QUALITY POLICY



Isotope - Regional Alliance, Joint Stock Company (Isotope JSC) is an enterprise that belongs to Rosatom State Corporation, engaged in promotion and sales of isotope products of Rosatom State Corporation, providing a full range of services in the market of isotope products for medicine, industry and science, as well as radiation equipment.

Isotope JSC keeps up on the values of Rosatom State Corporation and is focused on quality and safety of products, works and services, always ensuring sustainability as regards an impact to environment, society and corporate governance competence.

Strategic goal is to ensure the Rosatom State Corporation's leadership on Russian and global markets of high-tech isotope products for nuclear medicine, industry and science.

Quality goals for Isotope JSC:

• Ensuring compliance of products, works and services with the quality and safety requirements set by consumers and regulatory authorities on the target markets

- Coordination of activities of the Rosatom State Corporation's isotope complex entities in the field of isotope and radiopharmaceutical products quality assurance
- Implementation of Good Pharmaceutical Practices GxP throughout the lifecycle of radiopharmaceutical products.

Isotope JSC adheres to the following quality principles while achieving the goals:

- Safety of patients, consumers, personnel and environment as a priority in the activities
- Leadership and the management commitment to the quality and safety assurance

• Continuous development and improvement of the quality management system in accordance with the requirements of ISO 9001:2015 and GOST R ISO 9001-2015, Good Practice of Storage and Transportation of Pharmaceuticals for Medicinal Applications in the Russian Federation, EAEU Good Distribution Practice, and requirements of regulatory authorities throughout the target markets

- Continuous increase of satisfaction of consumers and striving to exceed their expectations
- Continuous advancement of competences and engagement of personnel

• Taking managerial decisions based on the monitoring and analysis of objective data, including risks and opportunities

- Openness and availability of information on the quality
- Efficient use of any types of resources
- Process improvement based on the process approach and risk-basedthinking
- Mutually beneficial cooperation with suppliers and partners

Use of all opportunities for continuous improving the performance and effectiveness of the quality management system

The management of Isotope JSC undertakes to implement, analyze and update the Quality Policy on a regular basis in order to meet high expectations of patients, consumers and all concerned parties.

General Director

M.S. Kushnarev