NTP Radioisotopes SOC Ltd

Reflections of 4 Years of Conversion Experience

G Ball

Topical Meeting on Mo-99 Technological Developments
Washington D.C., 24-27 June 2014

www.ntp.co.za
Outline

- Brief Background
- Current Status
- Experienced gained
- Future sustainability
# Background - Time Line

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>Theoretical feasibility studies</td>
</tr>
<tr>
<td>2008</td>
<td>Cold and depleted uranium experiments</td>
</tr>
<tr>
<td>Oct 2009</td>
<td>NNR approval received for test stage and first hot runs commence</td>
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<tr>
<td>Mar/Apr 2010</td>
<td>Process validation runs performed</td>
</tr>
<tr>
<td>Jun 2010</td>
<td>Submission to NNR for routine LEU $^{99}$Mo production Submission of DMF to Medical Regulators commenced</td>
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<tr>
<td>Jul 2010</td>
<td>Customer tests and validation runs commenced</td>
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<tr>
<td>Sep 2010</td>
<td>NNR approval received for routine operation with LEU</td>
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<tr>
<td>Sep 2010</td>
<td>US FDA approves LEU $^{99}$Mo for a customer in the US</td>
</tr>
<tr>
<td>Dec 2010</td>
<td>First large scale commercial FDA approved batch of LEU $^{99}$Mo produced and shipped to US for patient use</td>
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<tr>
<td>Jun 2011</td>
<td>Routine commercial supply of LEU $^{99}$Mo commenced to some customers</td>
</tr>
<tr>
<td>Sep 2011</td>
<td>Commencement of investment in plant modifications (due to conversion)</td>
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<tr>
<td>Mar 2012</td>
<td>Commenced with project to regain lost production capacity</td>
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# Background – Target Details

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LEU</th>
<th>HEU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat</td>
<td>Dispersion</td>
<td>Alloy</td>
</tr>
<tr>
<td>Enrichment (%)</td>
<td>19.75</td>
<td>45.0</td>
</tr>
<tr>
<td>Uranium Density (g.cm(^{-3}))</td>
<td>2.75</td>
<td>1.42</td>
</tr>
<tr>
<td>Dimensions (mm)</td>
<td>200/50/1.66</td>
<td>200/50/1.66</td>
</tr>
<tr>
<td>Cladding</td>
<td>Alloy</td>
<td>Pure aluminium</td>
</tr>
<tr>
<td>U-235 Loading</td>
<td>Maintain (or minimise decrease)</td>
<td></td>
</tr>
</tbody>
</table>
Current Status – $^{99}$Mo

% LEU Distribution relative to all LEU runs

- 2009
- 2010
- 2011
- 2012
- 2013
Current Status – $^{131}\text{I}$

% LEU 131I Distribution

- 2009
- 2010
- 2011
- 2012
- 2013
Current Status – Projects

Dissolution Cell

Reason: Required due to significant increase in uranium volumes

Status: Commissioned

Future: Upgrade existing dissolution hot cells
Current Status – Projects

Uranium Residue Storage Facility

Reason: Required due to significant increase in uranium volumes

Status: Cold commissioning completed

Future: Hot commissioning to be completed later in 2014
Experience Gained

Technical Issues

• Target Specifications
• Process Parameters
• Scalability
• Combined HEU and LEU based $^{99}$Mo production
• Increased waste volumes

$^{99}$Mo Production with LEU is far more difficult than with HEU
Experience Gained

Financial & Other Issues

• Lower production capacity per target

• Increased cost of production

• Unrealistically low $^{99}\text{Mo}$ price expectations by industry

• Failure of implementation of full-cost recovery initiatives

• Customer appetite & Regulatory complexities

Threatening the future of the nuclear medicine industry
Future Sustainability – Industry Quotes

• Publication of the High Level Group on Medical Radioisotopes (HLG) said: “This means that recent Mo-99 supply shortages were a symptom of the longer-term problem related to insufficient capital investment for a reliable supply.”

• NucNet News, No. 304 of 20 December 2012: NEA Warns of “Unsustainable Economics” of Radioisotope Supply Chain

• Publication of OECD-NEA (2014): “… any delays in production from new entrants, which are not unlikely given the innovative nature of the production technologies involved, could cause supply difficulties.”
Future Sustainability – New Producers

Since the start of the $^{99}$Mo Topical Meetings, the following has happened:

- Numerous alternative methods of producing $^{99}$Mo have been proposed and some initiated
- Molybdenum activation in BWR’s; terminated in January 2012
- Aqueous homogenous reactor; Mallinckrodt withdraws from project due to unfavorable financial outlook
- Completion dates of many new entrants continue to slip
Future Sustainability – Credible option

Collaborative partnership gives industry a low risk, credible option for the future
The future of the nuclear medicine industry depends heavily on:

- Full-cost recovery through the entire supply chain
- Realistic $^{99m}$Tc pricing
- Aspirant entrants realisation of the actual level of effort for development, industrialisation, validation and regulatory processes
- Realistic time frames from new market entrants
Economic and technological challenges pose a serious threat to the future use of $^{99m}$Tc in nuclear medicine!