



**Association of Imaging Producers & Equipment Suppliers**  
**European Industrial Association for Nuclear Medicine and Molecular healthcare**

Brussels, the 27th October 2015

*Subject: Conditions in 2016 for reliable and sustainable supply of medical radioisotopes*

Dear President,

Following the last meeting of the European Observatory for Medical Isotope Supply at EANM 2015 in Hamburg, AIPES would like to inform you about the recent demands regarding the supply of medical radioisotopes produced in reactor and more specifically Mo-99.

AIPES, the European Association of Nuclear Medicine Industry together with the European Commission in the European Observatory, and OECD and its High Level Group on Supply of Radiopharmaceuticals have regularly informed EANM on the present and future conditions of medical radioisotope production.

It was in this context that EANM had communicated in November 2013 to the nuclear medicine community what were the conditions for a reliable and sustainable supply of medical radioisotopes: a better funding and a reviewed pricing system for the Mo-99/Tc-99m generators. This new pricing system was critical to take into account the major investments required by authorities and needed at each step of the supply chain.

In 2013, the new pricing approach recommended in a transparent manner:

- the full implementation of the agreed NEA/OECD policy of Full Cost Recovery (FCR) and payment for Outage Reserve Capacity (ORC);
- the upgrade of security and safety requirements for nuclear operations, which have become more stringent over the last few years,
- conversion from High Enriched Uranium to Low Enriched Uranium for all materials irradiated to comply with the implementation of nuclear non-proliferation measures ;
- the upgrade of processes and equipment for the facilities managing radioactive waste;
- all technical and organizational requirements for full implementation of Good Manufacturing Practice (GMP) and related principles;

This EANM message forwarded in 2013 had certainly a powerful impact for a better understanding of these issues both by the hospital procurement departments as well as the Nuclear Medicine community. It also gave confidence to investors supporting the Nuclear

Medicine industry, demonstrating the plain and full commitment of the different stakeholders for the sustainability of the supply chain. .

Recently, two new constraints have emerged in the nuclear medicine industry which will add to the financial burden of the Full Cost Recovery requirement of the OECD principles:

- at the express request of the nuclear safety authority (French ASN), a new plant has to be built for the manufacturing of nuclear fuel rods and uranium targets used for Mo-99 and I-131 supply. The existing plant does not comply and cannot be upgraded to the last safety and security standards. The involved fuel rods are only dedicated to research reactors and the involved targets in those research reactors only used for medical radioisotopes. This investment is estimated in the range of 100 to 150 million Euros, and obviously a large part of it will be dedicated to nuclear medicine needs.
- the recent terrorist threat has increased worldwide at such a level that the governmental security authorities request that active and passive security at nuclear and radioisotope production sites be considerably strengthened as soon as possible. In particular, the US government put, as a condition to send enriched uranium to Europe, the implementation of such measures. This translates both in upfront investments and in recurrent operating costs.

However, it is the conviction of AIPES that the returned value of nuclear medicine, per se and in comparison with other modalities remains competitive. To this regard, AIPES has initiated new activities to support fair assessment of the added value of Nuclear medicine procedures.

If you need more information on this subject, please contact me.

Yours sincerely,

*Guy Y. TURQUET de BEAUREGARD*

*President*