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

Outline

- Brief Background
- Current Status
- Experienced gained
- Future sustainability

Actively enhancing life

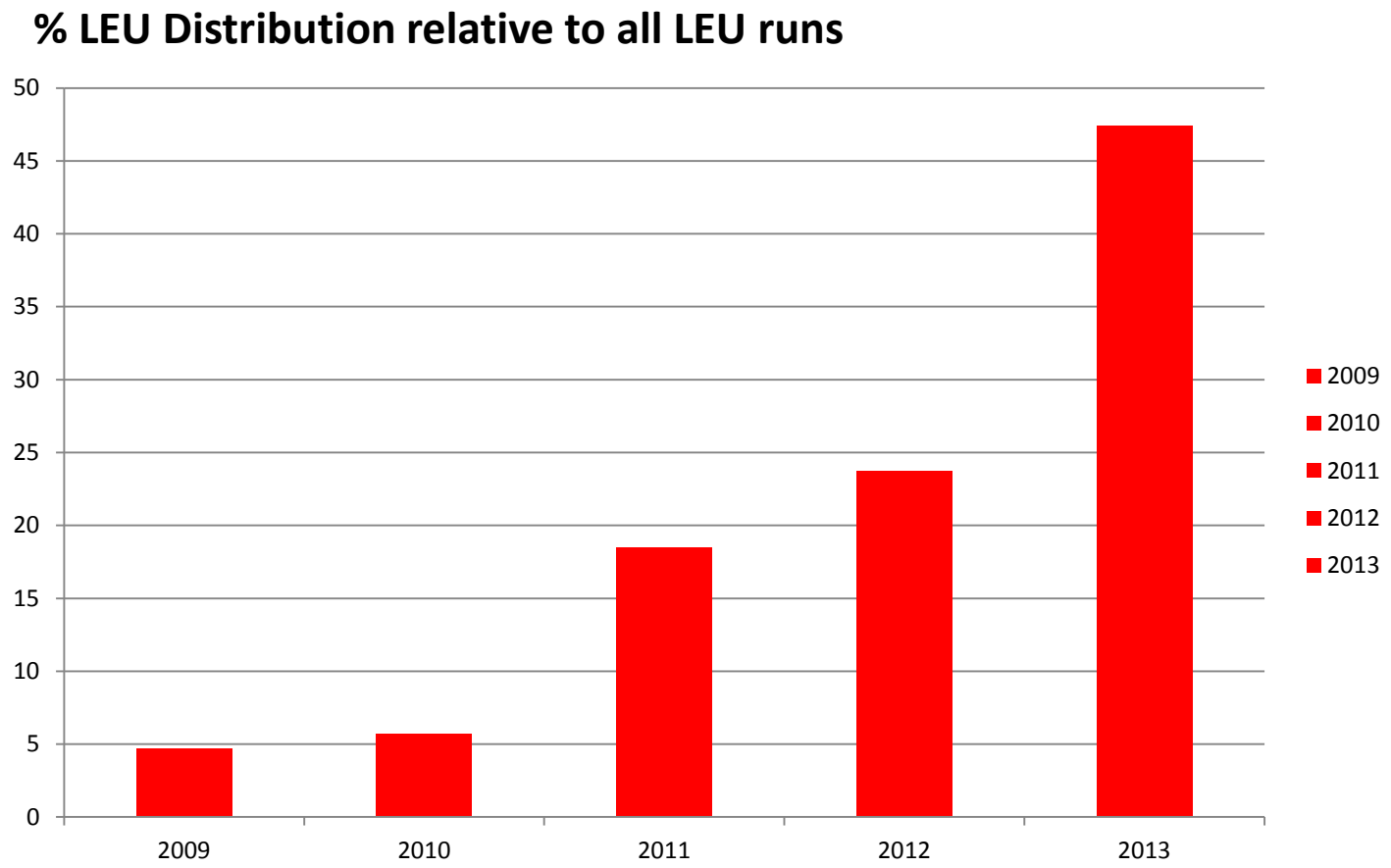
Background - Time Line

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

