

# Development and evaluation of Standard Operating Procedures (SOPs) for quality control tests and radiological protection activities in a Nuclear Medicine Service

## Desenvolvimento e avaliação de Procedimentos Operacionais Padrão para testes de controle de qualidade e atividades de proteção radiológica em um Serviço de Medicina Nuclear

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### Abstract

The quality management in Nuclear Medicine Services is a requirement of national and international standards. The Brazilian regulatory agency in health surveillance, the Agência Nacional de Vigilância Sanitária (ANVISA), in its *Resolução de Diretoria Colegiada* (Collegiate Directory Resolution) n° 38, requires the elaboration of documents describing the technical and clinical routine activities. This study aimed to elaborate, implement and evaluate Standard Operating Procedures (SOPs) for quality control tests and radiological protection activities in the Nuclear Medicine Service of a university hospital. Eighteen SOPs were developed, involving tasks related to dose calibrator, gamma camera, Geiger-Müller detectors and radiological protection activities. The performance of its application was evaluated for a period of six months. It was observed a reduction in 75% of reported operational errors and 42% of the number of reported incidents with contamination by radioactive material. The SOPs were adequate and successful in its application. New procedures involving clinical activities will also be developed and evaluated.

**Keywords:** quality management, nuclear medicine, quality control.

### Resumo

O controle de qualidade em Serviços de Medicina Nuclear é uma exigência de normas nacionais e internacionais. A Agência Nacional de Vigilância Sanitária (ANVISA), na Resolução de Diretoria Colegiada n° 38, solicita a elaboração de documentos que descrevam as atividades da rotina técnica e clínica. Este estudo teve o objetivo de elaborar, implementar e avaliar os Procedimentos Operacionais Padrão (POPs) para testes de controle de qualidade e atividades de proteção radiológica no serviço de medicina nuclear de um hospital universitário. Dezoito POPs foram desenvolvidos com tarefas relacionadas ao calibrador da dose, à gama câmara, aos detectores Geiger-Müller e às atividades para proteção radiológica. O desempenho da aplicação destes foi avaliado durante seis meses. Observou-se redução de 75% dos erros operacionais relatados e de 42% do número de incidentes relatados com contaminação por material radioativo. Os POPs foram adequados e bem sucedidos em sua aplicação. Novos procedimentos envolvendo atividades clínicas também serão desenvolvidos e avaliados.

**Palavras-chave:** gestão de qualidade, medicina nuclear, controle de qualidade.

### Introduction

The quality management of procedures performed and radiological protection of patients and professionals should be priority in any Nuclear Medicine Service (NMS)<sup>1,2</sup>. The Brazilian regulatory agency in health surveillance, the *Agência Nacional de Vigilância Sanitária* (ANVISA),

published with this purpose the *Resolução de Diretoria Colegiada* – RDC n° 38<sup>2</sup>, which requires the preparation of documents describing the technical and clinical activities undertaken in the NMS. These documents must consist of Standard Operating Procedures (SOPs).

A SOP is a detailed description of all activities required to perform a particular procedure, i.e., a standardized checklist

to perform an activity<sup>3</sup>. It has great importance in any functional process, whose basic objective is to ensure, through standardization, the expected results for each task performed. This is a quality management tool that strives for excellence in service delivery, minimizing errors in routine actions<sup>4</sup>.

Basically, the process for quality assurance through the SOP involves planning, development, verification and implementation. Good clinical practice involves the quality management of established and well-controlled processes<sup>5</sup>.

The aim of this study was elaborate, implement and evaluate Standard Operating Procedures for quality control tests and radiological protection activities in the Nuclear Medicine Service of a teaching hospital, in accordance with national and international standards.

## Materials and methods

### SOPs elaboration

First, it was conducted in the NMS a survey of the following items: (i) technical activities undertaken; (ii) equipment installed; (iii) technical and operational equipment manuals; (iv) documentation relating to the quality control tests performed; and (v) radiological protection activities. The service has two gamma cameras Millennium (GE Healthcare), a dose calibrator CRC-10BC (Capintec Inc.) and two detectors Geiger-Müller MIR-7026 (Norton Helthcare) with surface probe.

Quality control tests were routinely performed. However, there were no documents standardizing its implementation, and results were recorded only in printed documents.

The second step was to divide the activities in groups relating to procedures for dose calibrator, gamma camera, detectors and radiological protection activities.

The third step was to define the correct procedure for each quality control test, consulting recommendations in national and international documents<sup>6,7</sup> and even in equipment manuals.

The fourth step was the SOPs elaboration. Each SOP is composed mainly of cover sheet, instructions sheet and attachments sheet.

The items contained in each part are following presented.

- *Cover sheet:*
- Name and logo of hospital.
- Title (activity/process).
- Name of the author.
- Date of elaboration and approval.
- Name of the reviewer.
- Number of the current version.
- Number of the document.
- Paging.
- Coverage.
- Distribution.
- Number of copies.
- Name of the radioprotection supervisor.

### *Instructions sheet:*

- Objective.
- Acronyms.
- Equipments used.
- Step by step of the procedure.
- Calculation (when applied).
- Reference values.
- Instructions for completing the forms.
- Bibliographic references.
- List of attachments.

### *Attachments sheet:*

- Figures.
- Tables.
- Examples.

### Implementation and evaluation of SOPs

After the SOPs elaboration, they were reviewed, approved and delivered to an intern in Medical Physics and to other in Radiopharmacy, according to the procedure purpose, in order to test the understanding and clarity of the instructions. After this initial application, information was corrected or added.

