



## LEU TechneLite<sup>®</sup> Generator Update

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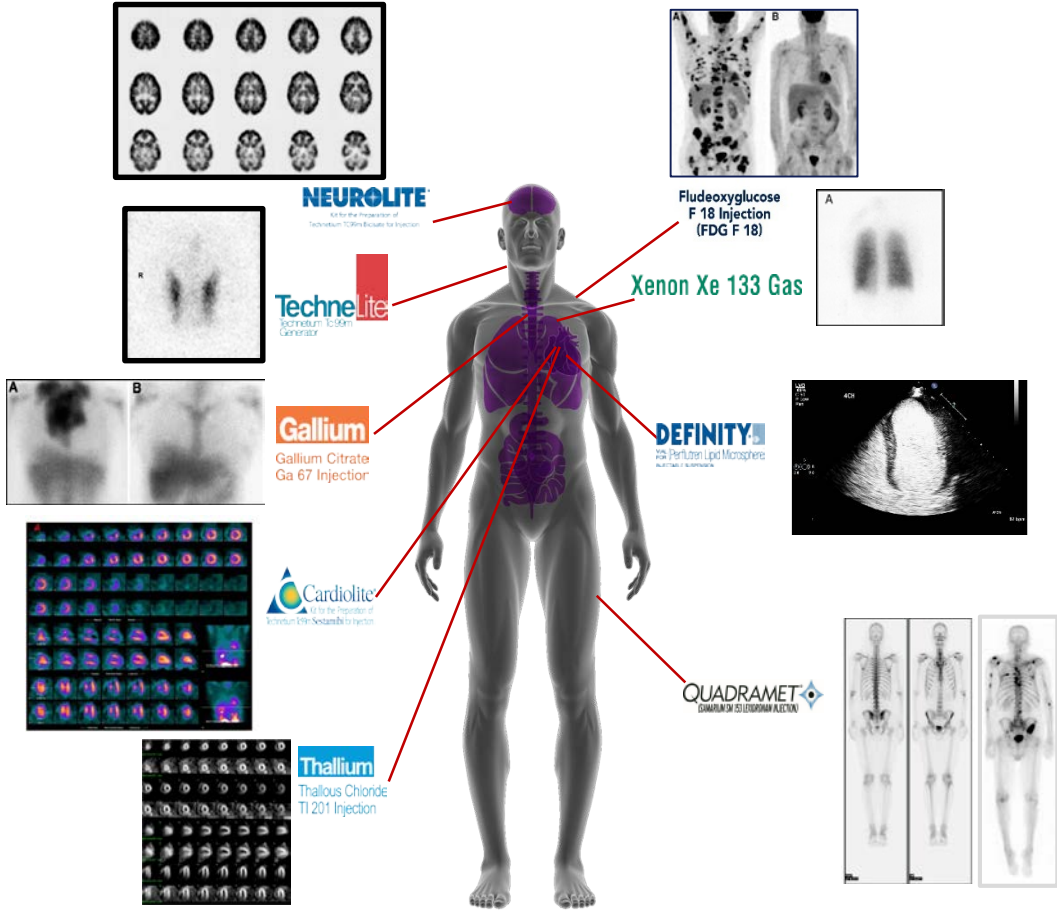
**Kathy McFadden**

**Vice-President, Commercial – Nuclear Products**

***DOE Mo-99 Topical Meeting  
September 25, 2018  
Knoxville, TN***



# 60+ Years of Innovation, Providing Leading/Best-in-Class Imaging Agents and Products



## Lantheus at-a-Glance

- Global leader in diagnostic medical imaging
- Develop, manufacture and commercialize essential diagnostic imaging agents and products that help healthcare professionals identify disease and improve patient treatment and care
- Diversified portfolio serving Echocardiography and Nuclear Medicine specialties
  - Lead products include *DEFINITY*®, *TechneLite*® and *Xenon*
  - Dynamic pipeline contains promising next-generation imaging agents
- Worldwide distribution partnerships covering EU, APAC, and LatAm regions
- Operations in U.S., Puerto Rico and Canada with headquarters in North Billerica, MA
- 2017 worldwide revenue: \$331.4 million
- ~480 employees including the largest dedicated echocardiography sales force based in North America
- IPO in June 2015 (Ticker: LNTN)

Schematic for illustrative purposes only. Please see Indications and full Prescribing Information on product specific pages of Lantheus.com.

