

# Coordinated International Efforts for Reliable Supply of Medical Radioisotopes

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Chairman, Security of Supply (SoS) WG

**DOE Mo-99 Topical Meeting**

IAEA Headquarters  
Vienna, Austria  
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## Nuclear Medicine Europe

- **The European Industrial Association for Nuclear Medicine and Molecular Healthcare – “working together to improve molecular healthcare”**
- **33 members, 5 Associate Partners, and 10 reactor operators**
- **Executive Committee and 5 Working Groups:**
  - **Security of Supply (SoS WG)**
  - **Transport Experts**
  - **Communications**
  - **Therapy**
  - **Regulatory Affairs**

## **Security of Supply (SoS) Working Group Mission/Objectives**

- **Nuclear Medicine Europe members and research reactors (RR) which irradiate targets for medical isotope production.**
- **Ensure isotope production continuity and supply of radiopharmaceutical imaging and therapy products to patients.**
  - **Coordinate research reactors operating schedules to provide adequate global coverage during planned reactor shutdown periods for refuelling and maintenance.**
  - **Respond to potential or actual disruptions in production (Emergency Response Team, ERT).**
- **Exchange info on medical isotope developments between radiopharm manufacturers and RR operators; discuss issues of common concern.**
- **Coordinate within NMEu; consult and communicate with external stakeholders (EU Observatory; SAMIRA/ERV; OECD/NEA, IAEA).**

## SoS WG Activity

- **Virtual meetings only in 2020 (June, November) and 2021 (June, December) for reactor schedule coordination and other issues.**
  - ERT – Covid, March-May 2020
  - ERT – OPAL, March-April 2021
- **Participated/contributed to EU SAMIRA studies (2020-2021).**
- **Communications in fall 2021 to EU re: I-131 supply, IRE HEU outage.**
- **24 Jan-21 March 2022 HFR unplanned outage**
  - ERT meetings and 9 written communications.
- **Discussions with and communications to EU regarding Russian isotope supply and potential sanctions**
- **SNMMI Vancouver, June 2022 (1st in-person meeting since 2019).**
  - 2022/2023 Reactor Schedule Coordination (2022 Rev. 4/5; 2023 Rev. 0/1)

## Spotlight - COVID-19 Response

- SoS WG/ERT met weekly beginning 9 March 2020 thru 28 May 2020; exchanged info – especially transport situation - and shared best practices.
- The medical radioisotope supply chain demonstrated resiliency.
- Patients were able to receive life-saving diagnostic and therapeutic isotopes despite the various challenges posed by the pandemic.
- Certain regions were impacted by reduced and/or re-scheduled deliveries.
- However, global Mo-99 production continued un-interrupted.
- The Mo-99 supply chain – medical isotope target production; research reactors; Mo-99 processing facilities; Tc-99m generator production facilities and logistics/transportation providers took actions to protect workforces from COVID-19 to ensure continuity of service.
- Greatest challenge was in the global transport of Mo-99 and Tc-99m generators, due to the major disruptions and reductions in commercial air passenger (and related cargo) service.
- Security of supply of medical isotopes was maintained by the sustained efforts of many institutions, companies, and employees during this difficult and challenging period.

## SoS WG Current Activities

- **Communication to EU Observatory/external stakeholders re: I-131 situation for Fall-Winter 2022**
  - MARIA research reactor maintenance September 2022 thru February 2023
- **Virtual meeting 6 September to discuss potential adjustments to 2023 Rev. 2; letters subsequently sent requesting schedule changes.**
- **SoS WG in-person meeting, 17 October, EANM Barcelona – 2023 schedule finalized.**
- **Continued monitoring concerning potential Russia stable and radioactive isotope sanctions.**
- **Provide advice/assistance for SAMIRA Action Plan/European Radioisotope Valley Initiative re: emerging isotope requirements.**

## Conclusions

- **Coordinated nuclear medicine industry and stakeholder efforts have played a critical role in efforts to strengthen the Mo-99 and other isotopes supply chain.**
- **Industry-supported measures have been successful in improving the reliability and security of supply of Mo-99 and other isotopes.**
- **Attention required for new developments in nuclear medicine (theranostics/therapy) and interaction with efforts such as European Radioisotope Valley Initiative.**





# DOE Mo-99 Topical Meeting

**FIND. FIGHT. FOLLOW.**

IAEA HQ Vienna

October 6-7, 2022



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# 65 Years of Imaging Innovation



**Nearly 50 years of  
Technetium Tc-99m  
generator  
manufacturing  
expertise**



**Most used  
radiopharmaceutical  
imaging agent in the  
U.S.<sup>1</sup>**



**#1 ultrasound  
enhancing agent  
used in the U.S.  
for 20 years<sup>2</sup>**



**Best-in-class  
PSMA PET  
imaging agent  
for prostate  
cancer**

(1) Sestamibi was the most used radiopharmaceutical in the U.S. based on procedure volume, DRG 2019 Imaging Market Guide.

