





### Medical Isotope Supply Review: <sup>99</sup>Mo/<sup>99m</sup>Tc Market Demand and Production Capacity Projection 2018-2023

### 2018 <sup>99</sup>Mo Topical Meeting, Knoxville 23-26 September 2018

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### The Nuclear Energy Agency (NEA)

- The NEA is a specialist agency of the Organisation for Economic Co-operation Development (OECD), the NEA is an intergovernmental organisation of 33 industrialised countries based in Paris
- The NEA MISSION To assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal basis required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purpose





### **Medical radioisotopes**

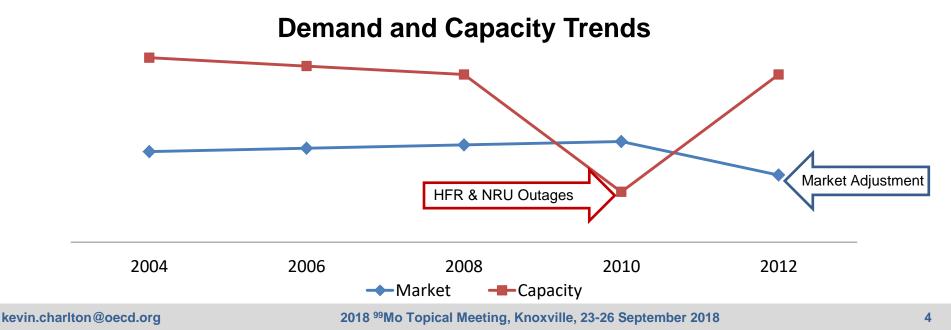
- The medical radioisotopes market is global and secure economically sustainable supply is essential
  - they are utilised in a wide range of diagnostic procedures, heart, brain, kidney, bone and in cancer: between 30-40M patient doses/year
  - medical radioisotopes with their short half-lives <sup>99</sup>Mo (66 hours) and <sup>99m</sup>Tc (6 hour) can not be stored
  - they must be produced near continuously and are the original "Just-In-Time" (JIT) products, pre-dating the JIT concept
  - any disruption to the supply chain can cause immediate disruption to patient services leading to sub-optimal care





### **HLG-MR**

 The High-Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) was established at the request of NEA member countries, following global supply shortages of <sup>99</sup>Mo/<sup>99m</sup>Tc in 2009-2010 that resulted from simultaneous unplanned outages of ageing research reactors in Canada and the Netherlands and processing problems in Belgium





