TechneLite® Generators Manufactured with LEU-based Mo-99

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Washington, DC
Content

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• LEU TechneLite® Manufacture
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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
# Lantheus Medical Imaging (LMI)

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<th>Company Overview</th>
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<td>• A global leader in innovative diagnostic medical imaging agents</td>
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<td>• Pharmaceutical imaging agents used to diagnose coronary artery disease,</td>
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<td>congestive heart failure, stroke, peripheral vascular disease and other</td>
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<td>diseases</td>
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<th>Headquarters</th>
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<td>• N. Billerica, Massachusetts</td>
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<th>Offices</th>
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<td>• Canada, Puerto Rico, Australia</td>
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<th>Commercial Products</th>
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<th>Development Pipeline</th>
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<td>• Three next-generation product candidates that use Positron Emission Tomography</td>
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<td>(PET) and Magnetic Resonance Imaging (MRI)</td>
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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 Technetium Tc 99m Generator to our Nuclear Medicine Portfolio.

Available NOW!
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

January 2013 - May 2014
LEU Mo-99 activity shipped
% increase per LEU manufacture run

January 2013 - May 2014

LEU Mo-99 activity shipped, % increase

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

% of LEU generators shipped of total shipped generators per Monday run

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

Tc-99m elution Efficiency, %

Elution #

- Radiopharm 1 18Ci HEU
- Radiopharm 1 18 Ci LEU
- Radiopharm 2 18Ci LEU
- Radiopharm 2 18Ci HEU
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?