Follow up to the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

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Forward Plan Beyond 2018

- At the HLG-MR Meeting on 9 October 2018, delegates reconfirmed the recommendation of the activities that should be transferred to the NTE Programme of Work for the 2019-2020 period:
  - continued preparation and publication of the Mo-99 Demand and Capacity Projection report series
  - retain the ability to arrange ad hoc meetings of stakeholders (up to two per year)
  - ability to coordinate communications among the current members of the group should the need arise
  - follow-up work/analysis on the OECD Health Division project

Demand and Capacity Review 2019-2024

- The 2019 Medical Isotope Supply Review: $^{99}Mo/^{99m}Tc$ Market Demand and Production Capacity Projection, 2019-2024 - the latest in a series of reports has been reviewed and is now in the publication process:-
  - Positive News
    - the market has converted to >70% non-HEU based supply
    - first alternative technology project licensed (NorthStar RadioGenix)
    - new ANM (Australia) facility recently licensed (June 2019)
  - Negative News
    - NTP (South Africa) problems led to “chronic” shortage situation in most markets during late 2017, during 2018 and in early 2019
    - further project delays and some projects stopped due to economics
    - processing capacity is likely to be tight until at least 2021

2019 Demand and Capacity Report - Table 4 new processors

Processor	Targets[5]	Anticipated Mo-99 production weeks/year	Expected available capacity per week (6-day Ci) by 2023[6]	Expected available capacity per year (6-day Ci ^{99}Mo) by 2023[6]	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[1]	Enriched Mo target	52	+2 250	+117 000	**2021**	In production scale up
NorthStar	Non-fissile	52	3 000	156 000	**2022**	Accelerator vendor selected, initiating scale up
SHINE	LEU solution	50	4 000	200 000	**202?**	Construction Permit Granted
CNEA	LEU	48	2 500	120 000	**2021**	Building start by end 2018
Korea[2]	LEU	43	400	17 200	**2024+**	Construction permit in review by regulatory body
MARIA: Mo-99 2010[3]	LEU	40	300	12 000	**2024+**	Financing – not yet agreed
Brazil MR	LEU	41	1 000	41 400	**2024+**	Detailed design still to be contracted. Construction depends on budget
China Advanced RR[4]	LEU	34	1 000	34 000	**2024+**	Financing decision after 2017 tests

