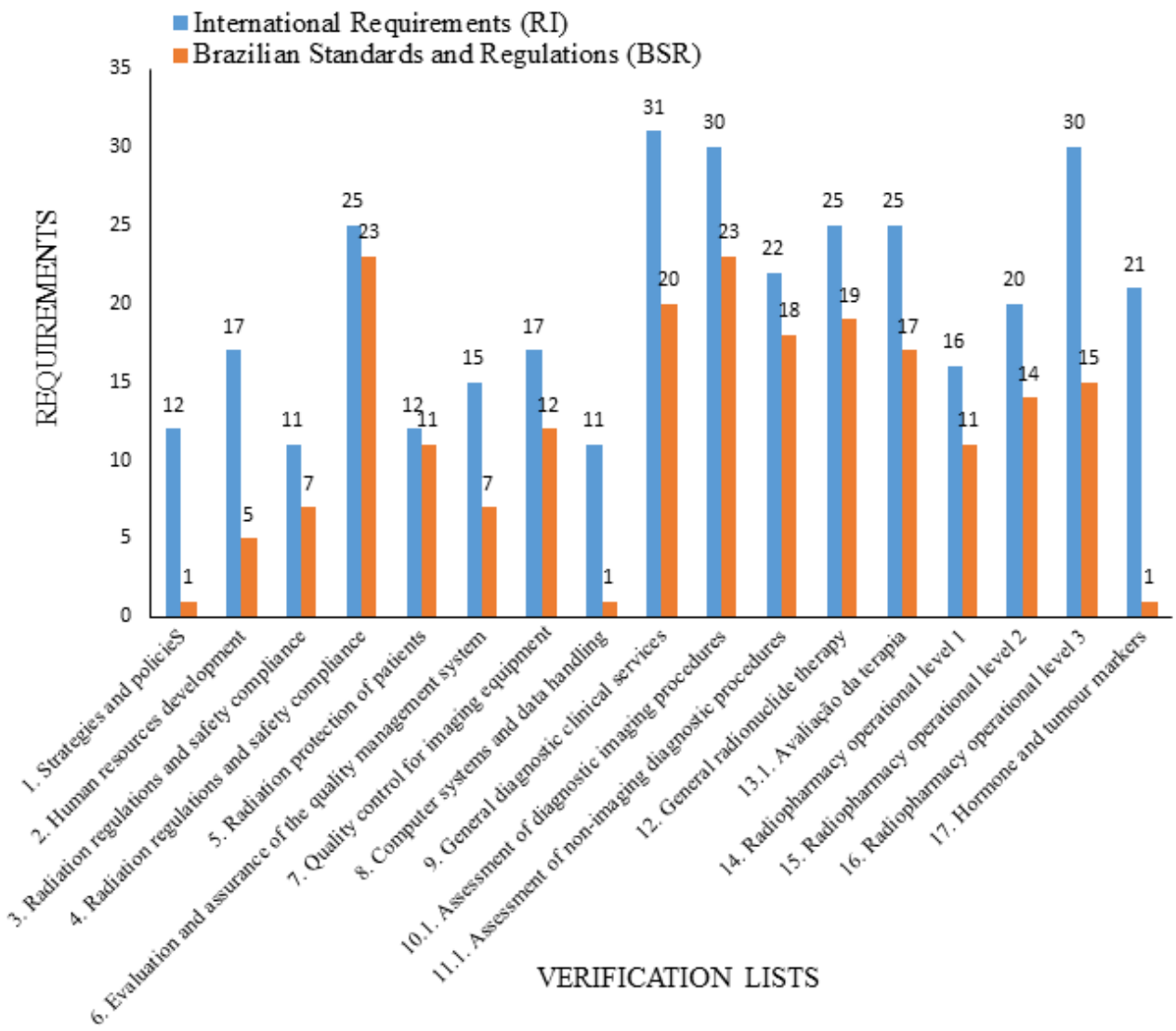
QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE

