



TechneLite[®] Generators Manufactured with LEU-based Mo-99

I. Goldman, T. Moller, K. McFadden

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Content

- **Lantheus LEU leadership**
- **LEU TechneLite[®] Manufacture**
- **LEU TechneLite[®] Commercial Status**
- **Conclusions**

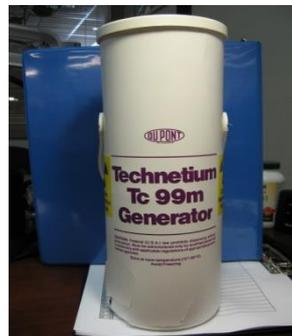
TechneLite® Generator - History

- ^{99m}Tc - generator developed in Brookhaven National Labs in 1958 and commercialized in the mid 1960s
- ^{99m}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}Mo (n, γ) ^{99}Mo)
 - NDA for generator based on Mo-99 from fission of U-235 (^{235}U (n,f) ^{99}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 Medical Imaging (LMI)

Company Overview

- A global leader in innovative diagnostic medical imaging agents
- Pharmaceutical imaging agents used to diagnose coronary artery disease, congestive heart failure, stroke, peripheral vascular disease and other diseases

Headquarters

- N. Billerica, Massachusetts

Offices

- Canada, Puerto Rico, Australia

Commercial Products

- 10

Development Pipeline

- Three next-generation product candidates that use Positron Emission Tomography (PET) and Magnetic Resonance Imaging (MRI)



Lantheus Medical Imaging

LEU Leadership

- **FIRST** – to receive FDA approval for LEU Mo-99 in North America:
 - ANSTO: June 2009, May 2011
 - NTP: September 2010
- **FIRST** – to commercially sell a generator made with only LEU Mo-99 (December 2010)
- **FIRST** – to have LEU Mo-99 as a routine part of blended Tc-99m production (May 2011)
- **FIRST** – to commercially manufacture and regularly distribute CMS non-HEU incremental add-on HOPPS payment compliant generators (beginning Jan. 7, 2013)



Lantheus Medical Imaging
adds the innovative
LEU TechneLite[®]
(Technetium Tc 99m Generator)
to our Nuclear
Medicine Portfolio

Available NOW!



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LEU TechneLite® Manufacture

- LMI has performed 55 LEU TechneLite® generator runs 2013-14
- Validated cleaning process after each run ensures manufacture line is clean and no carryover of HEU Mo-99 can occur
- All aspects of LEU TechneLite® generators including product insert and labeling are identical to blended or HEU generator
- TechneLite® LEU generators marked as eligible for CMS add-on HOPPS payment by circular green sticker affixed to top of generator can and unique item number
- LEU TechneLite® generator segregation and identification
 - manufacturing batch records - different code for LEU Mo-99 than HEU Mo-99
 - specific catalog/item number in the Lantheus product catalog and systems (18000-ML versus 18000-M for HEU generator)
 - identifying item number is also on packing, shipping documents and invoice
 - lot number unique identifier – with an “A” incorporated (non-HEU generator - M123456A)
- Certification document provided by LMI to customers receiving an LEU TechneLite® generator