Background – Target Details

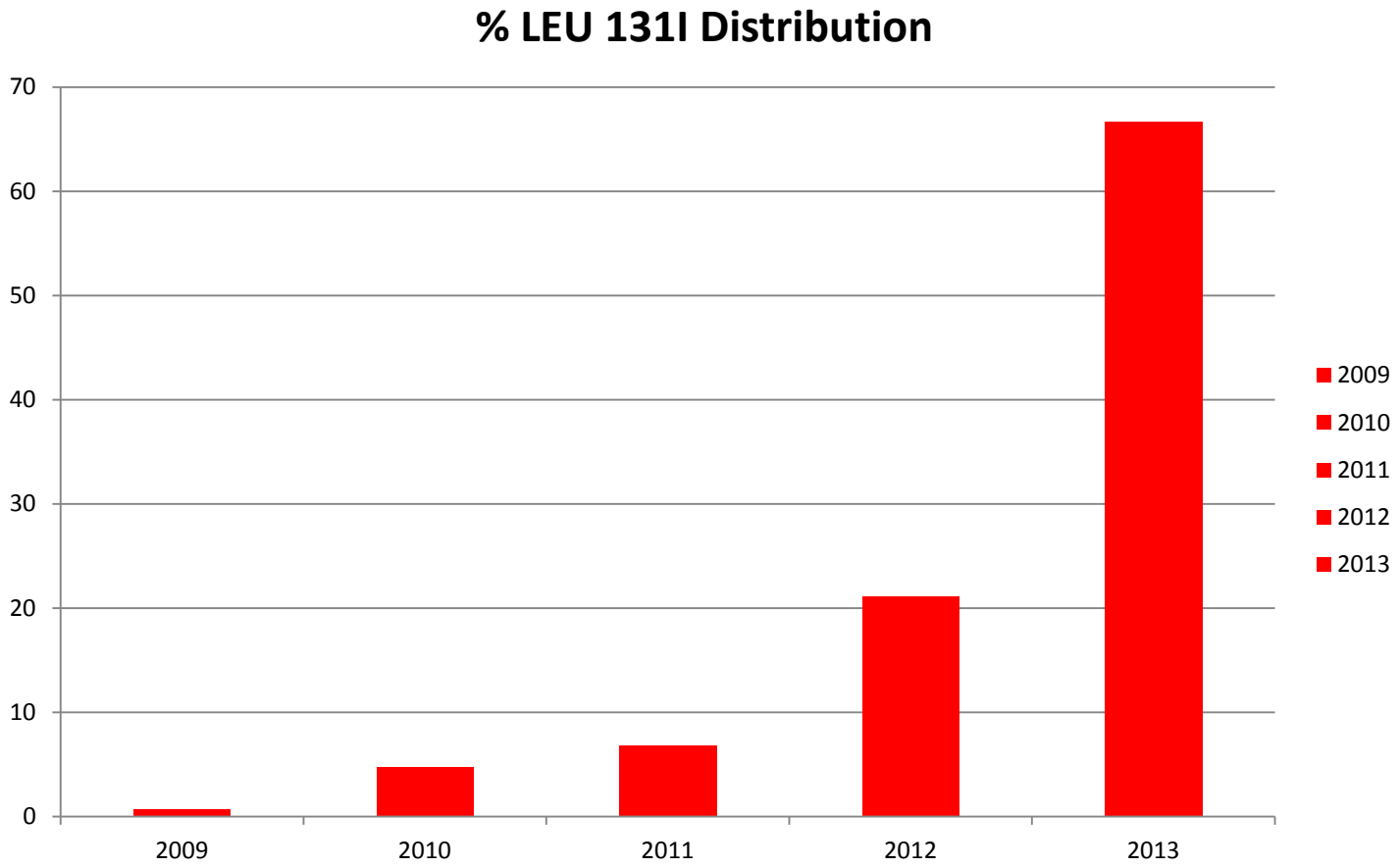
Parameter	LEU	HEU
Meat	Dispersion	Alloy
Enrichment (%)	19.75	45.0
Uranium Density ($g.cm^{-3}$)	2.75	1.42
Dimensions (mm)	200/50/1.66	200/50/1.66
Cladding	Alloy	Pure aluminium
U-235 Loading	Maintain (or minimise decrease)	

