



Addressing Societal Challenges Through Advancing the Medical, Industrial and Research Applications of Nuclear and Radiation Technology

Security of Supply of Medical Radioisotopes

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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

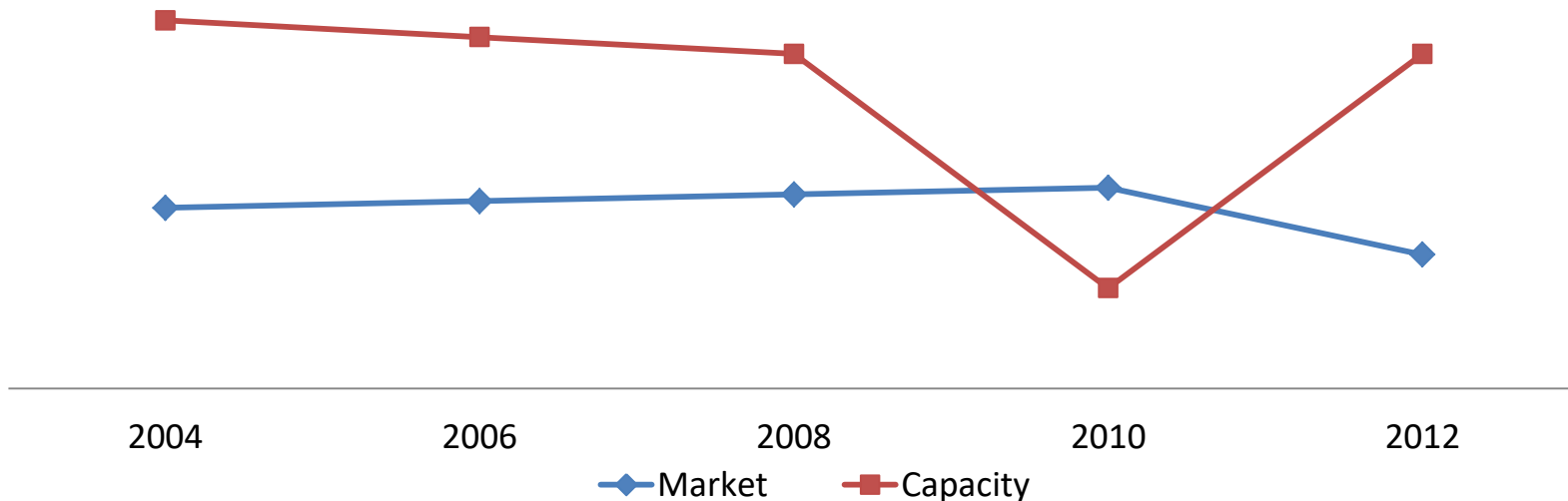
Medical radioisotopes

- 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/year
 - medical radioisotopes with their short half-lives ^{99}Mo (66 hours) and $^{99\text{m}}\text{Tc}$ (6 hours) 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
- As medical radioisotopes move from diagnosis towards therapy with the development of so-called theranostic pairs, security of supply will be even more important

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 $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ 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 Trends



HLG-MR Activities

- HLG-MR Membership: includes 18 countries (including some non-NEA countries e.g. Brazil and South Africa), EC and the IAEA, the **global** radioisotope supply chain (commercial companies) and healthcare society representatives
 - performs reviews of the whole $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ supply chain
 - (**Patient** < Clinic < Nuclear Pharmacy < Generator Manufacturer < Processor < Irradiator < Target Manufacturer)
 - recommends options to address identified weaknesses to help ensure reliable and sustainable supply
 - works with stakeholders to implement policy recommendations and ensure clear communication about the need for effective global implementation of the agreed policy approach