Lantheus LEU Mo-99

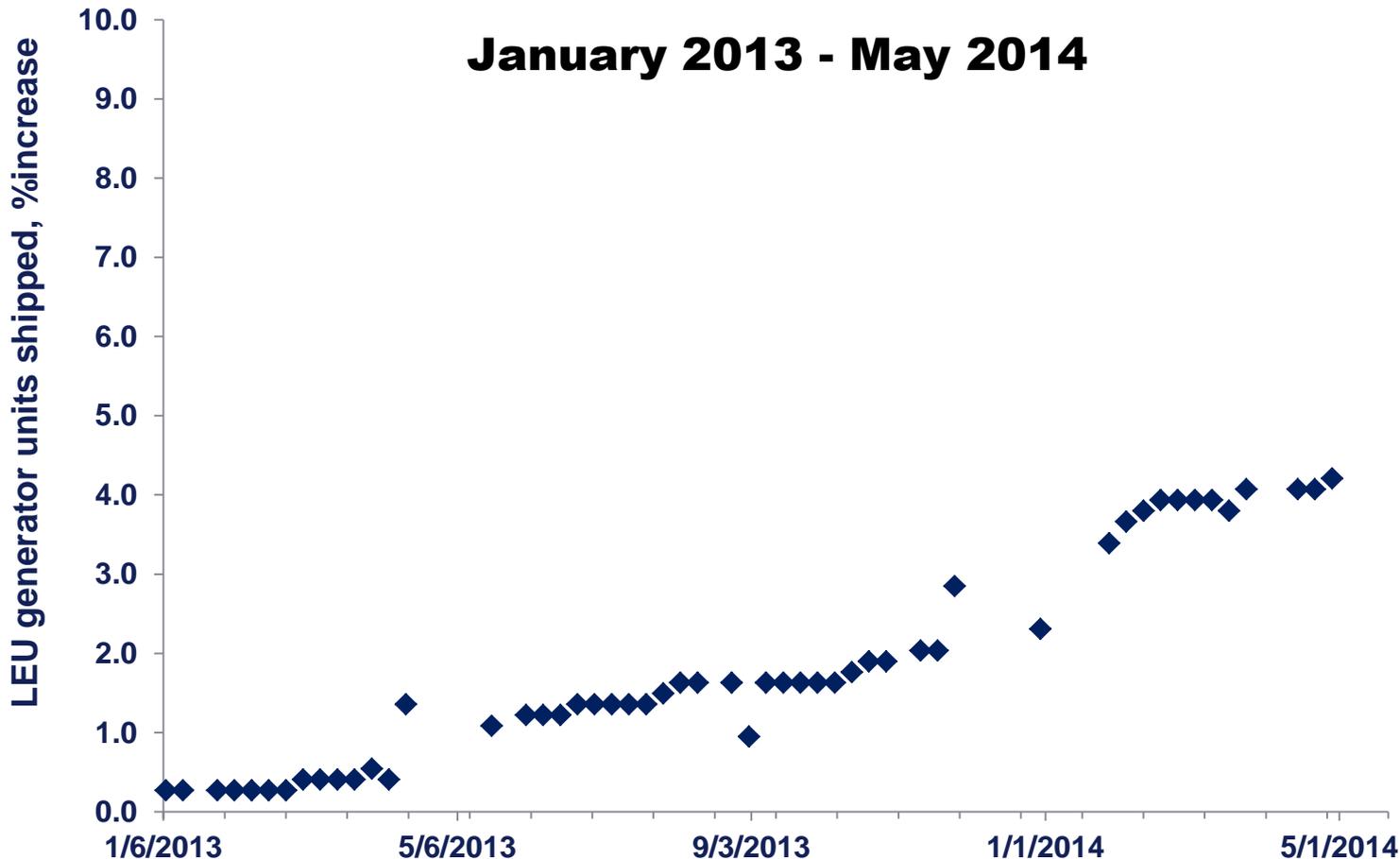
- LEU Mo-99 as proportion of total LMI purchased Mo-99