A seminar was held to present the SOPs to the Administration of NMS and the professionals involved in its implementation and training on its use.

Printed copies were distributed among the NMS sectors and put in places easily accessible to those responsible for implementing the procedures.

Spreadsheets for data analysis were developed using Excel software (Microsoft Corporation) to record the tests results. The choice of this software was due to its versatility and easy development of mathematical calculations and data binding.

The SOPs were implemented and evaluated for six months, as the implementation and performance results. The indicators used for evaluation were: (i) number of occurrences of contamination by radioactive material and (ii) number of occurrences of operational errors in the equipments.

## Results and discussions

Eighteen SOPs were elaborated and implemented, being 04 for the dose calibrator, 07 for the gamma camera, 01 for the detectors and 06 for radiological protection activities (Table 1).

Being a teaching hospital, the NMS has a large turnover of staff employed, students, residents and interns. Thus, the implementation of SOPs facilitated the process of training these professionals to perform their activities.

Table 2 shows the performance assessment results of SOPs. There was a 75% reduction of the operational errors recorded. The number of recorded incidents with contamination by radioactive material was reduced by 42%.

The registers were made in accordance with occurrences reported to the radiological protection supervisor of NMS. However, even with seminars presenting the objectives of SOPs and the training of professionals involved in the

**Table 1.** List of elaborated SOPs.

Group	Nº	Procedure
Dose calibrator	1	Accuracy and precision test
	2	Linearity test
	3	Reproducibility test
	4	Dial adjustment
Gamma camera	5	Intrinsic uniformity test
	6	Intrinsic linearity test
	7	Extrinsic uniformity test
	8	Linearity extrinsic test
	9	Energy resolution test
	10	Sensitivity test
	11	Center of rotation test
Radiation detectors	12	Reproducibility test
Radiological protection activities	13	Evaluation of surface, skin, instruments and clothes contamination
	14	Skin, instruments and surfaces (countertops, tables and floors) decontamination
	15	Radiometry service
	16	Elution of <sup>99m</sup> Tc generator
	17	Calculation of the fraction of molybdenum in the solution of eluted <sup>99m</sup> Tc
	18	Radioactive waste management

practices of NMS, there was some fear of punishment by the operational errors. Thus, the number of occurrences may differ from the actual number of incidents recorded during the evaluation period. This discrepancy tends to disappear with time, when the professionals understand that the purpose of SOPs is to optimize the tasks executed in the NMS.

The employees with more than five years of service had reservations about the use of SOPs. They did not meet the steps properly. The operational errors were recorded in the tasks performed by them.

The quality control tests results were inserted in the spreadsheets for analysis and register. This form of registration allows generation of practical graphs and charts to management consultation, and analysis of equipment performance.

The Figures 1 and 2 show the final format designed for the cover sheet and instruction sheet, respectively.

**Table 2.** Average monthly number of incidents recorded before and after the implementation of SOPs.

Indicator	Before	After	Reduction (%)
Number of occurrences of contamination by radioactive material.	12	07	42
Number of occurrences of operational errors in the equipments.	08	02	75

PROCEDIMENTO OPERACIONAL PADRÃO		POP.ENF.GE-XXX		Logomarca
		Revisão:	000	
		Liberação:	dd/mm/aaaa	
		Exemplar:	00	
		Página 1 de N		
<b>TÍTULO DO PROCEDIMENTO</b>				
Abrangência:				
Elaborado por:		Data:	Assinatura:	
Revisado por:		Data:	Assinatura:	
Aprovado por:		Data:	Assinatura:	
<b>HISTÓRICO DO DOCUMENTO</b>				
Nº Revisão	Emissão	Descrição das Alterações		
000	dd/mm/aaaa			

**Figure 1.** Format designed for cover sheet.

PROCEDIMENTO OPERACIONAL PADRÃO		POP.ENF.GE-XXX		LOGOMARCA		
TÍTULO DO PROCEDIMENTO		Revisão:	000			
		Página 2 de N				
1. OBJETIVOS:						
2. ABRANGÊNCIA:						
3. RESPONSABILIDADE:						
4. DEFINIÇÕES E SIGLAS:						
5. PROCEDIMENTO:						
5.1. Material empregado						
5.2. Instruções						
6. REGISTROS MANTIDOS:						
Identificação	Responsável (pelo arquivo)	Armazenamento (forma de arquivo)	Localização (forma de localização)	Retenção		Desorte (forma de desorte)
Nome do registro Código do registro				Arquivo vivo	Arquivo morto	
7. INSTRUÇÕES PARA O PREENCHIMENTO DOS FORMULÁRIOS:						
8. REFERÊNCIAS:						
9. LISTA DE ANEXOS:						

**Figure 2.** Format designed for instructions sheet.

## Conclusions

The developed SOPs were adequate and successful in its application.

New procedures will be developed and implemented involving clinical activities, such as:

1. Pregnancy protocols (patients/employees).
2. Staff monitoring.
3. Specific protocols for image and non-image.
4. Patient assessment.
5. Education, preparation and release of patient.
6. Acquisition and image processing.
7. Data storage/transfer.
8. Adverse drug events and misadministrations.

The new SOPs will be evaluated for a period of one year, considering the indicators as: (i) rate of repeat tests stratified by subject (dose errors, technique, image acquisition protocols) and (ii) rate of intercurrentence (stratified in clinical intercurrentence, techniques and of

radiation protection, with the record of corrective measures taken).

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