NTP Radioisotopes SOC Ltd

A subsidiary of Necsa SOC Ltd
Pelindaba, South Africa

Status of NTP’s Conversion Programme

www.ntp.co.za

2017 Mo-99 Topical Meeting on Molybdenum-99 Production Technology Development
10-13 September 2017; Montreal Mariott Chateau Champlain; Montreal; QC Canada
Outline

• Who are we?

• Broad Principles of Conversion

• Current Status

• Reflections
**NECSA MANDATE**

The Company derives its mandate from the Nuclear Energy Act, No. 46 of 1999. In terms of Section 13 of this Act, Necsa is mandated to:

- Undertake and promote research and development (R&D) in the field of nuclear energy and radiation sciences and technology and, subject to the Safeguards Agreement, to make these generally available;

- Process source material, special nuclear material and restricted material and to reprocess and enrich source and nuclear material; and

- Co-operate with any person or institution in matters falling within these functions, subject to the approval of the Minister.
Who are we?

- AEC Amersham SOC Ltd (100%)
- NTP Logistics SOC Ltd (51%)
- Gammatec NDT Supplies SOC Ltd (55%)
- NTP Radioisotopes (Europe) S.A. (99%)
- Gamwave Gauteng (Pty) Ltd (40%)

  - Gammatec Middle East (90%)
  - Gammatec Aseana (100%)
  - Lectromax (90%)
  - Oserix (25%)
Who are we?

NTP Mo-99 Supply Chain

Reactors - Target Irradiation Facility
Mo-99 Targets
Mo-99 Processing Facility
Mo-99 ‘Bulk’ Liquid and Containers
Generator Manufacturing Facility

Patients
Pharmacies/Hospitals
Transportation
Mo-99/TC-99m Generators

NTP
Actively enhancing life
Who are we?

Radiochemicals

Mo-99, I-131, Lu-177

Radioactive Sources

Ir-192, Cs-137, Co-60

Irradiation Services

Neutron Transmutation doping of Silicon, Neutron Irradiation Services

Radiopharmaceuticals

NovaTec-P Tc-99 Generator, FDG, MIBG, Cold kits, I-131 Capsules and Solution

Radiation Technology Products

Transport containers
Broad Principles of Conversion

Strategic Considerations

– Minimum changes to target, irradiation, handling & chemical processes

– Retention of production capacity

– No interruption in current production
Broad Principles of Conversion

Envelope

- Within HEU safety envelope
- With existing handling equipment
- With existing transfer flasks
**Broad Principles of Conversion**

NEA OECD HLG-MR principles:

• Take co-ordinated steps, within our countries’ to implement a verifiable process for introducing full-cost recovery at all;

• Ensure availability of reserve capacity;

• Ensure availability of $^{99m}\text{Tc}$ produced on an economically sustainable basis;

• Encourage those not party to the present Joint Declaration, to take the same approach;

• Report on an annual basis to the OECD Nuclear Energy Agency (NEA) on the progress made.
## Current Status

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007/8</td>
<td>Theoretical feasibility studies &amp; cold experiments</td>
</tr>
<tr>
<td>2009</td>
<td>NNR approval received for test stage and first hot runs commence</td>
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<tr>
<td>2010</td>
<td>Hot runs, process validation, regulatory approval</td>
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<tr>
<td>Sep 2010</td>
<td>US FDA approves LEU $^{99}\text{Mo}$ for a customer in the US</td>
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<tr>
<td>Dec 2010</td>
<td>First large scale commercial FDA approved batch of LEU $^{99}\text{Mo}$ produced and shipped to US for patient use</td>
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<tr>
<td>Jun 2011</td>
<td>Routine commercial supply of LEU $^{99}\text{Mo}$ commenced</td>
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<tr>
<td>Sep 2011</td>
<td>Commencement of investment in plant modifications for increased LEU residue storage requirements</td>
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<tr>
<td>Jan 2014</td>
<td>Hot commissioning of new LEU specific production line</td>
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<tr>
<td>Dec 2014</td>
<td>Commencement of project to manufacture &amp; install 2$^{nd}$ LEU design dissolver cell</td>
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<tr>
<td>Jan 2017</td>
<td>Hot Commissioning of new uranium residue facility</td>
</tr>
<tr>
<td>May 2017</td>
<td>1$^{st}$ month that 100% LEU based Mo-99 production achieved</td>
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</tbody>
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Current Status

Previously

• 2 production lines (HEU design)

Currently

• 1 LEU designed and 1 HEU designed production line

Future

• 2 LEU designed and 1 HEU designed backup production line

LEU based Mo-99 production
Current Status

SAFARI-1 Power History

Year Operational availability compared with schedule
2008 99.9
2009 99.4
2010 101.1
2011 102.4
2012 101.4
2013 100.5
2014 100.1
2015 100.3
2016 100.1

Expected Mo-99 Curies and Yields
Current Status

Mo-99: % LEU Distribution relative to all LEU runs since inception

<table>
<thead>
<tr>
<th>Year</th>
<th>% Conversion</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>38</td>
</tr>
<tr>
<td>2015</td>
<td>47</td>
</tr>
<tr>
<td>2016</td>
<td>77</td>
</tr>
<tr>
<td>2017 (Latest)</td>
<td>95 - 100</td>
</tr>
</tbody>
</table>

Conversion to LEU completed!
Current Status

I-131: % LEU Distribution relative to all LEU runs since inception

<table>
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<th>Year</th>
<th>% Conversion</th>
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<tr>
<td>2014</td>
<td>39</td>
</tr>
<tr>
<td>2015</td>
<td>46</td>
</tr>
<tr>
<td>2016</td>
<td>63</td>
</tr>
<tr>
<td>2017 (Latest)</td>
<td>95 - 100</td>
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</table>

Conversion to LEU completed!
Reflections

- Technically feasible
- Full cost recovery not implemented
- More challenging production operations
- Sustainability of the industry questionable

Full cost recovery not implemented
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
Thank you for your attention