

THE MINISTRY OF HEALTH THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA

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QUALITY POLICY

Through adoption of its Quality Policy, the NAMMDR management is committed to establish, implement and maintain a quality policy in order to meet the needs and expectations of stakeholders, through delivery of its products and services.

In this respect, the NAMMDR management is committed to implement, maintain and continuously improve the effectiveness of its Quality Management System (QMS) in accordance with requirements of SR EN ISO 9001: 2015 integrated with the Internal Management Control System (IMCS) through a set of measures and procedures directed towards attainment of objectives and regular, economical, efficient and effective conduct of activities.

The NAMMDR mission is **to contribute to public health protection** and promotion through a leadership committed to making the best management decisions, so that the Agency delivers products and services in accordance with legal requirements, regulated both at national and European level, by using the available mechanisms so that the delivered products and services best correspond to stakeholders, aiming to be in line with economic and social realities.

Starting from the premise that the quality policy represents one of the

sources of continuous improvement of the QMS, based on the **seven** principles of quality management, NAMMDR management is committed to:

- ✓ determine and understand current and future customer, partner and stakeholder needs and expectations and aim to meet respective needs and overcome their expectations in a fair and balanced manner;
- ✓ provide effective, efficient, systematic and transparent Agency leadership and management meant to achieve high performance standards and compliance with good professional practices;
- ✓ maintain an internal working environment where staff are aware of the importance of individual contribution to attaining the Agency's objectives;
- ✓ manage the Agency's activities as correlated and interacting processes, by identifying the required inputs and expected outcomes, by assigning responsibilities in carrying out the processes, documented through system and operational procedures;
- ✓ handle the risks which may influence the outputs of processes as well as overall results of the OMS;
- ensure education and training of staff at all Agency levels on how to apply basic tools and methodologies in order to achieve quality improvement objectives;
- ✓ make evidence-based decisions by analysing and assessing accurate, reliable and secure data and information;
- ✓ establish and maintain mutually beneficial relationships with stakeholders, in order to increase the Agency's ability to create value for its performance;
- ✓ demonstrate NAMMDR competence to similar European and international bodies by participation in inter-laboratory studies/comparisons, external audit programmes and benchmarking;
- ✓ safeguard QMS integrity whenever changes are planned and

implemented at Agency level, through continuous optimization of processes in carrying out the activity in the organization;

✓ maintain and support patterns of ethical and deontological behaviour by establishing a culture of trust, independence, integrity and impartiality;

✓ identify, minimize and plan actions to address risks so as not to affect the achievement of objectives, as well as the ability to meet stakeholders' requirements;

✓ review Agency performances by measuring performance indicators, conduct of self-evaluation and management review.

The quality policy is compliant with the Agency's scope and context; it is communicated to, understood and applied by all NAMMDR staff and made available to all stakeholders.

NAMMDR President, Răzvan Mihai PRISADA

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