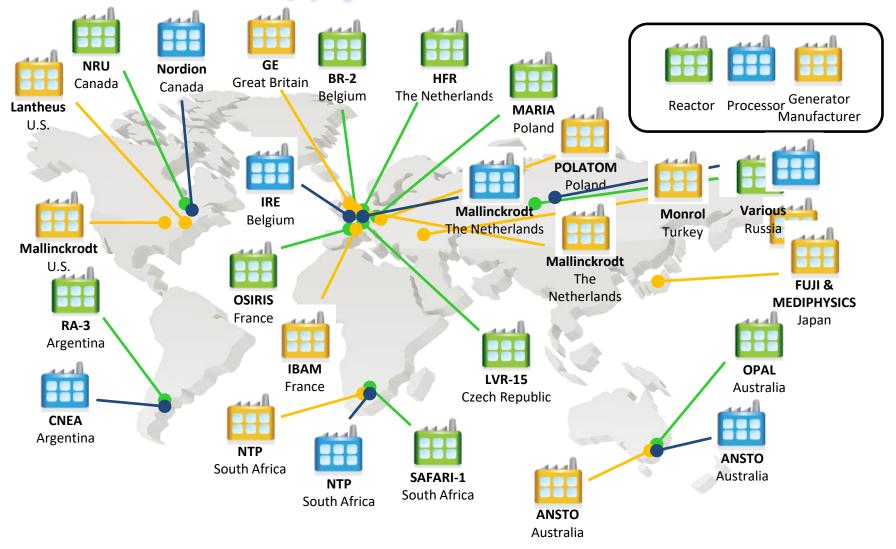


### **Demand and Capacity Review 2018-2023**

- The 2018 Medical Isotope Supply Review: <sup>99</sup>Mo/<sup>99m</sup>Tc Market Demand and Production Capacity Projection, 2018-2023 the latest in a series of reports has recently been published:-
  - Positive News
    - Curium conversion to 100% LEU targets
    - positive FDA decision for NorthStar RadioGenix project (non-HEU)
  - Negative news
    - multiple NTP problems led to "chronic" shortage situation in some markets for <sup>99</sup>Mo/<sup>99m</sup>Tc and some shortages of <sup>131</sup>I
    - Nordion/GA/MURR project terminated on economic grounds
    - some reported reductions in reactor irradiation capacity from LEU conversion
    - more project delays