2013: <30%

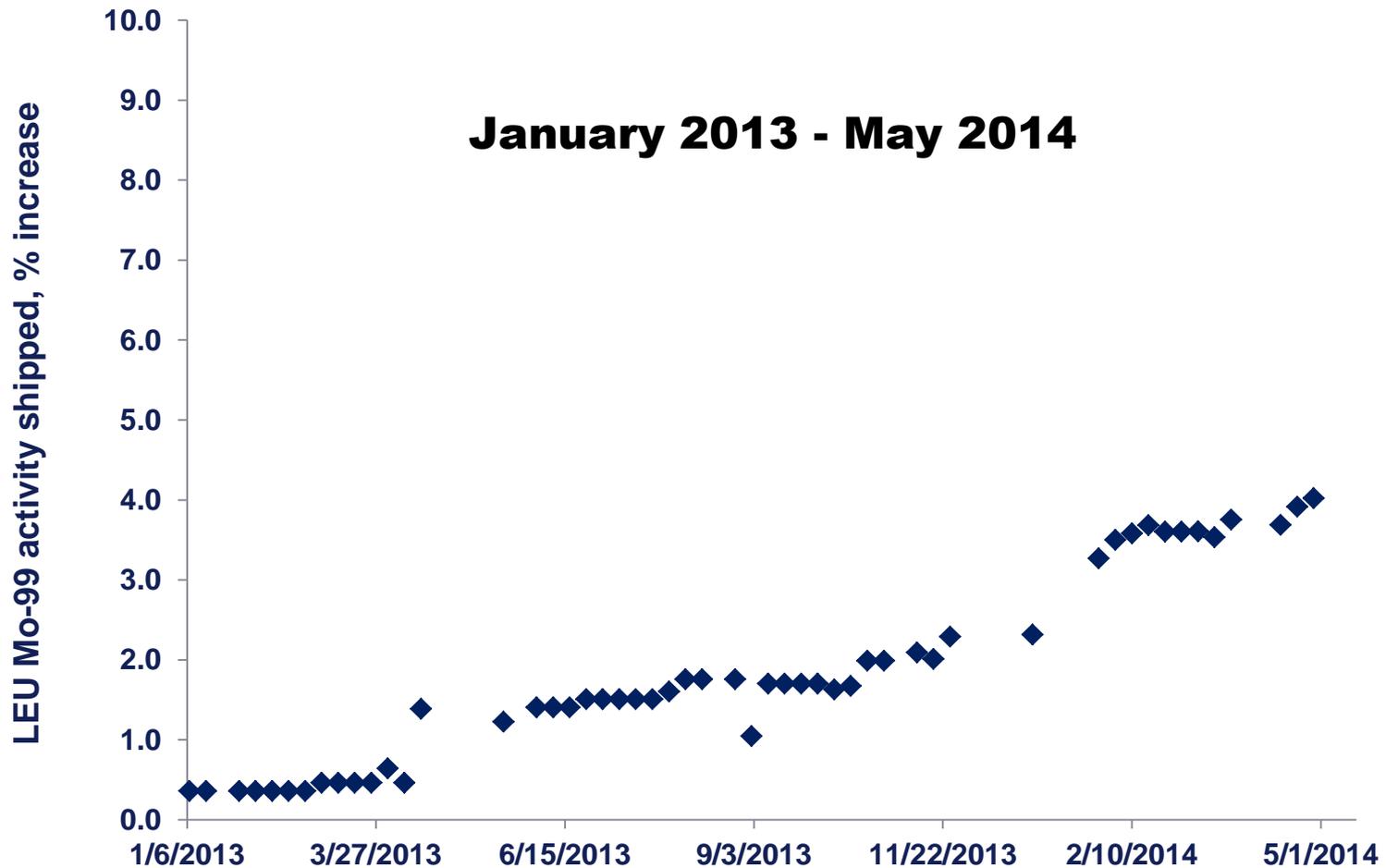
2014 (thru May 31): <40%

- LEU supply chain issues in 2014 have constrained the ability to meet rising market demand
- Actions underway with LEU Mo-99 suppliers to strengthen and improve reliability and availability of LEU Mo-99 for 2H 2014.
- Plan to reliably supply LEU Technelite[®] generators on weekly basis going forward
- Depending upon demand and customer committed orders, may add an additional or different day of manufacture