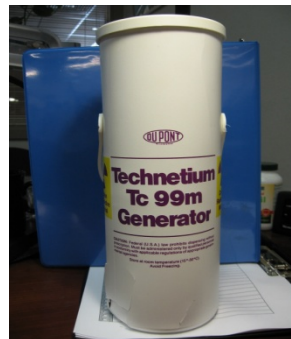
# TechneLite® Generator History

- $^{99m}\text{Tc}$ - generator developed in Brookhaven National Labs in 1958 and commercialized in the mid 1960s
- $^{99m}\text{Tc}$  generator manufactured by LMI and predecessors since 1967
  - New England Nuclear (NEN) introduced Tc-99m Generator based on Mo-99 produced by neutron capture ( $^{98}\text{Mo}$  (n, $\gamma$ )  $^{99}\text{Mo}$ )
  - NDA for generator based on Mo-99 from fission of U-235 ( $^{235}\text{U}$  (n,f)  $^{99}\text{Mo}$ ) approved in 1975
- TechneLite®, terminally sterilized generator introduced in 1993
- TechneLite®, CMS compliant LEU sourced Mo-99 introduced in 2013

1967-1974



1974-1993



1993

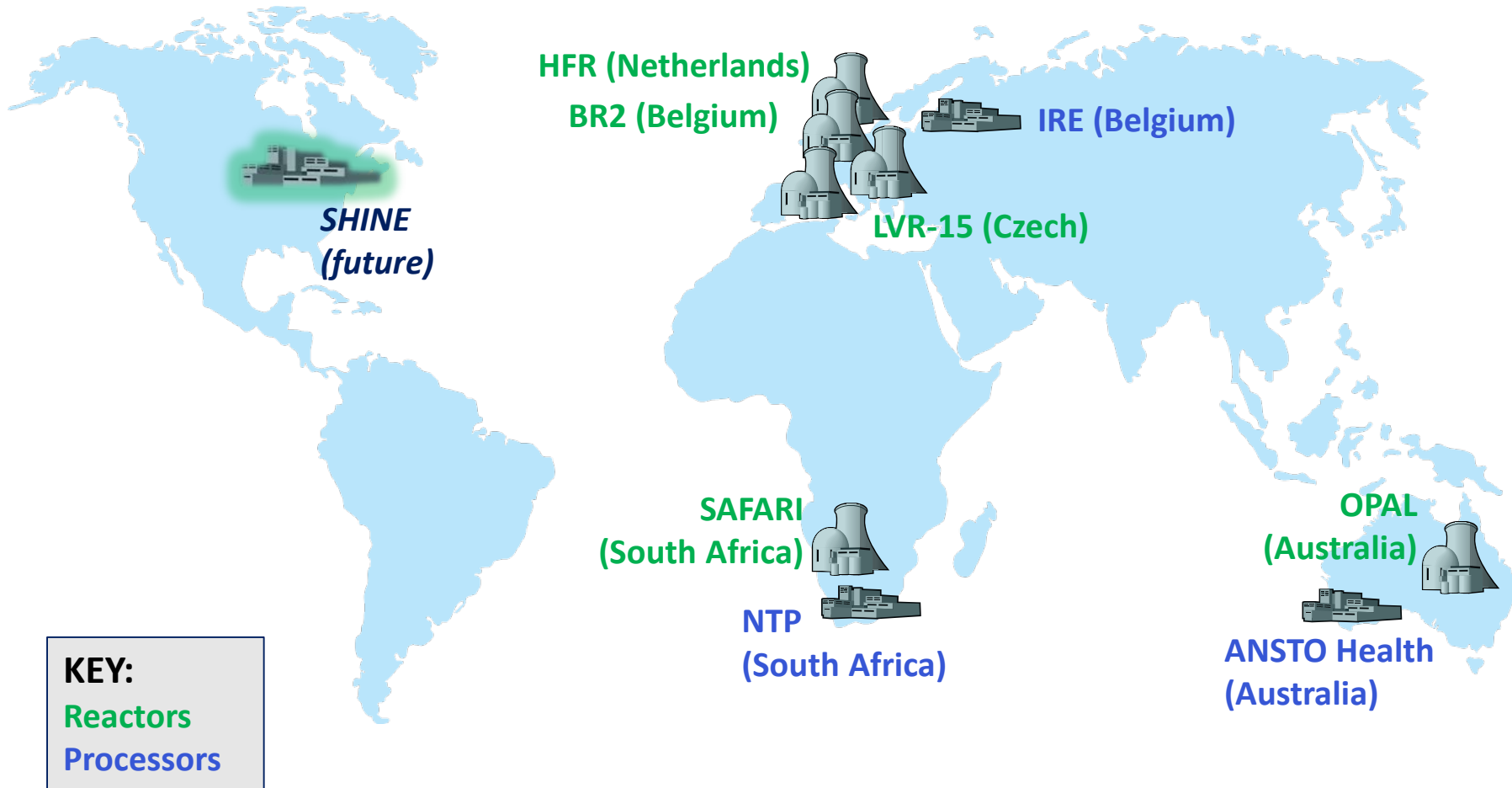


2013



# Lantheus Mo-99 Supply Chain

## Reactors & Processors



# Support for Non-HEU U.S. Domestic Supply

- **Lantheus has supported U.S. Government efforts to establish domestic, non-HEU Mo-99 production**
  - Lantheus testimony, House Energy and Commerce Committee, 2009
  - Supported American Medical Isotope Production Act (AMIPA); passed in 2012, signed into law Jan. 1, 2013
  - CORAR engagement with Congress and DOE
  - Lantheus consistent participation in informal coalitions to promote additional U.S. cooperative funding and Q9969 \$10 add-on payment
- **Lantheus has supported U.S. Government efforts to convert medical isotope production to LEU**
  - First generator manufacturer to qualify LEU-produced Mo-99 for use in TechneLite<sup>®</sup> generators (South Africa 2010; Australia 2011)
  - First to produce all LEU Mo-99 generator in January 2013 which met Center for Medicare Services criteria for \$10 add-on payment

# Upcoming LEU Mo-99 Supply Developments

- **ANM hot commissioning underway**