(2) DRG Echo Monthly Monitor.

# Lantheus Business Groups

## Portfolio categories:

1

Precision  
Diagnostics



Xenon  
Xe 133 Gas



2

Radiopharmaceutical  
Oncology



1095\*

LMI 1195\*

3

Strategic Partnerships  
& Others

Pharma Services: Biomarkers

NTI-1309\* RATIO NM-01\* reflexion\*\*



Microbubble Partnerships\*\*\*



piflufolastat F 18\*\*

CURIUM™ EU ONLY

flurpiridaz\*



1404\*



Product candidates; \*\* Revenue will be reported under the Radiopharmaceutical Oncology category; \*\*\* Revenue will be reported under the Precision Diagnostic category; \*\*\*\* Revenue will be reported under the Strategic Partnerships & Other category



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## Radioactive Diagnostic Agent

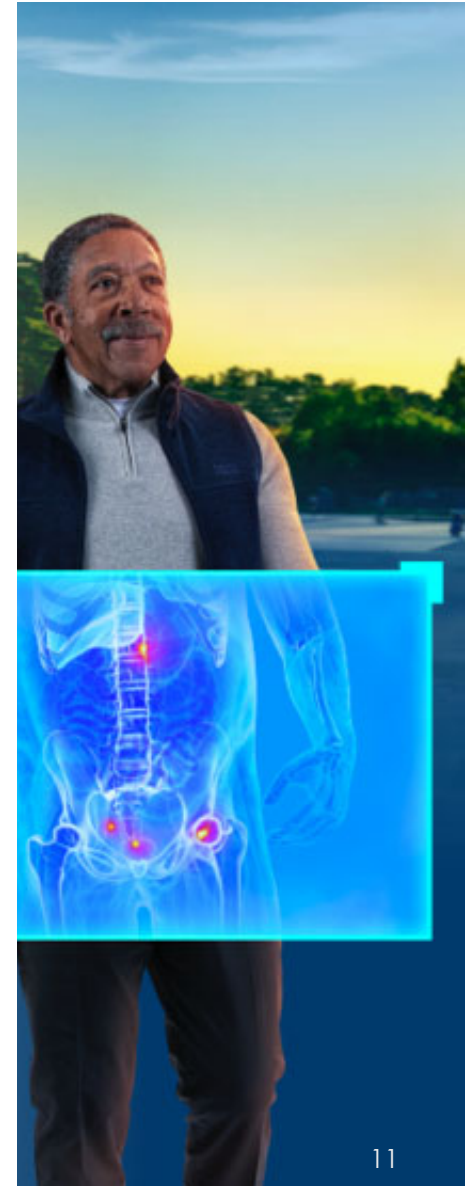
PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

## Radiopharmaceutical Oncology

PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company.

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# Medical Radioisotope Update

## **Current Mo-99 and Radiopharmaceutical Market/Recent Developments:**

- Mo-99 supply has been reliable and sufficient:
  - global supply chain had adequate capacity to adjust to unplanned February-March HFR outage (no impact to Lantheus).
  - MARIA research reactor began six month planned maintenance at beginning of September, reduces global I-131 supply.
- Lantheus Mo-99 producers have largely completed conversion to LEU.
  - Due to our balanced and diversified supply chain, Lantheus remains confident in Moly supply despite planned and unplanned outages at individual reactors.
  - IRE I-131 LEU conversion still underway.
- Russia:
  - logistics and financial sanctions have complicated export of Russian isotopes (no impact to Lantheus).
  - Inflation Reduction Act promotes increased U.S. domestic isotope production.

## **Domestic Mo-99 and radioisotopes:**

- Lantheus pleased to see SHINE construction progressing; logistics & regulatory preps.
- Tc-99m will continue to be an important imaging modality even as demand for theranostic radiopharmaceuticals increases (e.g. PMSA for prostate cancer Rx/Dx).