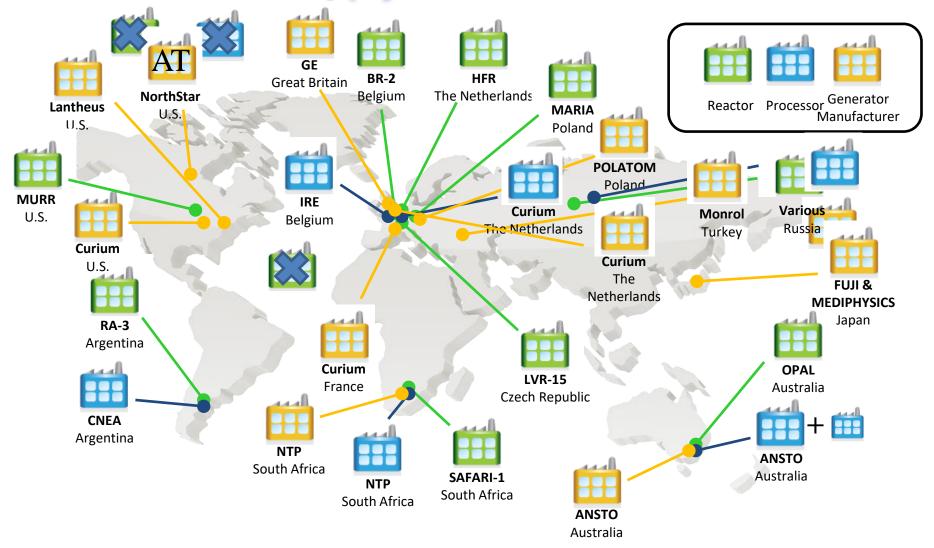






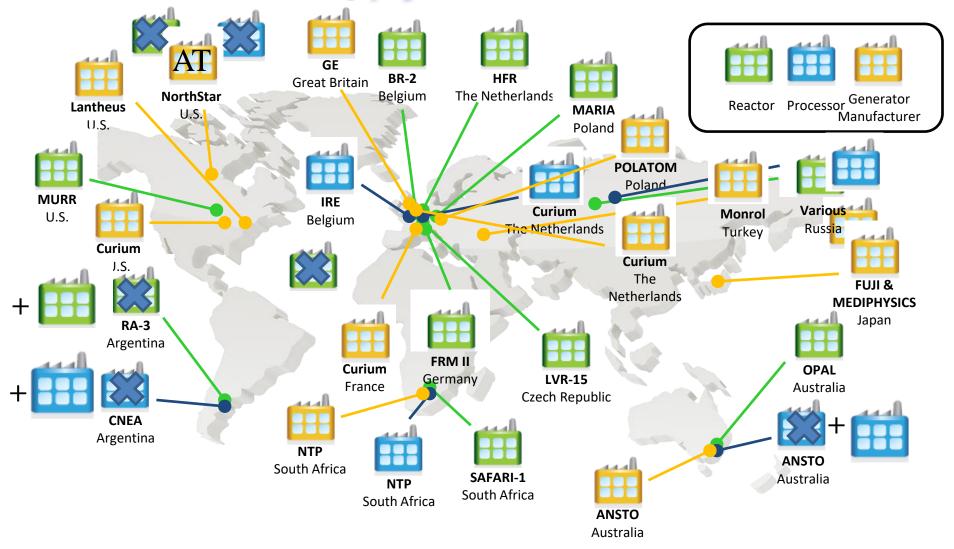






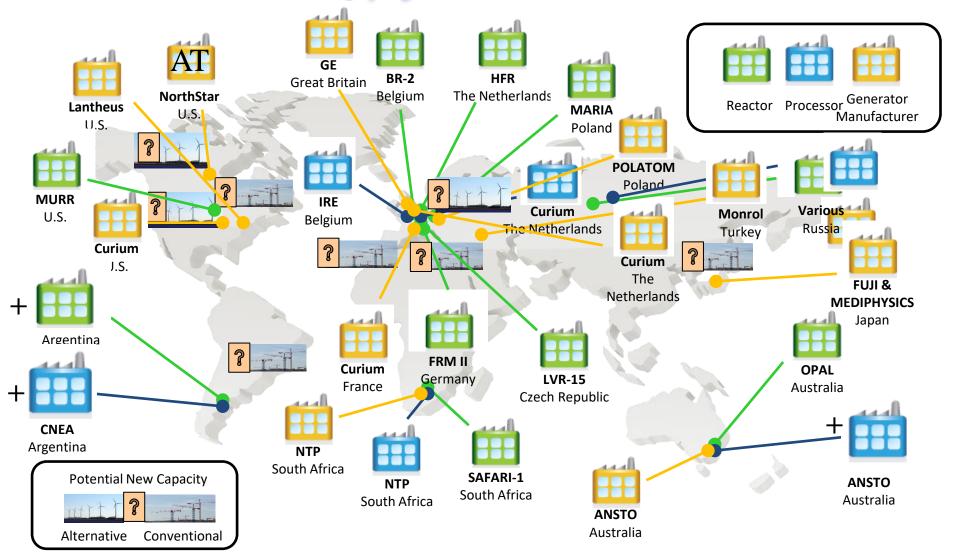
















#### TABLE 4 – January 2018 (Revised April 2018)

Processor	Targets⁵	Anticipated Mo- 99 production weeks/year	Expected available capacity per week (6- day Ci) by 2023 <sup>6</sup>	Expected available capacity per year (6- day Ci <sup>99</sup> Mo) by 2023 <sup>6</sup>	Estimated first full year of production	Project status (January 2018)
MURR/NorthStar	Natural Mo target	52	750	39 000	2019	FDA approval Feb 2018
MURR/NorthStar <sup>1</sup>	Enriched Mo target	52	+2 250	+117 000	2020	In production scale up
NorthStar	Non-fissile	52	3 000	156 000	2021	Accelerator vendor selected, initiating scale up
Nordion	LEU-SGE	<del>52</del>	<del>3 200</del>	<del>166 400</del>	2020	Phase 2 underway PROJECT CANCELLED
SHINE	LEU solution	50	4 000	200 000	2021	Construction Permit Granted
CNEA	LEU	48	2 500	120 000	2021	Building start by end 2018
Korea <sup>2</sup>	LEU	43	400	17 200	2023+	Construction permit in review by regulatory body
MARIA: Mo-99 2010 <sup>3</sup>	LEU	40	300	12 000	2023+	Financing – not yet agreed
Brazil MR	LEU	41	1 000	41 400	2023+	Detailed design still to be contracted. Construction depends on budget
China Advanced RR <sup>4</sup>	LEU	34	1 000	34 000	2023+	Financing decision after 2017 tests





