

**GOOD RADIOPHARMACY PRACTICES (GRPP) FOR
RADIOPHARMACEUTICALS IN NUCLEAR MEDICINE**

Jovanović MS

Medicines and Medical Devices Agency of Serbia, Belgrade, Serbia and Montenegro

In this paper draft guidelines on good radiopharmacy practices (GRPP) for radiopharmaceuticals in nuclear medicine is shown. Its application would ensure a necessary and sufficient level of safety and efficacy in the production, reconstitution and handling of radiopharmaceuticals in hospitals.

The preparation of radiopharmaceuticals in a hospital radiopharmacy is considered a manufacturing process. The pharmaceutical requirements as described in the principles and guidelines on Good Manufacturing Practice are not yet very well known nor generally applied but radiation protection rules are commonly known and generally applied. Therefore a Quality Assurance system established in the hospital radiopharmacy should cover these two aspects of radiopharmaceutical preparation.

The responsibilities of trained personnel involved in the preparation, quality control and release of radiopharmaceuticals should be clearly identified. An authorized person should take a formal, recorded decision on approval before the product is released. The authorized person should be suitably trained and have documented evidence of competence. The minimal range of quality control testing of radiopharmaceuticals covers parameters to be assessed in every product prior to release such as total radioactivity or radioactivity concentration and appearance and freedom from gross particulate contamination. The used equipment should be well maintained and calibrated on a regular basis. For sterile radiopharmaceuticals, the working zone where products or containers may be exposed should comply with appropriate environmental requirements.

Continuous assessment of the effectiveness of the Quality Assurance system is essential in order to prove that the procedures applied in the radiopharmacy lead to expected results.