

Implementation of ISO 17025 Standard and accreditation process of Radiopharmacy Laboratory

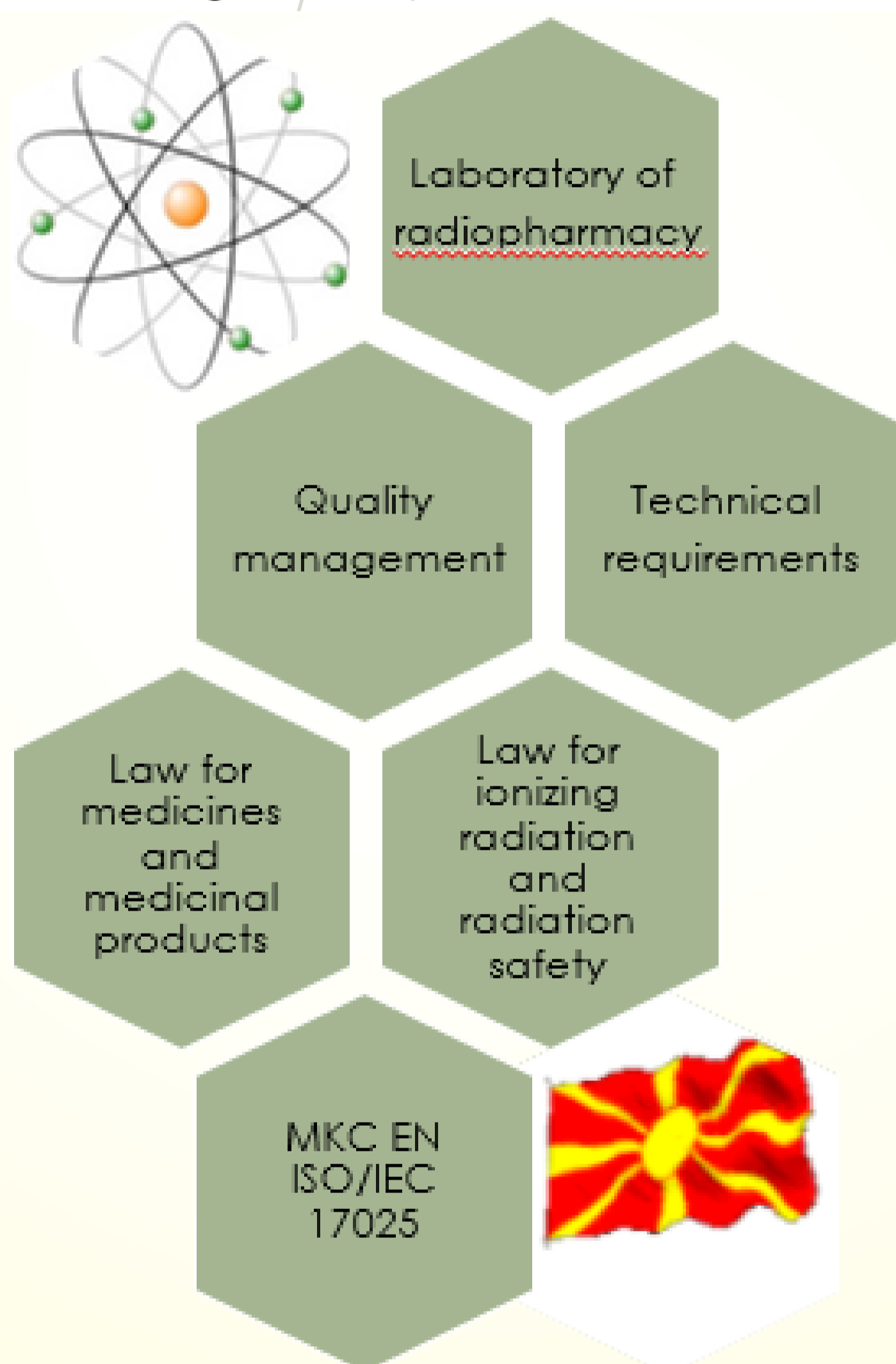
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Purpose:

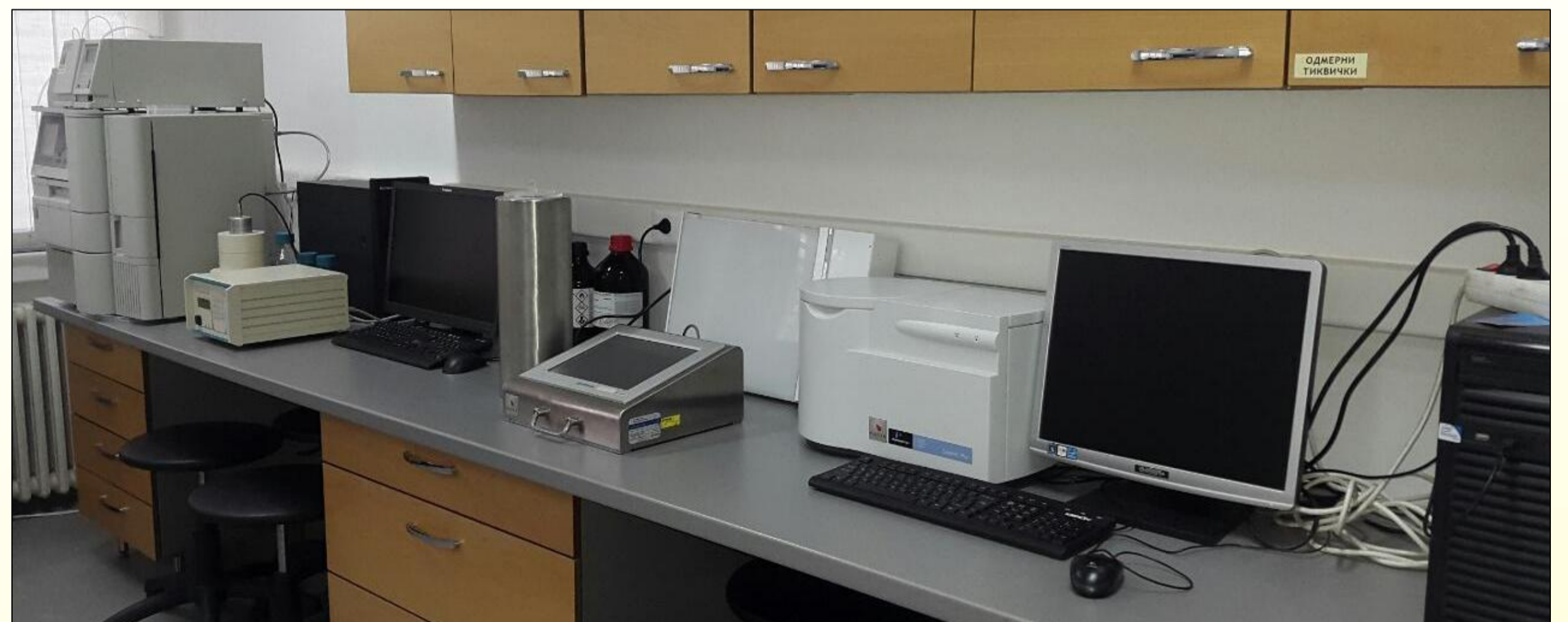
The Laboratory of Radiopharmacy a part of the Department of Pharmacy in the Faculty of Medical Sciences, at the Goce Delcev University in Stip has a main activity of testing radiopharmaceuticals, but also serves research and educational purposes.

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.