### 2018-2023 Demand and Demand +35% ORC



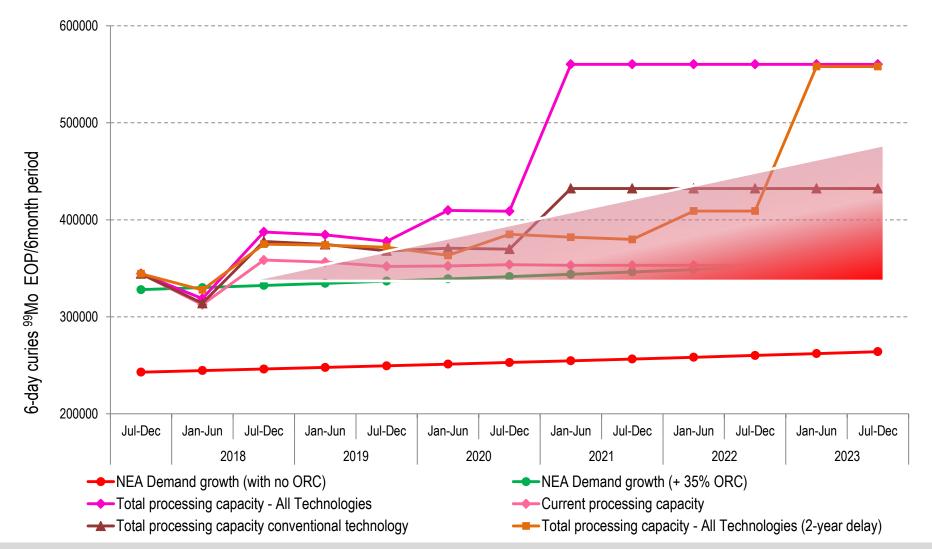
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### 2018-2023 Processing Capacity (Fig. 6.2 Projections)



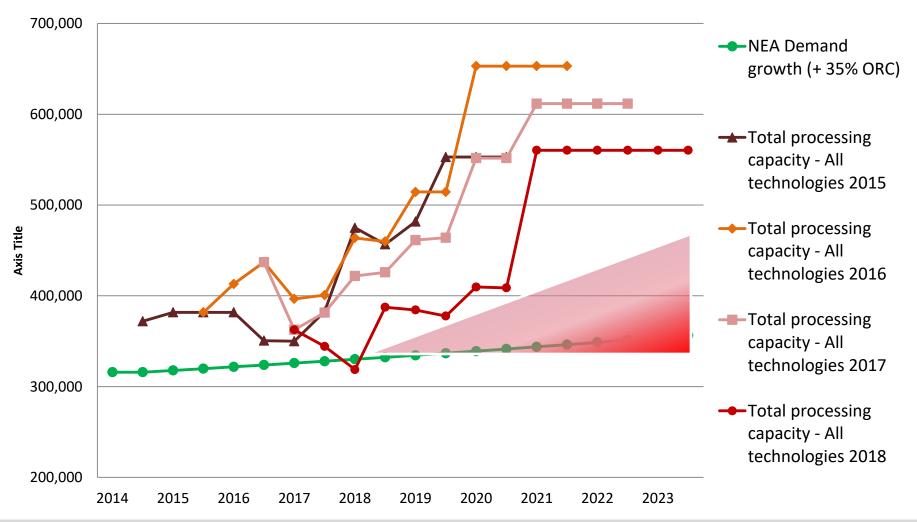
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### The Effect of Multiple Project Delays

