



Association of Imaging Producers & Equipment Suppliers
(European Industrial Association for Nuclear Medicine and Molecular Healthcare)

Brussels, 4 February 2009

**URGENT UPDATE ON THE EUROPEAN SITUATION CONCERNING
THE PRODUCTION OF TC-99M FOR MEDICAL IMAGING
(DAUGHTER ISOTOPE OF THE MO-99 PRODUCED BY IRRADIATION OF THE U-235 TARGETS IN
RESEARCH REACTORS)**

In Europe there are 2 producers of Mo-99: COVIDIEN in Petten (NL) and IRE in Fleurus (B).

- IRE has irradiation positions in the following reactors: HFR (NL), OSIRIS (F) and BR2 (B)
- COVIDIEN has irradiation positions in HFR (NL) and BR2 (B).

The combined Mo-99 output from COVIDIEN + IRE is about 40 to 45 % of the worldwide demand (total 27 million of Tc-99m imaging procedures per year worldwide).

The combined Mo-99 output from COVIDIEN + IRE represents more than 90 % of the European demand (about 8 million procedures per year).

Normally about 50 % of the European Mo-99 requirement is produced with targets irradiated in the HFR reactor which is equivalent to 4 million SPECT (single photon tomography) clinical procedures per year in Europe.

In terms of production capacity, the HFR reactor is very important. In a normal situation the HFR schedule covers at least 280 days per year whereas OSIRIS and BR2 are only available respectively around 180 days and 120 days per year.

The operating schedules of the BR2 and OSIRIS reactors together with the Canadian NRU and the SAFARI reactor in South Africa are co-ordinated and optimised through AIPES (*). The schedules are fixed before the start of a calendar year and later modifications are very difficult to integrate (e.g. maintenance for reactors requires long term scheduling and is dependent upon specialised external contractors).

The original BR2 schedule for 2009 has already been changed following the unavailability of the HFR and this has involved moving forward to the spring period a production cycle that was scheduled for the 4th Quarter of 2009. An extra cycle has also been scheduled for 2010; but this requires additional staffing and funding. The result is that the BR2 and OSIRIS reactor schedules are now both heavily loaded towards the first half of 2009. Despite this there are still significant weak periods remaining when one or sometimes both reactors are unavailable at the same time due to necessary maintenance. It is very difficult to see how the schedule for the first half of 2009 can be strengthened further.

Most importantly, the changes already made have significantly weakened the schedule for the second half of 2009; when there will be a period of around 17 weeks from the 21st June to the 21st October when only the BR2 is scheduled to operate for one single 4-week period. Without operation of the HFR, this leaves more than 13 weeks when there will be no Mo-99 production in Europe.

The OSIRIS reactor has 2 long shutdown periods scheduled for refurbishment work: June – October 2009 and March – September 2010. This means that the OSIRIS reactor will essentially be unavailable for more than half of the time between June 2009 and the end of 2010. There is not much flexibility in this programme and it is clear that short term rescheduling of either BR2 or OSIRIS will only move the problems around.

The OECD/NEA Workshop held in Paris last week also identified that the reactors outside Europe, which are supporting the present supply situation, have been operating and producing at levels that are above a medium term sustainable level and that it is necessary to scale back production to protect their own security of supply. Therefore, reductions in the availability of material from outside of Europe can be anticipated in the coming weeks. The perspective from the radiopharmaceutical industry is that supply problems will become worse; with shortages in the 40-60% range when no reactor in Europe is operating and with the deeper shortages of more than 75% during periods when supplies from outside of Europe are also restricted.

To overcome the present shortage of Mo-99 on a global basis and more particularly for the European healthcare community and to avoid the worsening of the supply situation in the coming weeks and months; it is essential to restart the HFR reactor as soon as possible. This should of course be achieved without compromising safety.

The need for increased investment in essential infrastructure to support the European medical isotope production is evident.

The limited availability of the ageing reactors jeopardises the supply of medical isotopes for the detection of cancers, heart disease and dementia as well as providing medical therapy for oncology purposes; this is reducing the quality of medical care and damaging the quality of life of many patients.



Marc Gheeraert,
President AIPES

(*) About AIPES

AIPES (Association of Imaging Producers & Equipment Suppliers) brings the major pharmaceutical laboratories in nuclear medicine together with the major producers of medical equipments for this area of medicine, both multinationals and local medium size companies.

In addition to its role as lobbyist to the European institutions for positive treatment of diagnostic imaging procedures at the European Commission, both in respect to reimbursement and regulatory constraints; its role as provider of a forum for addressing specific radiopharmaceutical issues similar to CORAR in the US and its role as an industrial partner to the European Association of Nuclear Medicine and any other European medical society that could help in the promotion of diagnostic imaging, AIPES has as its goal, to communicate to the public the medical potential and the latest technical developments in the field of nuclear medicine.

Avenue Louise 65 – B 1050 – Brussels, Belgium – Tel: +32 2 535 89 45 – www.aipes-eeig.org

