

Regulatory Requirements of Quality Assurance Program in Nuclear Medicine – Review of the Procedures

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The quality assurance program ensures that the entire radiological system and associated equipment are functioning properly and optimally. To this end, it is essential that a quality assurance program be in place in each medical facility where ionizing radiation sources are used, to verify the proper functioning of these instruments as well as the radionuclides measured in nuclear medicine. In addition, the procedures of the quality assurance program must comply with regulatory requirements and international recommendations. The method of this study is to review the regulatory requirements adopted by different countries regarding the quality assurance program procedures as well as various recent scientific works and those published by the International Atomic Energy Agency. In addition, to compare the radiation protection requirements of the procedures of the mentioned works; exposure justification and optimization, quality control, registration system, professional training and audit system and to suggest improvements. The result of the review study, add a procedure to the quality assurance program, so that the quality assurance attempts to cover all procedures involving sources of ionizing radiation, thus ensuring compliance with the standards of radiological safety in nuclear medicine facilities.

Keywords: Nuclear Medicine; Quality assurance program; Radiation protection; Radiation safety; Regulatory requirements.

Quality assurance is defined as all planned and methodical actions necessary to assure that a structure, system or component will work successfully in service according to the International Organization for Standardization (ISO); indeed, satisfactory performance in diagnostic nuclear medicine implies optimal quality of the entire process¹. Indeed, the regulatory requirements

at the national level, in particular Law 142-12², encourage the obligation to define and implement a quality assurance program in an installation using sources of ionizing radiation. During this study, we have reviewed various regulatory requirements from different countries (France, Belgium, and Switzerland) and the published scientific work of the International Atomic Energy Agency (IAEA),

which states that an optimal quality of the whole process and the procedures of the quality assurance program ensure satisfactory performance in nuclear medicine, particularly in diagnostic and therapeutic areas¹. Review of the procedures made it possible to have a global perspective of radiation protection requirements in a nuclear medicine facility and to try to find avenues for improvement for the procedures of the quality assurance. During this research, recommendations were made to encompass the full range of quality assurance in nuclear medicine.

Procedures of quality assurance program

Justification

Various works reviewed in this paragraph encourage that the principle of justification be present in the quality assurance program, specifically; the procedures implementing the principle of justification are present in the said program: the stages from receipt of the request act until the decision to execute it³. According to the principle of justification, a practitioner in a medical establishment (nuclear medicine) can only practice if it is justified⁴. Various points are identified while prescribing an examination in a medical facility (nuclear medicine), such as the patient's identity, the assessment of the advisability of executing the radiological act, the presence of any contraindications, and good patient preparation⁵. Medical applications of ionizing radiation must be justified in terms of radiation protection and safety by comparing the advantages of exposure against the risk of radiation harm and examining alternative procedures that do not entail medical exposure⁶.

Optimisation

The application of the requirements of the optimization principal procedures is present in the quality assurance program, specially:

- Identification the roles and responsibilities of each function of the stakeholders involved in the implementation of optimization procedures³;
- The written procedures by type of act as well as the methods of their preparation³;
- The processes for treating high-risk patient groups, such as women of childbearing age, pregnant women, and children, as well as persons with problems that necessitate periodic examinations³. The essential precautions about the importance of notifying the existence or possibility of pregnancy

in a woman undergoing a radiological examination, or in the event of the administration of radioactive products to the nursing woman⁴.

Quality control

The protocols for checking medical devices after receipt and before use, as well as the procedures for performing medical device maintenance and quality control, included when a change in software version has an impact on the dose or image quality³. The quality assurance program, in accordance with international standards and recommendations, must include all quality control modalities, including radiopharmaceuticals⁷. Quality control procedures must be performed on a regular and planned basis, and they must include acknowledged useful technologies. It is important that the facilities using ionizing radiation sources adhere to applicable requirements instituted from regulatory bodies, the purpose it's to be in compliance at all times⁸. Quality control is a critical for routine nuclear medicine practice⁹.

Training of professionals

According to some of the work reviewed, professional training is critical in the quality assurance program, specifically: the training and qualification procedures for professionals are specified in the quality assurance program for any newcomer when changing their position, workstation, or medical equipment³. Implementation of appropriate training for all professionals with responsibility for quality assurance. It also includes the implementation of continuing education sessions to keep employees up to date for the benefit of professionals participating in the medical facility's quality assurance⁸.

Record system

The quality assurance program provides for the development of a recording system, which will be beneficial in the event of a material, human, or organizational incident that is likely to result in the accidental or unintentional exposure of individuals during a medical imaging procedure³. The recording system includes the dates of detection and recording of the incident, a description of the event, the circumstances surrounding its occurrence and its consequences, and mechanisms for notifying the exposed person or his representative³. The system also provides records of equipment performance, radiopharmaceutical and nuclear

medicine equipment monitoring results, any performance deviations or difficulties detected as well as the established corrective actions⁸.