Scenario B - "Technological Challenges" Projection Creep with Time







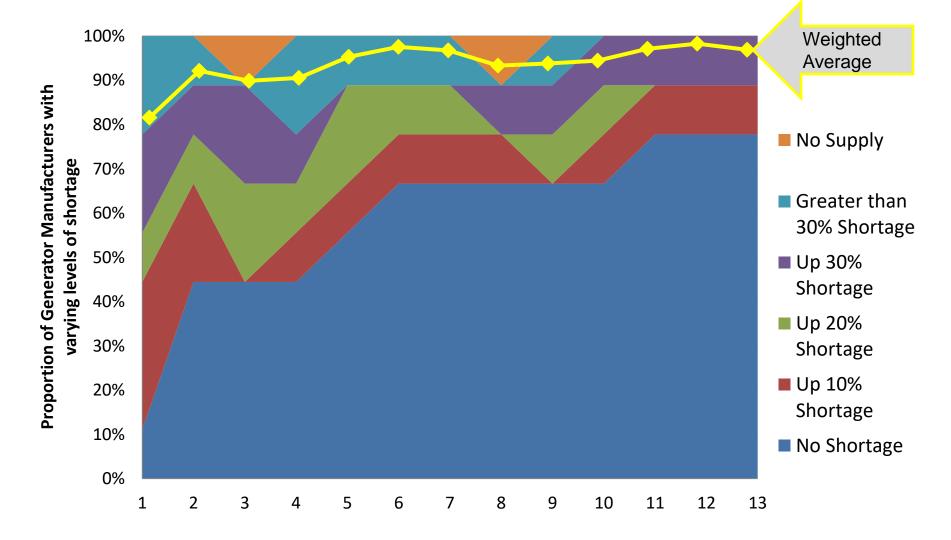
### **HLG-MR Status Summary**

- Many technical problems have been solved and a range of alternative production technologies demonstrated
  - the first alternative technology is being introduced into the US market
- Supply stabilised as a result of the actions of existing supply chain participants and the co-ordination activities of the Association of Isotope Producers and Equipment Suppliers (AIPES), but challenges remain
  - supply has been stressed since mid-November 2017 due to an unplanned outages at NTP (South Africa) and disruptions at other facilities
    - the AIPES Emergency Response Team (ERT) convening weekly
    - supply shortages of up to 15% of world demand in some weeks





### **Supply Performance to Gen Manufacturers 1Q 2018**







### **HLG-MR Status Summary**

- Conversion to LEU targets (a market externality determined by governments) has technical challenges; it is less efficient, produces more waste and has a higher unit cost
  - >70% market conversion to LEU recently achieved
- 3<sup>rd</sup> Self-Assessment 6-policy principles slow implementation
  - FCR pricing levels have not yet achieved
  - paid ORC remains under utilised by the supply chain
  - reimbursement levels remain unchanged in many markets
- The market remains economically unsustainable
  - risk to secure supply remains
  - some risk of delay or cancellation of new investment
- Further work needed to reform healthcare economics

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### **Co-operation with OECD Health Division**

- At the 5<sup>th</sup> meeting of the 4<sup>th</sup> mandate (February 2018) of the HLG-MR, the OECD Health Division (HD) joined a review session on work programme proposals and the HLG-MR delegates agreed to support the proposal
  - final project amendments were agreed with a smaller HLG-MR working group
  - sufficient Voluntary Contribution pledges have been received to allow HD to perform the work
  - work started early April 2018
  - interim update mid June 2018
  - closed presentation to HLG-MR 9 October 2018
  - open presentation EANM 2018, Düsseldorf 17 October 2018
  - final report late 2018





### EANM 2018 Special Session Wednesday, October 17, 2018, 08:00-09:30 Hall 6

Session Title: High-level Group of the Security of Supply of Medical Radioisotopes (HLG-MR) - Open Briefing Session for Participants and Stakeholders

#### Summary of the content

The Organisation for Economic Co-operation and Development -Health Division (OECD-HD) and the Nuclear Energy Agency (NEA) will present on the findings of recent joint work performed for the HLG-MR on health economics aspects of the medical isotopes supply chain (in particular <sup>99</sup>Mo/<sup>99m</sup>Tc) that are important in ensuring a long term economically sustainable market model. The NEA will also provide a short briefing on proposed future activities to support the security of supply of medical isotopes.





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# Thank you for your attention

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