

Multinational Production and Processing of Medical Radio-Isotopes:

A Vulnerable Supply Chain

Technetium-99m (Tc-99m) is the most commonly used Radio-Isotope in Nuclear Medicine. Worldwide, about 30 million patients are evaluated annually using Tc-99m based compounds for various diagnostic studies. Tc-99m has a short half life of 6 hrs and is obtained by periodic elution of a generator containing the parent Molybdenum (Mo-99), which in turn has a half life of 66 hrs. A recent (2009-2010) global shortage of Mo-99 adversely impacted patient care, involving 90% of practices in the United States, being forced to operate at less than 50% capacity.

This shortage was the result of an unexpected (a heavy water leak) and extended outage at the NRU Nuclear Reactor in Canada. More than 50 yrs old, the NRU reactor provides 30-40% of global demand for Mo-99. Along with the other 4 aging reactors (BR2 in Belgium, HFR in Netherlands, ORISIS in France, and SAFARI-1 in South Africa), NRU is also a government owned multipurpose research reactor, which produces Mo-99 by irradiation of high enriched Uranium (HEU) targets. Issues at this level involve low capacity, limited cooperation between reactors (sharing operating and maintenance schedules), low price of Mo-99 (government subsidy / social contract) and regulatory pressure to use low enriched (LEU) Uranium (to discourage proliferation).

The next step is the extraction and purification of Mo-99 from the irradiated targets, performed by local (within 1000 kms of the reactor) private companies like MDS Nordion (Canada), Covidien (Netherlands), IRE (Belgium), and NTP (South Africa). The irradiated targets are transported by road to these facilities in secured 4 ton containers. Limited by the half life of Mo-99, these companies have local capacity, but lack international capacity or cooperation. Greater harmonization is needed in communication protocols and regulatory approvals. Mo-99 is then used by the multinational companies to make generators which are shipped to nuclear pharmacies all over the world.

The shortage has stimulated: Multinational cooperation, facilitated by professional societies, the IAEA (International Atomic Energy Agency), the NEA (Nuclear Energy Agency), and the NRC (Nuclear Regulatory Commission); Increase in research spending to study Mo-99 production using LEU targets, non-Uranium based alternatives of Tc-99m supply (Cyclotron based production) and efficient waste management. Medical providers are looking into alternatives to Tc-99m based studies (cyclotron produced PET tracers, and using CT scanning and MRI where applicable). The American medical isotope production act (2009) aims to establish a domestic source of Mo-99 and eliminate exports of HEU. A stable supply chain of Mo-99 is essential to the survival of a medical imaging industry already struggling under lower reimbursements. Hopefully right lessons are learnt by all stakeholders from this devastating shortage.