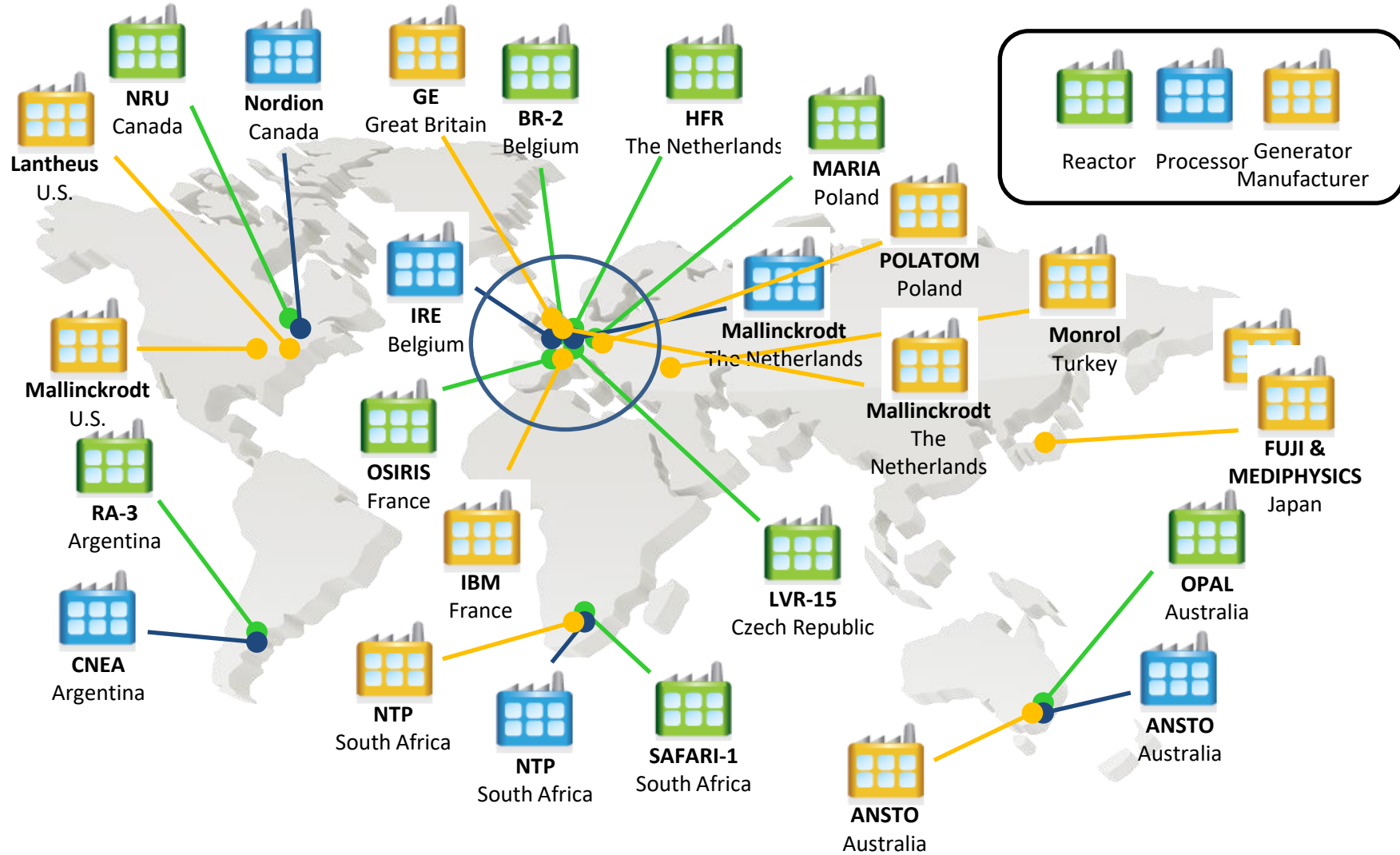
HLG-MR Activities

- Following the 2009-2010 supply crisis, the NEA investigated the market for the HLG-MR and identified
 - classical “market failure” at a number of levels
 - an economically unsustainable structure that did not support investment
 - the risk of potential future shortages as infrastructure reached the end of life
- Developed 6-policy principles to help ensure reliable, economically sustainable supply