Current Status – ^{99}Mo



Actively enhancing life

Current Status – ^{131}I



Actively enhancing life

Current Status – Projects

Dissolution Cell

Reason: Required due to significant increase in uranium volumes

Status: Commissioned

Future: Upgrade existing dissolution hot cells

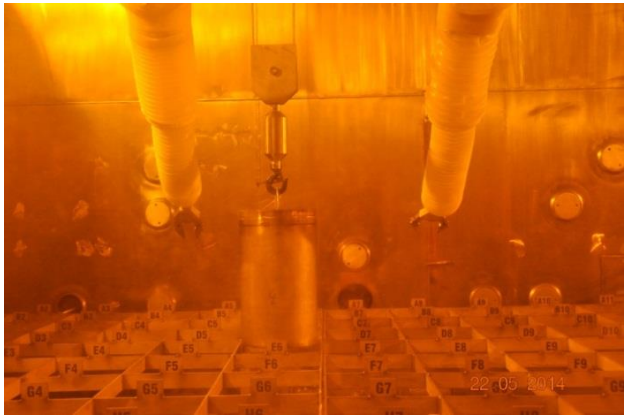
Current Status – Projects

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



Actively enhancing life

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

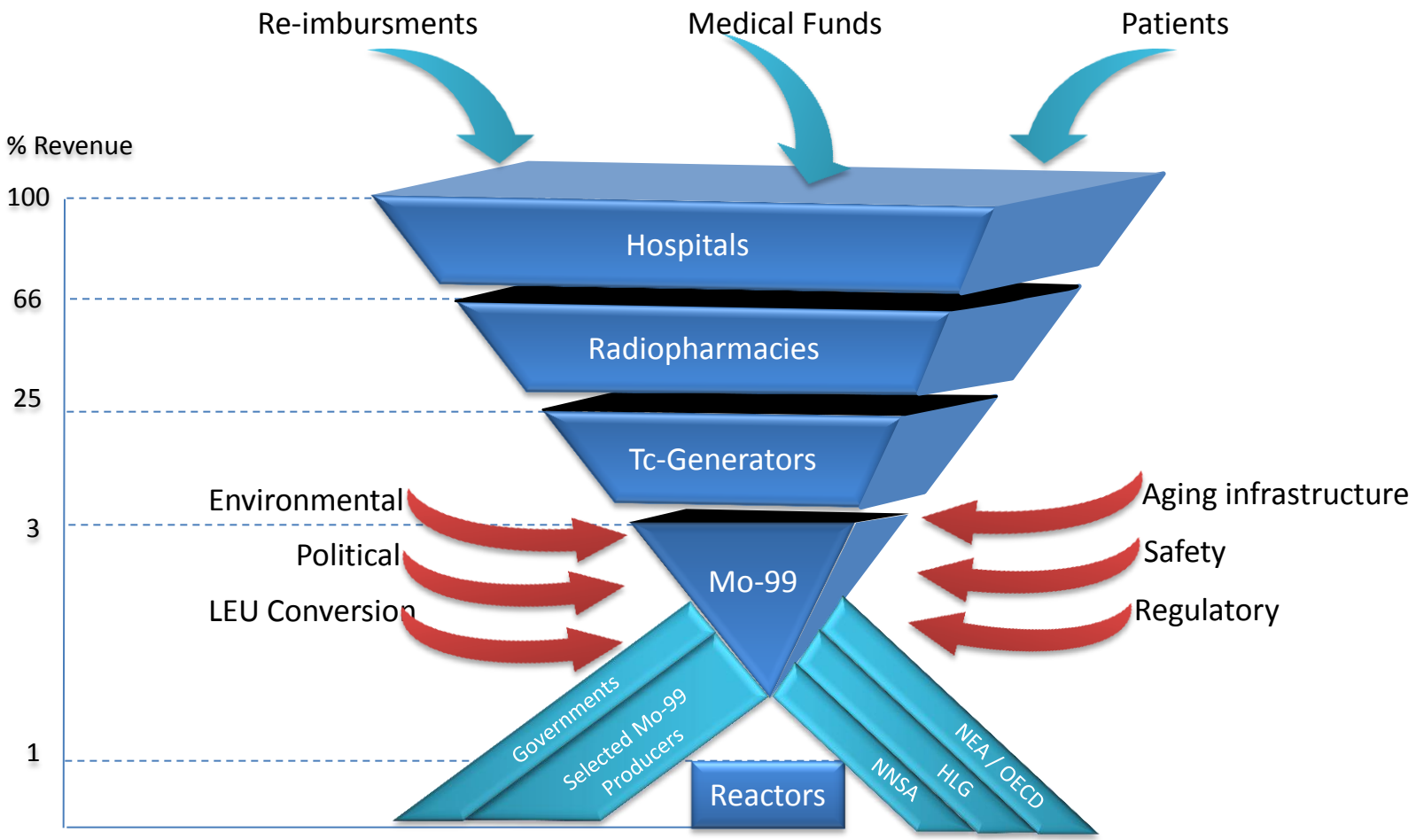
Experience Gained

Financial & Other Issues

- Lower production capacity per target
- Increased cost of production
- Unrealistically low ^{99}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 – Supply Chain Economics



Actively enhancing life

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

ansto

IRE

NTP
Actively enhancing life

NTP
Actively enhancing life

Future Sustainability – Concluding Comments

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**

Future Sustainability – Concluding Comments

Economic and technological challenges pose a serious threat to the future use of ^{99m}Tc in nuclear medicine!


NTP
Actively enhancing life