1. INTRODUCTION

The generator of radionuclide or milking system allows the obtention at the hospital of a solution of radionuclide for medical use. This system has greatly participated to the development of Nuclear Medicine over the past fifteen years. Although many couple of radioisotopes can be used, the most widespread generator of radioisotope is the 99Mo/99mTc generator system.

2. QUALITY OF A GENERATOR - DEFINITION

The quality can be defined as the fitness for use. In the special case of a generator which deliver a pharmaceutical product the quality concerns the physician who will eluate the generator and the patient who will receive the eluate direct as an injection or after labelling as a labelled compound. The common concept of quality covers in the physician's point of view: the delivery in time, the accuracy of the elution yield, the chemical strength and biological potency of the eluate. The patient is only waiting for an effective and safe drug.

3. THE PARAMETERS OF THE QUALITY

The parameters defining the quality of a generator can be attained by the manufacturer in two steps:

- The Research and Development step (R+D)
- The production step

The quality is reached in the R and D stage through an important analysis to define the parameters of the generator;
by this one must understand the definition of the intended usage. From this study the following parameters can be fixed:
- Nominal activities available
- Day of calibration
- Minimal elution volume
- Mode of elution
- Protection against radiation
- Security of the generator
- Convenience of handling

Some parameters are imposed by the pharmacopoeia:
- Radionuclidian purity
- Radiochemical purity
- Content in alumina
- pH
- Sterility

Some parameters such as pyrogenicity and toxicity which are not included in the pharmacopoeia can be taken into account by the manufacturer. An issued document will describe all these parameters and it will be considered as a reference quality standard document.

4. QUALITY ALONG THE MANUFACTURING PROCESS

From this document the manufacturing process and quality control analysis will be elaborated including the purchase, receipt and control of all the raw materials. To keep the quality of the product during its life cycle the manufacturer has to establish a Quality Assurance program to prevent any deviation from the quality standard. Furthermore the analysis of customer’s complaint - if so - will greatly help in taking the necessary actions to correct or improve the failing points. The implementation in the manufacturer's facilities of good manufacturing practices and quality control will be the most effective and less expensive ways to secure the quality of the produced generators. Among the quality controls which are performed during the manufacturing processes one must emphasize the importance of the control of the manufacturing environment as regard to the cleanliness and the control of the sterilization cycle to be sure to provide the users with a