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THE ROLE OF THE RADIO-CHEMIST IN SETTING, CONTROL AND QUALITY ASSURANCE OF TECHNETIUM RADIOPHARMACEUTICALS IN A U.C. OF NUCLEAR MEDICINE

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BACKGROUND-AIM

In accordance with the rules of good manufacturing practices of the radiopharmaceuticals in a Nuclear Medicine Department (GMP-NM), each department must be equipped with a functional organization chart that defines the responsible figures of the activities to be carried out.
It will be the task of the General Responsible (RG) to appoint, within the department, the Responsible of Quality Assurance (RAQ), the Responsible of Operations Preparation (ROP), the Responsible of Quality Control (QC), and the Responsible of Release Operations (RRO)
At the U.C. of NM of "Santo Spirito" hospital in Pescara, the figure of RQC has been identified in the Radiochemist.
The aim of this work is to describe our experience in order to verify the importance of this figure, in collaboration with other professionals, in the implementation of the Quality Assurance System (QAS), already in place at our facility, a guarantee of quality requirements, safety and efficacy of radiopharmaceuticals (RF) defined by GMP-NM.

METHODS

The analysis refers to the quarter 25/08/2014 - 29/11/2014 and it concerns the Quality Controls (QC) made by the Radiochemist during this period.
The methodological approach conferred by that figure has provided the following operations:
> Monitoring of the activities carried out in the hot room and review of the procedures;
> Reorganization of the organization chart / functions chart and drafting of Standard Operating Procedures (SOP) missing;
> Review of the Quality Manual (QM) and management of the documentation and recording systems;
> Process validation with particular reference to the microbiological validation inside the production process;
> Review of Quality Control methods of 99Mo/99mTc generator eluate and each technetium RF.
> Management of non-compliance and/or deviations;
> Periodical self-inspections and clinical audit;

RESULTS

During the considered period were made:
> 60 QCs of a total of 15 generators;
> 66 QCs of a total of 7 RF (Tc-99m; HMDP; Sestamibi; DTPA; Sulesomab; Monoclonal Antibodies; MAA)
The QCs made on the Generator Eluate and on the singles Rf were transferred on a report and concern respectively:
> visual inspection; pH control; yield of elution; RadioNuclidic Purity (RNP); Chemical Purity (CP); RadioChemical Purity (RCP) for the eluate;
> visual inspection; pH control; RCP for each Rf;
The final outcome has allowed the traceability of production processes and QC of RF, as well as the subsequent verification of the correctness of the operations performed.
The RCP of the eluate and individual RF has never been lower than the percentage specified by GMP-NM (average of the results: 97.4%)

CONCLUSION

Traceability of production processes and QC of RF, was made possible through a greater awareness of the personnel involved.
Teamwork has actually improved the existing QAS and the presence of a new profession, which the Radiochemist in the department of NM has led to the improvement in accuracy and precision of the controls carried out and a production of Rf quality, effective and safe.