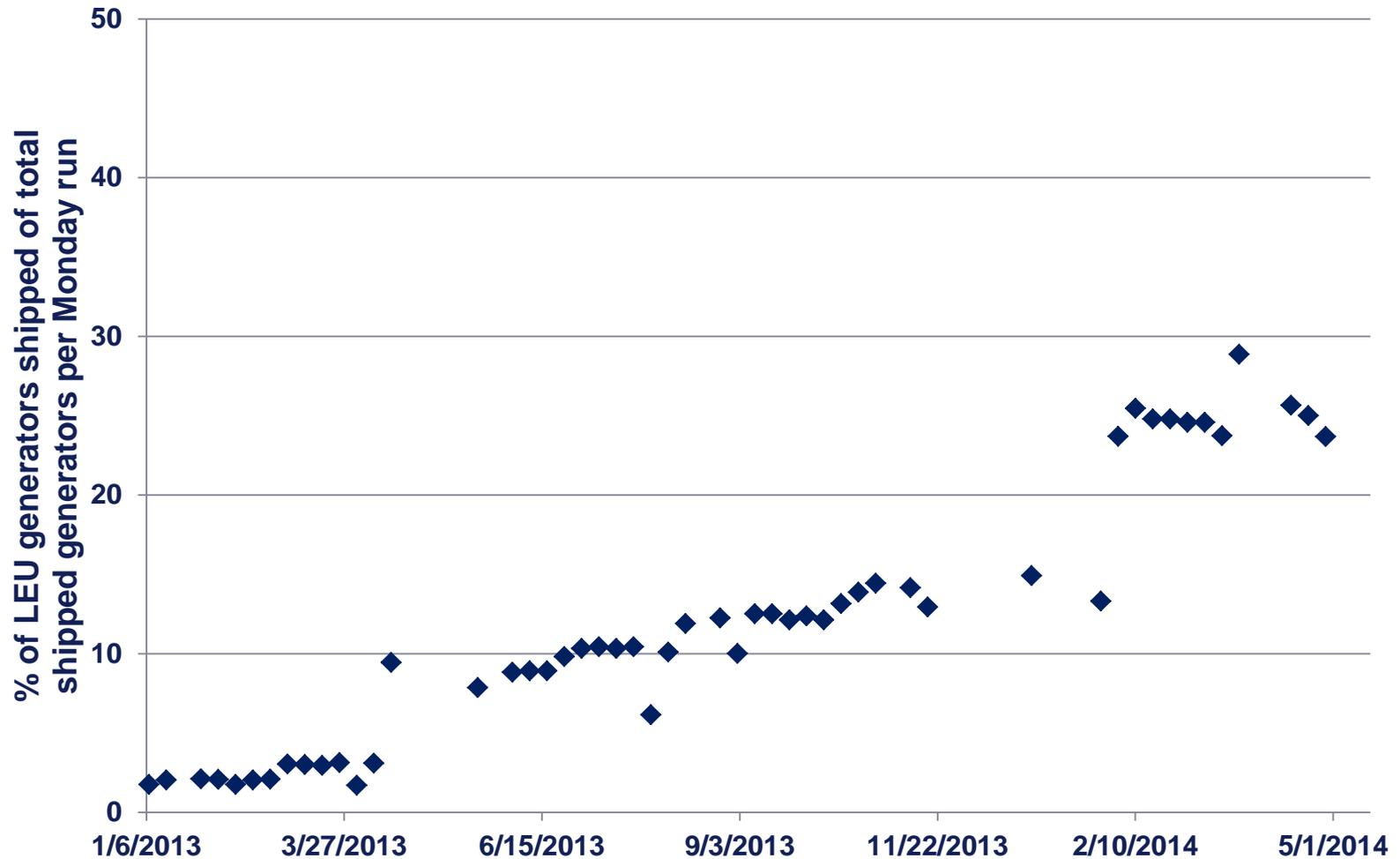
LEU TechneLite[®] generators shipped % increase per LEU manufacture run