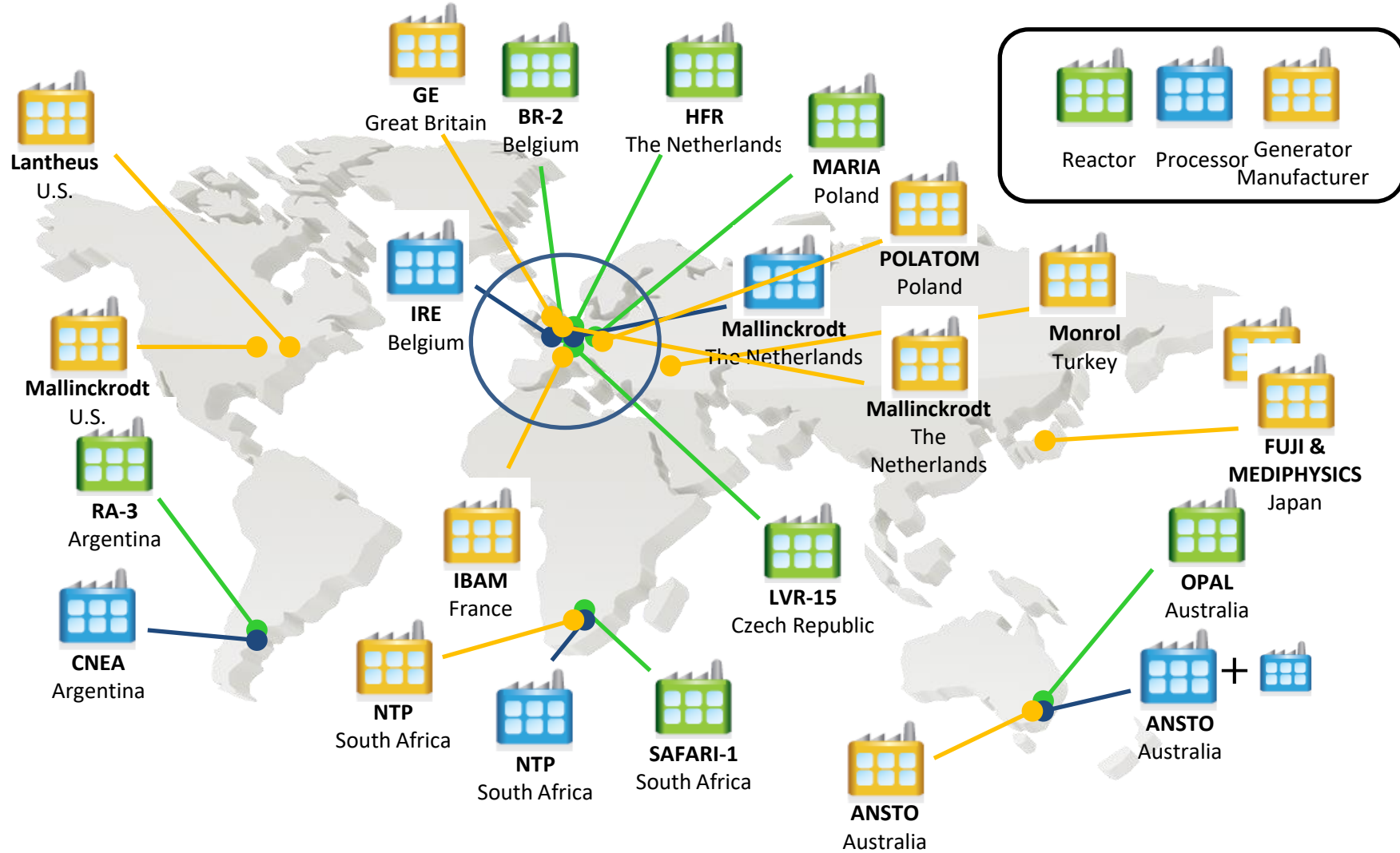
HLG-MR 6-policy principles

- Supply chain implement full-cost recovery (**FCR**) principles as soon as possible
- All levels of the supply chain hold sufficient **paid** reserve production capacity (**ORC** – Outage Reserve Capacity)
- Governments should help establish a proper environment for efficient and safe market operation
- Governments should help facilitate the conversion to low-enriched uranium (**LEU**) based production
- International co-operation should continue (**HLG-MR**)
- Periodic review on progress towards achieving economically sustainable, secure supply – (**Self Assessment**)