CHECKLIST 5 *PATIENT RADIATION PROTECTION*	CHECKLIST SUMMARY	NI	APPLICABLE	TOTAL SCORE	%SCORING	NC

N°	COMPONENT	CONFORMANCE LEVEL	RISK LEVEL	COMMENTS/PLANNED ACTION	DATE ACHIEVED	EXAMPLE OF RESULT/ TYPE OF EVIDENCE	INTERNATIONAL REFERENCES	BRAZILIAN REFERENCES
5.1	Are there standard operating procedures (SOPs) available to ensure correct identification of the patient prior to administration of the radiopharmaceutical?					Check the procedure/ Observation on site.	SRS No.40, par 3.2.1, 5.2,5.3 BSS, par.3.156	CNEN NN 3.05 - Cap.I Seç.V Art.13.IV.c
5.2	Are there SOPs and appropriate signage for alerting female patients of child bearing age to report any potential pregnancy or breast feeding?					Check the procedure/ Observation on site.	SRS No.40,par 2.3,3.5,3.1,5.3.2 BSS, 3.151,3.165,3.174 3.176	CNEN NN 3.05 - Cap III, Seç. VI,Art 45 RDC 38 - 5.2.3
5.3	Are written instructions available and verbal instructions given to patients before and after administration of radiopharmaceuticals?					Observation on site/ copy of the instructions.	SRS No. 40, par 3.2.1,5.2,5.3 BSS, par. 3.150 - 3.152	CNEN NN 3.05 - Cap.I, Seç.III, RDC 38 - 5.3, a, b.
5.4	Is the activity of each patient dose measured prior to administration and entered into the patient's record?					Observation on site/ copy of the instructions.	SRS No. 40, par 5.1,5.3 BSS, par. 3.153 - 3.162,3.164	CNEN NN 3.05 - Seç.III, Art.36./ Cap.I, Seç.V; Art. 13. I, II, III, IV.
5.5	Is there an SOP to ensure that the administered amounts of radioactivity do not exceed the reference values given in the Basic Safety Standards (BSS), national or international regulations or guidelines?					Check the procedure/ Check the Manual.	SRS No. 40, par 5.3, Apdx VI BSS, par. 3.168	CNEN NN 3.05 - Cap.I, Seç.III, Art.7, VII.g /Seç.V, Art. 13,b / Seç.III. Art.36

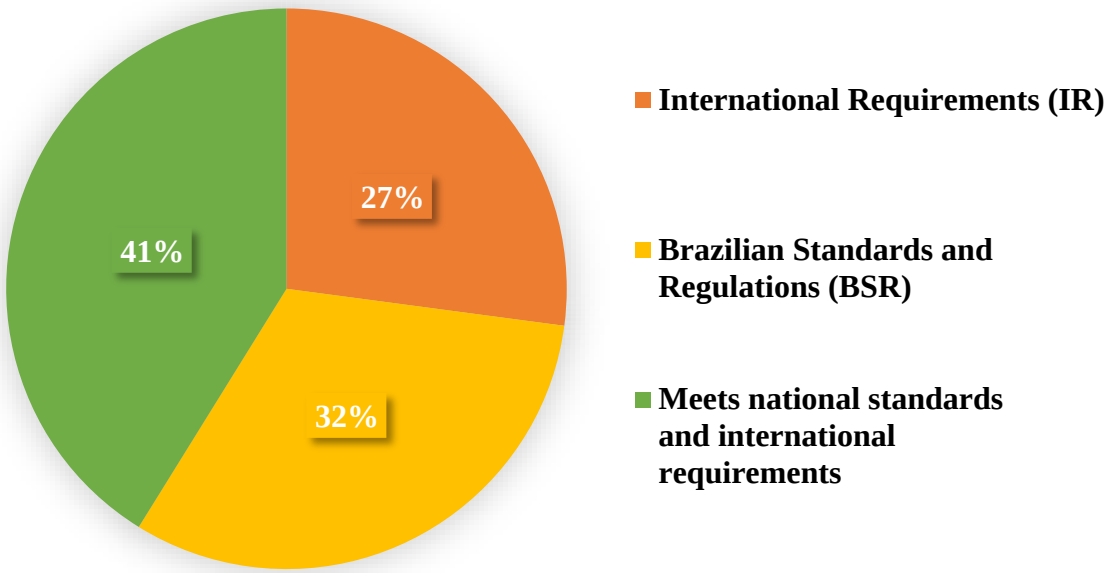
A semi quantitative comparison between the requirements evaluated based on both international and national recommendations and standards results shown in figure 2. According to the primary verification, national regulations and standards meet 60% of the international QUANUM requirements, as can be seen in figure 2.