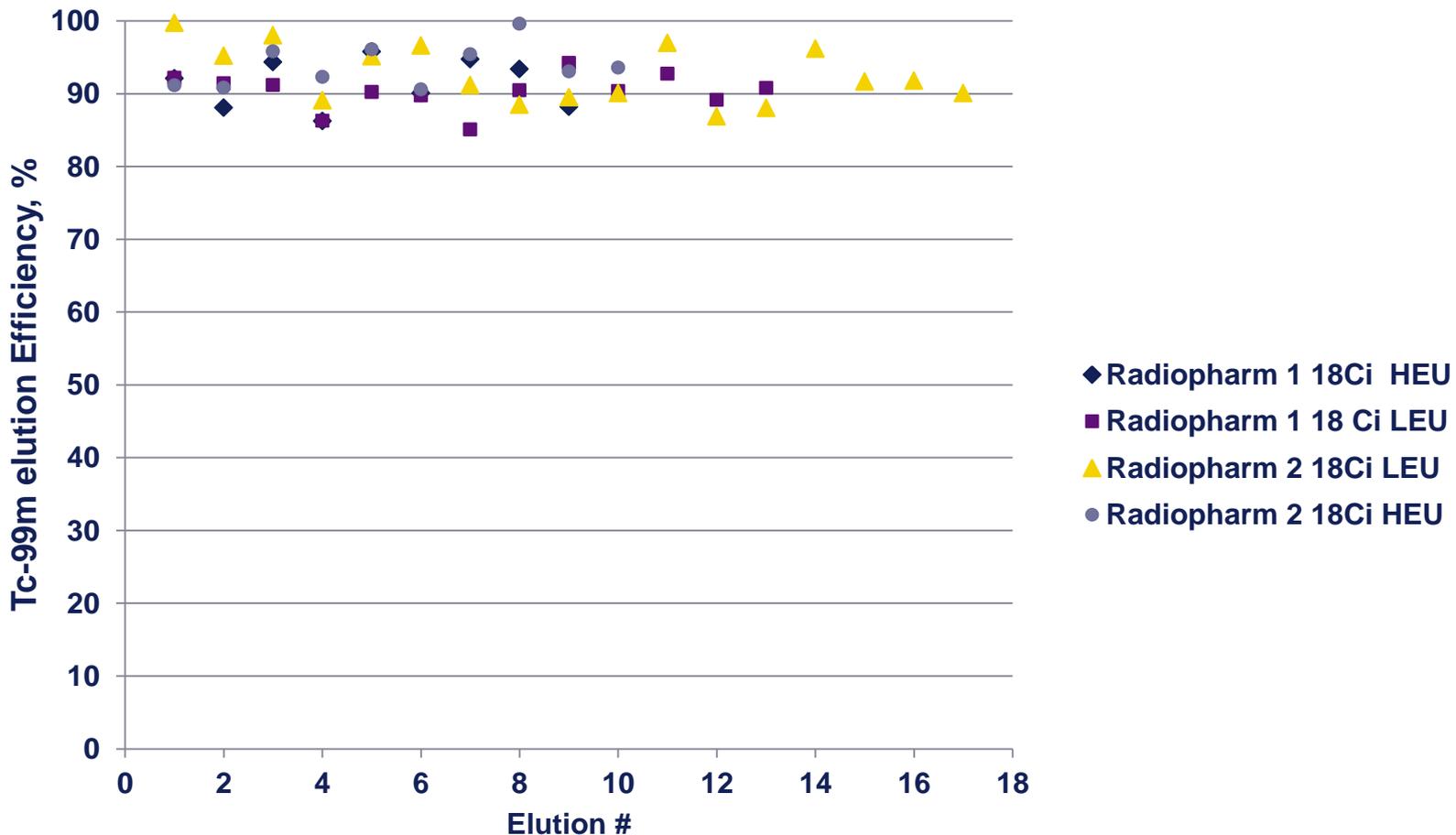
LEU Mo-99 activity shipped % increase per LEU manufacture run



Increase (%) in shipped LEU TechneLite[®] generators per manufacture run



Radiopharmacy experience - Tc-99m elution efficiency (%) from 18 Ci TechneLite[®] generators



Conclusions

- **Quality and properties of LEU TechneLite[®] generators are equivalent to HEU or blended LEU/HEU Mo-99 generators**
- **Tc-99m produced from > 95% LEU content TechneLite[®] generators meets the USP specification**
- **Lantheus has taken a leadership role in use of LEU Mo-99 in its TechneLite[®] generator supply chain**
- **Commercial adoption of LEU TechneLite[®] generators is steadily increasing**
- **LEU contributes to enhanced global nuclear security and creates foundation for more secure, reliable future supply of Mo-99**

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Thank you

Questions?