

## **Session 1 Comments**

**Sally W. Schwarz:** provide your main thoughts on the session topic from the perspective of your organization (3 min)

### **The main objective of the conference:**

Identify opportunities and challenges for the use and development of ionising radiation in medicine, non-energy industry and research and to discuss potential solutions to addressing challenges in areas where the EU can add value.

I would like to thank the European Commission for hosting a Conference on Medical Industrial and Research Applications of nuclear and radiation technology, and for inviting me to represent the United States, Society of Nuclear Medicine and Molecular Imaging (SNMMI)—sister organization of the EANM. Currently I am the Immediate Past President of the SNMMI. By training I am a nuclear pharmacist, and have worked both in traditional nuclear medicine using Tc-99m radiopharmaceuticals and in PET. I am the Co-Director of our Cyclotron Facility. I feel that one of the primary focusses for diagnostic and therapeutic radiopharmaceuticals should be the benefit that they bring to patients to assist in managing and treating their disease.

The SNMMI is very concerned about the supply of Mo-99 for the US since the US uses ~50% of the worlds supply. In 2009, the NRU reactor in Canada, which normally supplied about a third of U.S. Tc-99m demand, shut down, and the Petten HFR reactor in the Netherlands, which supplied half the U.S. Mo-99, shut down for routine maintenance. The NRU will now cease production at the end this month, March 2018, but the HFR reactor has been refurbished and has increased it Mo-99 production and the ANSTO and SAFARI reactors has been approved for supplying Mo-99 to the US.

I have attended the OECD High Level working Group on Mo-99 for the past 3 years. I feel that the working Group has provided a forum for the dissemination of information regarding Mo-99 production and provided a venue for open discussions that have helped to address problems. I feel that it would be beneficial if these meetings can continue, and to address the issues of reimbursement.

AIPES has managed the worldwide Mo-99 production since 2009 which currently includes six nuclear reactors located in the EU, Australia and South Africa. AIPES done a good job of assuring the Mo-99 supply during planned and unplanned reactor maintenance problems. This group been represented at the OECD during my tenure. The fact still remains that some of these reactors are aging, additionally, the move to LEU targets is still in progress and there are other technical/political challenges which have occurred and which will require continued oversight and management.

Additionally the SNMMI is also interested in development of LEU both in the EU and the US. Additionally radionuclide therapy is important for the future of nuclear medicine. This type of therapy requires increased production of the therapeutic radionuclides such as Lu-177, Ac-225 and Ra-223. The US FDA has finally moved forward to embrace these therapies. The EU has been at the forefront of radiotherapy efforts. This will also increase the demand for increased radionuclide production for clinical trials and SNMMI would like to encourage the continued EU support in the production of these radionuclides.

To close, I would like to thank you again for hosting this important conference focussing on the future of medicine and research involving the use of radionuclides, and for inviting SNMMI to be part of this event.

- **How do we ensure adequate production capacity for Mo-99 in order to ensure continuity of supply (e.g. US example)? What are the main factors that should be presented to facilitate EU investment decisions? (5 min)**

**The SNMMI is committed to assuring that the supply of Mo-99 is adequate to deliver the nuclear medicine diagnostic procedures for patients in the US.**

- Tc-99m remains the most commonly used radioisotope used in more than 30 million diagnostic studies performed annually
- The US uses over 50% of the world's Tc-99m supply and has only one recently approved source of Mo-99 in the US
- The US Government has proliferation concerns regarding use of highly enriched uranium (HEU) and has required the conversion to LEU by 2020. The EU has been in agreement with this requirement to change the production of Mo-99 from HEU to LEU and it is important to support this change.
- The US Department of Energy and National Nuclear Safety Administration (DOE/NNSA) is providing matching funding opportunities for development of Mo-99 domestic production methods, not relying on HEU.

#### **US DOE/National Nuclear Safety Administration (NNSA)**

- Has partnered with US commercial entities since 2009, to accelerate the development of non-HEU technologies to produce US based Mo-99
- DOE/NNSA is providing matching funding opportunities up to \$25 Million for each for development of four Mo-99 domestic production methods, not relying on HEU. Also it is likely that DOE will be adding an additional 10 million for each project.
- The 4 Current commercial partner projects include:
  - NorthStar that holds two of the four cooperative NNSA agreements. Both can use their new RadioGenix Generator
    1.  $^{98}\text{Mo}$  (n, $\gamma$ )  $^{99}\text{Mo}$  (2016)--Obtained FDA approval in February 2018 for this process
    2.  $^{100}\text{Mo}$  ( $\gamma$ ,n)  $^{99}\text{Mo}$  (2018-19? )
  - General Atomics (GA)/Nordion/ University of Missouri Research Reactor (MURR)
    - Selective Gas Extraction (SGE): extract Mo-99 from non-HEU targets at MURR
    - Processing at cGMP Nordion facilities (2018?)

- Shine Medical Technologies, Inc.
  - Accelerator-based neutron source
  - Deuterium-tritium fusion = neutrons
  - Liquid LEU target

## **Summary**

- EU should continue support for the AIPES management and the OECD High Level Meetings
- The increased Curium and ANSTO Mo-99 production capacity increases are a big help to global supply.
- Support the continued conversion to LEU-based targets and process
- Northstar received FDA approval of their generator in February 2018 which can assist in providing the first US supply.
- The prospect of additional Mo-99 supply from new market entrants needs to be encouraged.
- Support the EU Pallas reactors which can also provide the industry with additional LEU target irradiation capacity for Mo-99 in the future.
- The current supply outlook for Mo-99 remains good, even with the problems experienced by South Africa.