7. RADIOPHARMACEUTICAL PRODUCTION

All operations, from the preparation of the target to the dispensing of the final radiopharmaceutical preparation, must be clearly documented including their impact on the purity of the final product and the efficiency of the procedure. Where possible, in-process controls are performed and the results recorded at each production step to identify at which level a possible discrepancy from the normal production procedure may have occurred.

The production of radiopharmaceutical preparations may make use of mechanical and automated processes that are used in the pharmaceutical industry, subject to adapting these for use with radioactive material and to the requirements of radiation protection.

For radiopharmaceutical preparations containing short-lived radionuclides, such as certain positron emitters, remotely controlled production and automated radiosynthesis are generally used. For radionuclides with a very short half-life (less than 20 minutes), the control of the performance of the production system is an important measure to assure the quality of the radiopharmaceutical preparation before its release.

Any production procedure must be validated in test/trial production consecutive runs before its use in routine manufacture of radiopharmaceutical preparations, to ensure that under specified production conditions, the production system yields the radiopharmaceutical preparation in the desired quantity and specified quality.

The preparation of the dosage form of the final radiopharmaceutical preparation in the practice of nuclear medicine generally involves limited radioactivity starting from ready-to-use radiopharmaceutical preparations, generators, kits and radioactive precursors. All conditions which may affect the quality of the product (e.g. radiochemical purity, sterility, etc.) must be clearly defined and must include appropriate measures for radiation protection.