Audit system

The quality assurance program should include the audit system¹. It is divided into three

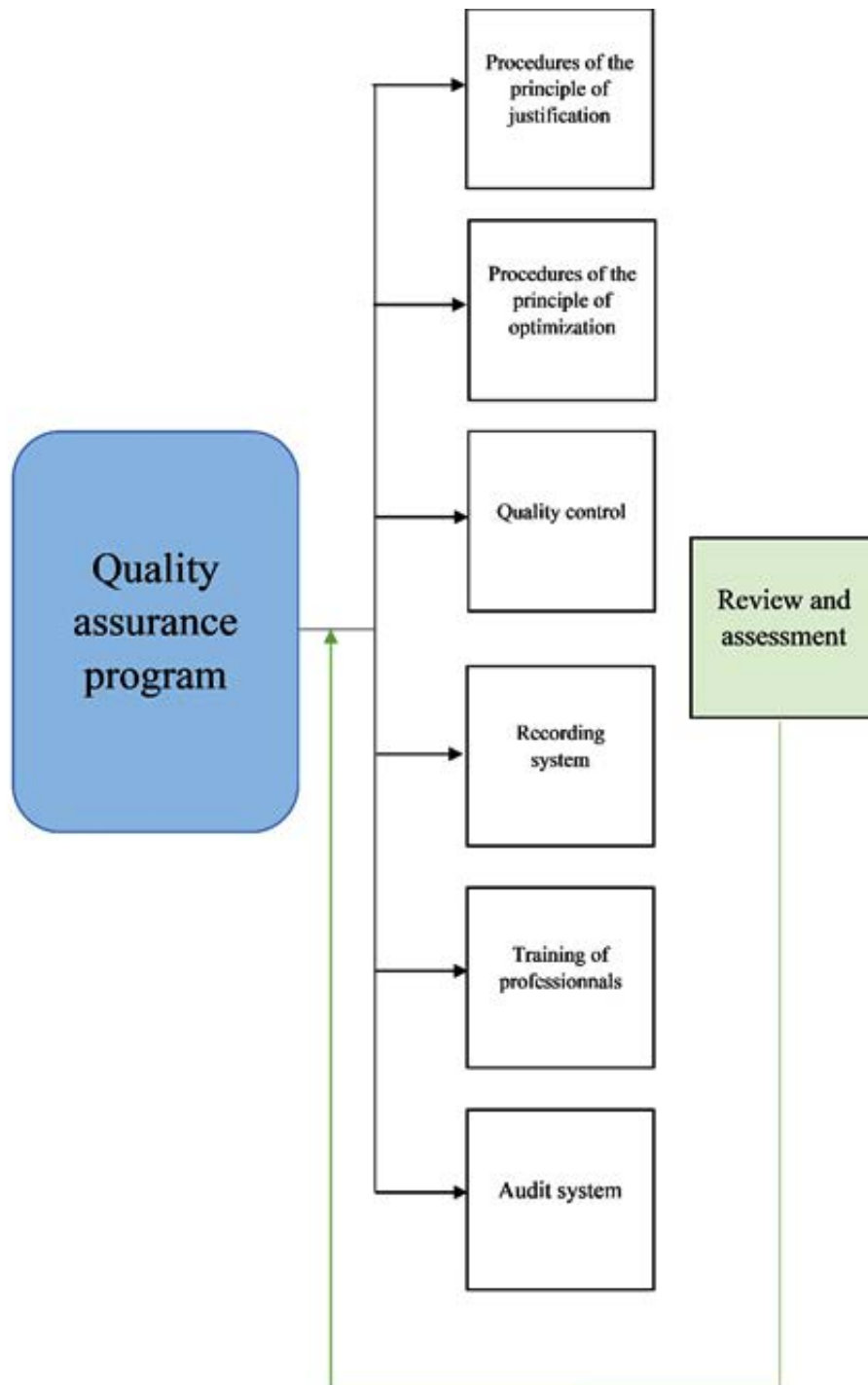


Fig. 1. Flow Chat of procedures of the quality assurance program

phases: self-assessment, internal clinical audit, and external clinical audit, the clinical audit must be documented at each step⁴. Quality Management Audits in Nuclear Medicine (QUANUM) is a program developed by the International Atomic Energy Agency to assist its member states in auditing the status of their nuclear medicine practices and their adherence to international standards, the program covers all aspects of nuclear medicine, in particularly quality assurance and control of instrumentation¹⁰.

Review of the procedures to the assurance quality program

Reviewing the procedures of the quality assurance program for the different regulatory requirements and scientific work. This revealed that most of the procedures are similar for the different works; it is suggested to add the review and assessment phase in the quality assurance program as a step that assesses all the program procedures⁸. To do this, an organization chart is proposed listing all the procedures of the quality assurance program:

CONCLUSION

The adoption of a quality assurance system allows the establishment of a radiation protection culture, thus ensuring radiation protection within a nuclear medicine or radiography facility. Furthermore, this is in accordance with regulatory requirements and international recommendations. During our review of the various regulatory requirements of the procedures of the quality assurance program and the scientific work as well as the evaluation of all the procedures of the said program. It was concluded that most of the reviewed works take into account most of the radiation safety and radiation protection requirements of the procedures of the quality assurance program. The result was the addition of the review and evaluation phase to the said program (flowchart established) according to the reviewed works. Its importance lies mainly in the improvement of medical procedures using ionizing radiation sources in nuclear medicine. This improvement must be continuous, which will minimize the risk of adverse events occurring in a nuclear medicine facility. For future research, we recommend that the regulatory requirements for

quality assurance of radioactive waste generated by nuclear medicine facilities (imaging and therapy) be reviewed.

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Conflict of Interest

All authors declare that there is no conflict of interest.

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