Figure 2*: Comparison of national regulations and standards with international requirements.*



After adaptation, a unified internal audit model was designed where 32% are requirements from Brazilian standards, 27% from international recommendations and 41% for both Brazilian standards and international requirements (see figure 3).

Figure 3: *QUANUM model adapted to Brazilian standards.*



4. CONCLUSIONS

An user-friendly tool to evaluate health system quality applied to Nuclear Medicine Services in Brazil was developed based in QUANUM process proposed by IAEA. The Internal Audit (IA) model will attend national regulations and can help to quantify risk levels concerned to the process as a whole. This tool can systematize and improve quality management policy in this field and, at least, be able to attend Regulatory Audit (RA) minimizing non-conformities. As a next step in this project, this audit model will be systematized to become dynamic and user-friendly.

REFERENCES

[1] MEDICINA NUCLEAR. Available at: <http://rle.dainf.ct.utfpr.edu.br/hipermidia/images/documentos/Medicina_nuclear.pdf>. Last accessed: 24 Nov. 2016.

[2] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. **Resolução de Diretoria Colegiada** – RDC nº 38. ANVISA, 2008.

[3] COMISSÃO NACIONAL DE ENERGIA NUCLEAR, "CNEN/NE-3.05 - **Requisitos de Radioproteção e Segurança para Serviços de Medicina Nuclear**", Norma Técnica, 1996.

[4] COMISSÃO NACIONAL DE ENERGIA NUCLEAR, "CNEN/NE-3.01, **Diretrizes Básicas de Proteção Radiológica**", Norma Técnica, 1988.

[5] INTERNATIONAL ATOMIC ENERGY AGENCY: **Quality Management Audits in Nuclear Medicine Practices**, 2nd edition. — Vienna, 2015.

[6] INTERNATIONAL ATOMIC ENERGY AGENCY: **Quanum Tool**. Available at: <https://humanhealth.iaea.org/hhw/nuclearmedicine/qualitypractice/quanum/qualitymanagement auditsinnuclearmedicinepractices/index.html>. Last accessed: 01 Dec. 2016.

[7] INTERNATIONAL ATOMIC ENERGY AGENCY: **International Basic Standards Protection against ionizing radiation and for the Safety of Radiation Sources**. Safety Series, N°l 15, Viena, 1996.

[8] INTERNATIONAL ATOMIC ENERGY AGENCY: **Nuclear Medicine Resources Manual**. Viena, 2006.

[9] MINISTÉRIO DE ESTADO E DO TRABALHO. Norma Regulamentadora – NR 16. **Atividades e Operações perigosas**. Portaria MTB Nº 3.214, DE 08 DE JUNHO DE 1978.

[10] NUCLEAR MEDICINE PHYSICS: **A handbook for students and teachers**. — Vienna: International Atomic Energy Agency, 2014.

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, **Application of the Management System for Facilities and Activities**: Safety Guide, IAEA Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006).

[12] COMISSÃO NACIONAL DE ENERGIA NUCLEAR, "CNEN/NN 6.02 - **Licenciamento de Instalações Radiativas**, Norma Técnica, 2011.

[13] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA, **Institucional**. Available at: <http://portal.anvisa.gov.br/institucional>. Last accessed: 23 Nov. 2017.

[14] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. **Resolução de Diretoria Colegiada** – RDC nº 50, 2002.

[15] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. **Resolução de Diretoria Colegiada** – RDC nº 64, 2009.

[16] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. **Resolução de Diretoria Colegiada** – RDC nº 210, 2003.

[17] INTERNATIONAL ATOMIC ENERGY AGENCY. **Operational guidance on hospital radiopharmacy: a safe and effective approach**, Vienna (2008).

[18] **Cartilha de Radiofarmácia**. Available at: <http://abrf.com.br/date/Cartilha_de_Radiofarmacia.pdf>. Last accessed: 27 Nov. 2017.

[19] INTERNATIONAL ATOMIC ENERGY AGENCY. **Quality control of nuclear medicine instruments**, Vienna (1991)

[20] INTERNATIONAL ATOMIC ENERGY AGENCY. **Yttrium-90 and Rhenium-188 radiopharmaceuticals for radionuclide therapy**, Vienna (2015).