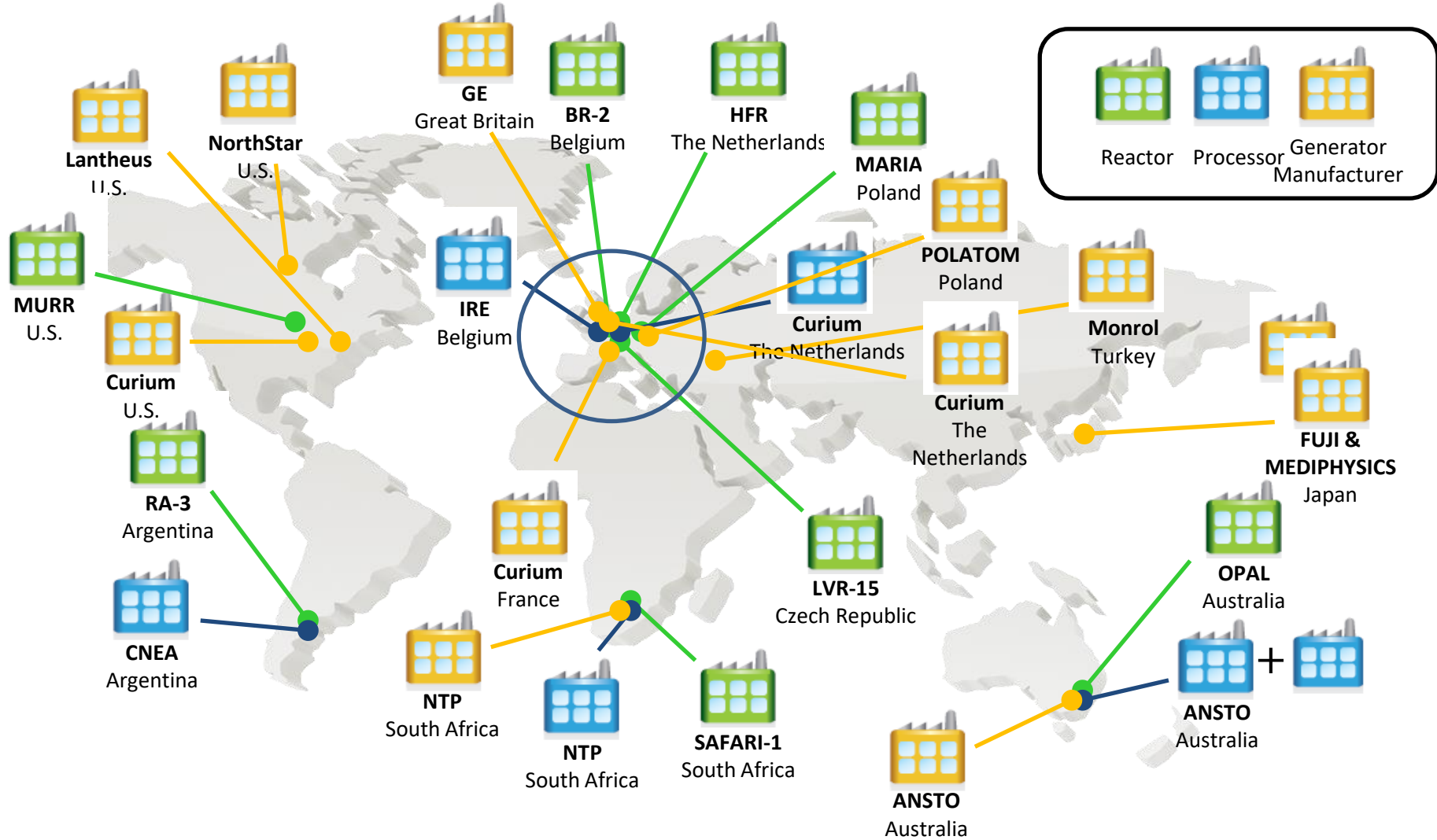
Global Supply Chain – around 2014



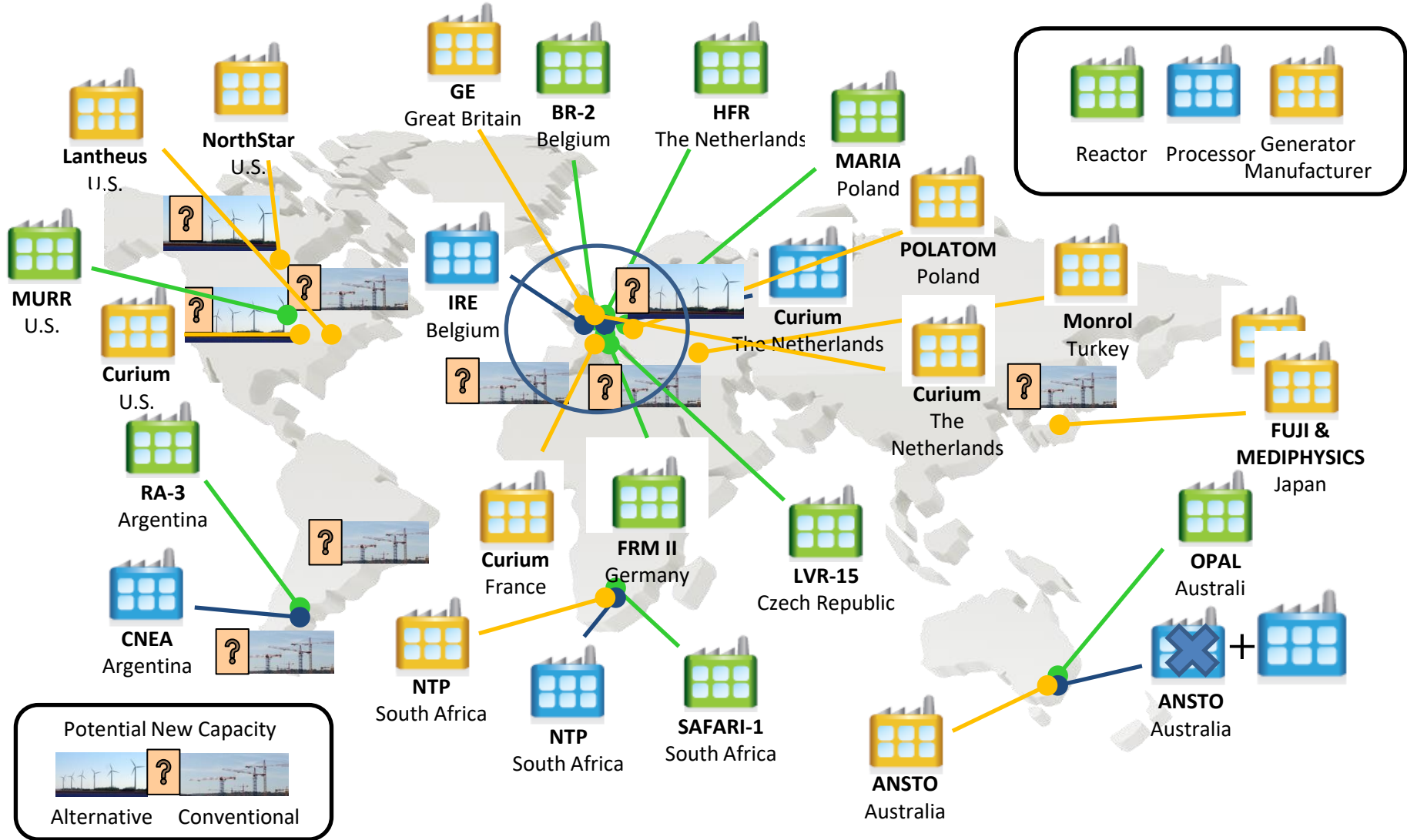
Global Supply Chain – around 2016



Global Supply Chain – around 2018



Global Supply Chain – around 2021



HLG-MR Status Summary

- 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 outage at NTP (South Africa)
 - the AIPES Emergency Response Team has convened nearly 20 times and continues to monitor the situation closely
 - some shortages of up to 15% of market demand in some weeks
 - the 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 for the product
 - >70% market conversion to LEU recently achieved

HLG-MR Status Summary

- Many technical problems have been solved and a range of alternative production technologies demonstrated
 - the first alternative technology is now being introduced into the US market
- Self-Assessment shows 6-policy principle implementation is slow
 - FCR pricing levels have not yet been achieved
 - paid ORC remains under utilised by the supply chain
 - reimbursement levels remain unchanged in many markets
- The market remains economically unsustainable
 - some risk of delay or cancellation of new investment
- Further work needed on healthcare economics

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Thank you for your attention