  - Validation runs planned for October
  - Commercial supply in 2Q2019
- **IRE LEU conversion progressing**
  - Validation runs expected in early 2019
  - Commercial supply in 2H2019

# Future – LEU Supply from SHINE Medical

- **Lantheus and SHINE concluded supply agreement in Oct. 2014**
- **SHINE evaluated and supported by Department of Energy Cooperative Agreement program**
- **SHINE High Specific Activity Mo-99 will be compatible with Lantheus TechneLite<sup>®</sup> Tc-99m generator with no design changes**
- **Use of several accelerators and production lines means continuous production**
- **Alternative technology strengthens Lantheus Mo-99 supply diversification**
- **Lantheus also engages in regular discussions with other domestic projects, monitors progress**

# Xe-133

- **Xe-133 used in U.S. for pulmonary imaging**
- **Lantheus longest continuous supplier of Xe-133 gas for pharmaceutical use**
- **Lantheus agreement with IRE in Jan. 2015 for supply of Xe-133 gas**
- **First commercial shipment June 30, 2016; IRE completely replaced NRU beginning in November 2016**
- **Additional diversification options being pursued**
- **LEU-based Xe-133 development advancing**



# Conclusions

- **Lantheus has taken a leadership role in use of LEU Mo-99 in its TechneLite<sup>®</sup> generator supply chain**
- **LEU TechneLite<sup>®</sup> generators poised for significant increase in 2019**
- **LEU key to enhanced global nuclear security and creates foundation for more secure, reliable future supply of Mo-99**
- **Anticipate full conversion to LEU in 2019**
- **Lantheus and IRE have demonstrated reliable Xe-133 supply**

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Thank you

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Questions?