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International guidance on the establishment of quality assurance programmes for radioactivity measurement in nuclear medicine

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Abstract

A new guidance document for the implementation of quality assurance (QA) programmes for nuclear medicine radioactivity measurement, produced by the International Atomic Energy Agency, is described. The proposed programme is based on the principles of ISO 17025 and will enable laboratories, particularly in developing countries, to provide consistent, safe and effective radioactivity measurement services to the nuclear medicine community.

Keywords: Radioactivity; Nuclear medicine; Quality assurance

1. Introduction

The use of radionuclides for diagnosing and treating diseases continues to be a growing area of radiation medicine. The level of radioactivity administered to a patient is governed primarily by the need to optimize the radiation dose delivered while achieving the required objective (e.g. diagnostic image quality or therapeutic outcome). The dose that is received by the patient from a radiopharmaceutical can be thought of as being controlled by a combination of the amount of administered activity and its chemical form.[1] The correctness of these factors is a primary determinant in ensuring safe and effective use of these drugs. It is therefore important that the radiopharmaceutical to be administered to the patient be well characterized in terms of contained activity and radiochemical and radionuclidic purity.

The assessment of these parameters involves a number of tests that ultimately depend on at least one measurement of radioactivity. The implementation of a quality assurance (QA) programme for radioactivity measurements in nuclear medicine is important for ensuring the accuracy and consistency of those measurements and helps in maintaining the safety and efficacy of both diagnostic and therapeutic nuclear medicine procedures that employ unsealed sources of radioactivity.

The implementation of such programmes has been slow to develop and keep pace with the rising number and complexity of the nuclear medicine procedures. This is probably due to the fact that until recently, there has been no uniform, international guidance that was available to assist institutions in developing and implementing such programmes in their countries, particularly in the developing world. The International Atomic Energy Agency (IAEA), in consultation with a group of experts in the representative fields of radioactivity measurement in nuclear medicine, has developed a guidance document, entitled "Quality Assurance for Radioactivity Measurement in Nuclear Medicine" (International Atomic Energy Agency, 2006) that will address this need. While it seeks to cover all of the components necessary for the successful

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[1]There are, of course, a larger number of variables that influence the actual dose received by the patient and by the individual organs (and tumour) themselves. These tend to be mostly biological in nature and are often unpredictable a priori. Discussion of such variables is beyond the scope of the guidance described in this paper.

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implementation of a QA programme for radioactivity measurement, the scope of the document includes only those aspects relevant to measurements and calibrations in nuclear medicine. The purpose of this paper is to provide a summary of the programme described in the guidance document (hereafter referred to as simply the "Guidance"). While it tries to be as complete as possible, it should not be considered a substitute for the complete document.

2. Background

One of the important components of the programme discussed in the Guidance is the need to establish measurement traceability to international standards in order to ensure accurate and consistent measurement results. The definition of traceability used is that specified in the *International Vocabulary of Basic and General Terms in Metrology* (Bureau International des Poids et Mesures, 1993):

> the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually international or national standards, through an unbroken chain of comparisons, all having stated uncertainties.

The Guidance assumes a chain of measurement traceability that has as its basis a national or regional laboratory that itself has established a degree of equivalence with at least one National Metrology Laboratory that maintains primary standards of radioactivity. The chain of traceability extends to the user, usually a hospital or clinic, through one or more secondary laboratories, one of which could be a Secondary Standards Radioactivity Laboratory (SSRL). Because the definition requires that traceability be established through direct comparisons, it is recommended that this be achieved through regular proficiency tests and participation in locally- and regionally-organized interlaboratory comparisons.

3. Management requirements

A successful QA programme is one that ensures that measurements are not only consistently carried out with the best possible accuracy, but are conducted under safe conditions. This requires not only technical competence, but also administrative procedures that help to prevent mistakes and, if they should occur, provides a means to document and correct them. The following paragraphs describe the most critical management components of the Guidance.

3.1. Regulatory notification

It is crucial that any institution performing services for a nuclear medicine facility be in full compliance with local regulations and that regulators have the opportunity to review the procedures and policies that will be used as part of the provision of those services. Therefore, the institution or person responsible for the laboratory must notify the relevant regulatory authority of their intention to carry out these activities and obtain appropriate authorization. If necessary, they must provide relevant information to demonstrate the safety of the practice.

3.2. Commitment to QA

In order to be effective, any QA programme must have the full support of the institution's management. This requires a commitment to an effective QA policy, particularly at a senior level, and full support for those persons with direct responsibility for the QA programme. This commitment shall be expressed in a written policy statement that clearly assigns prime importance to QA in the nuclear medicine services, while recognizing that the prime objective is the medical care of the patients. This commitment must be supported by the allocation of sufficient resources to implement the proposed programme.

3.3. Definition of responsibilities

A laboratory can operate safely and efficiently, and consistently provide reliable services only if the duties of its personnel are clearly defined and understood by everyone involved. For this reason, the organization and management structure of that part of the laboratory engaged in making measurements of radioactivity for nuclear medicine purposes needs to defined and documented. Personnel with particular responsibilities associated with administering the QA programme, including the Quality Manager (QM) need to be appointed by management and in some cases, it may be decided that the overview of the quality system can be operated most effectively by a group designated as the QA committee (QAC).

Clear responsibilities and authorities for personnel (e.g. in the case of the end-user: medical practitioners, nuclear medicine physicists, nuclear medicine technologists, radiopharmacists, radiation protection officers and other health professionals; for an SSRL: chemists, technicians, physicists, and other personnel associated with preparing, calibrating, and disseminating calibrated radioactivity standards) also need to be defined to ensure adequate QA of administered patient radioactivity. The need for qualified experts should be determined, their responsibilities defined and suitable persons appointed to carry out the tasks.

3.4. Safety

One of the key components of the Guidance is the need for a policy to be developed for radiation protection and safety in order to ensure that all necessary procedures are developed and implemented in compliance with local regulations. The policy should cover the entire process from the initial decision to adopt a particular procedure