## Radiochemistry_10

### Implementation of ISO 17025 Standard and accreditation process of Radiopharmacy Laboratory

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**Objectives:** The Laboratory of Radiopharmacy a part of the Department of Pharmacy in the Faculty of Medical Sciences, at the Goce Delcev University in Stip has a main activity of testing radiopharmaceuticals, but also serves research and educational purposes.

The regulatory body for accreditation of laboratories in our country is The Institute for Accreditation of The Republic of Macedonia, which is responsible for the inspection procedures and the issue of the formal document, The Certificate of Accreditation, upon fulfilling all requirements.

**Methods:** In order to improve the quality system in the Laboratory of Radiopharmacy, and to fulfill the criteria needed for testing Radiopharmaceuticals, in accordance with the Law for medicines and medicinal products, as well as the Law for ionizing radiation and radiation safety, we have implemented the Standard MKC EN ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories.

**Results:** The standard MKC EN ISO/IEC 17025 includes two major clauses, highlighted as Clause 4, that specifies the management requirements, and Clause 5, that specifies the requirements for technical competence for the type of tests the laboratory undertakes. Our organization scheme includes the following staff: Head of Laboratory, responsible for implementation of all standard requirements, management and coordination of the work; Quality Manager, that creates the documentation of the quality system and administrates, maintains, controls and monitors the functionality of the quality system; Laboratory Chief, responsible of control of the laboratory activities, as well as issuance of the reports and result interpretation, Analysts, qualified analysts responsible for performing the analyses and Administrative person, responsible for the administrative work.

**Conclusions:** The accreditation road that is to be paved by this laboratory will help other similar-type laboratories in country in orienting their activities toward increasing the level of professionalism and organization, thus enabling international recognition.

## Radiochemistry_12

### Radiopharmacy in Africa: perspective of Ethiopia and Kenya

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**Objectives:** The article seeks to describe the current status of Radiopharmacy practice in Eastern Africa using the perspective of Kenya and Ethiopia.

**Methods:** Non-communicable diseases (NCDs) are a challenge of epidemic proportion and that they will be the commonest cause of mortality in Africa by 2030. Since early detection and treatment is known to significantly improve patient outcomes, radiopharmaceuticals have become of invaluable benefit because they offer the most sensitive tools in the detection, diagnosis and targeted therapy of NCDs and also infectious diseases. In light of the foregoing, therefore, radiopharmacy has a huge role to play in responding to the unfolding new disease trends in sub-Saharan Africa.

**Results:** The preparation of radiopharmaceuticals for human use requires that it is carried out in well-defined and controlled conditions to avoid the risk contamination with microbes, pyrogens and particulate matter as well as cross contamination with other radiopharmaceuticals.

Accordingly, principles of Good Manufacturing Practices and Good Laboratory Practices should strictly be observed in the production, preparation, testing and the packaging of the final product ready for use. Most radiopharmaceuticals are parenterally administered and must therefore be prepared in such condition, and using such techniques and procedure, that guarantee sterility of the product. Every procedure undertaken should be done according to the clearly defined protocol and under the right conditions so as to build quality into the product. Radiopharmacy professionals should have adequate training in all aspects of sterile production, quality control, GMP , GLP, radiation safety and radiochemistry to ensure that they are competent to handle radioactive materials and that they can take responsibility for their level of practice

**Conclusions:** The exact information on the number and status of radiopharmacy units, regionally, is still not clearly documented. Important information for the Eastern Africa region that also needs to be documented includes issues of human resource and local demand for the radiopharmacy services. It is the existence of this gap that necessitated the preparation of this article.