Approved

Cancelled

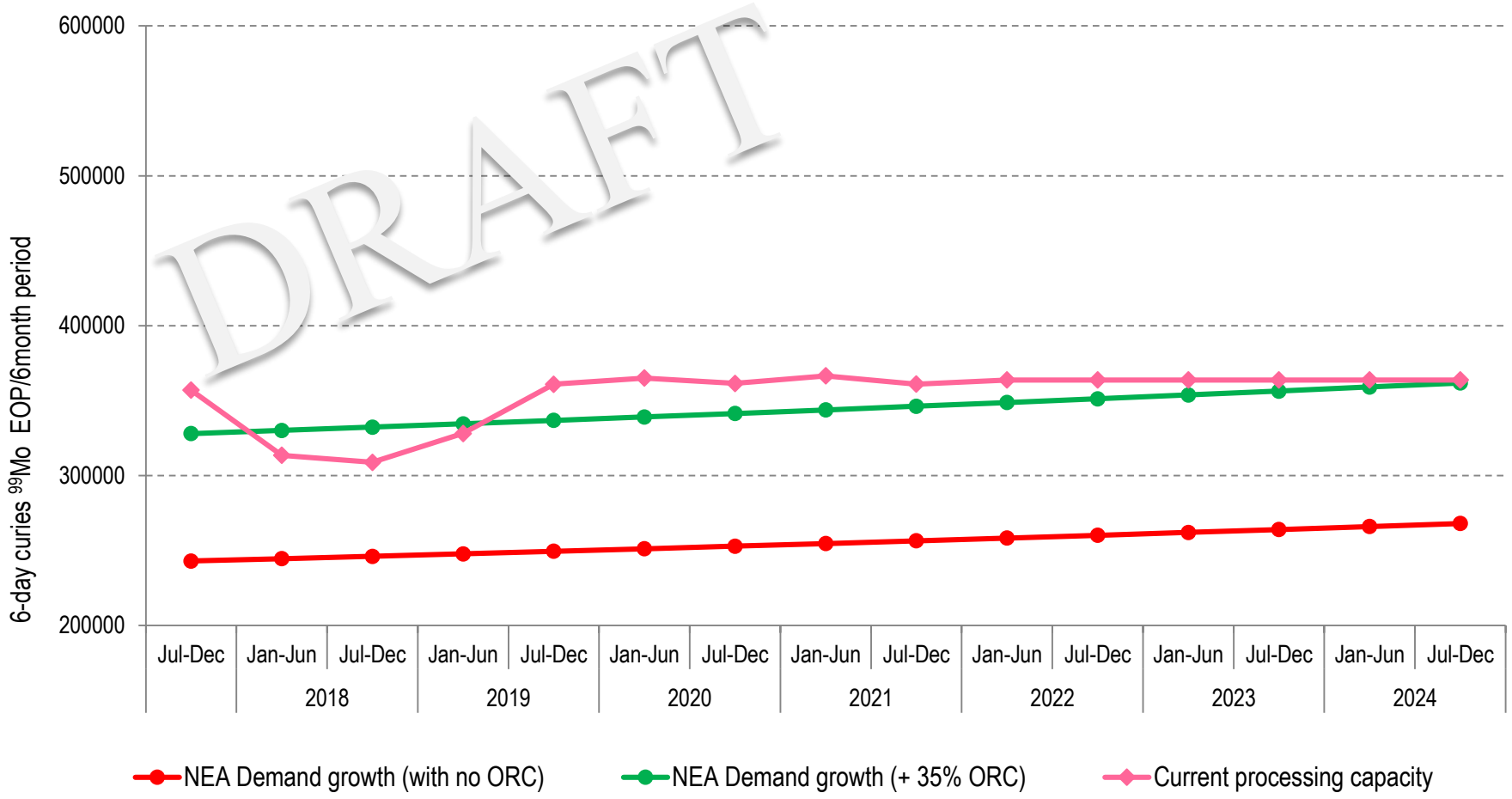
Further delayed

Further delayed

Further delayed

Further delayed

2019-2024 Processing Capacity (Fig. 6.2 Projections)



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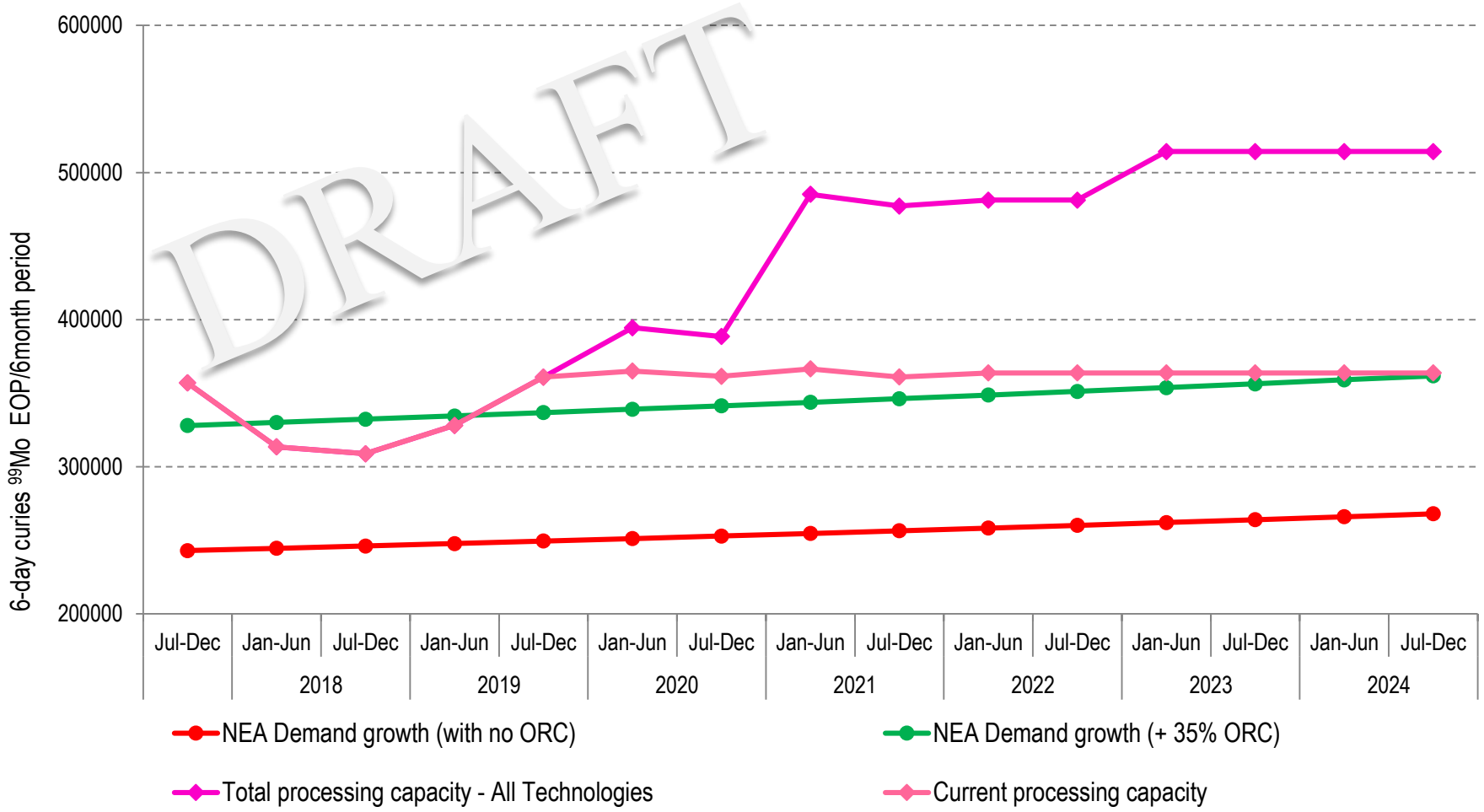

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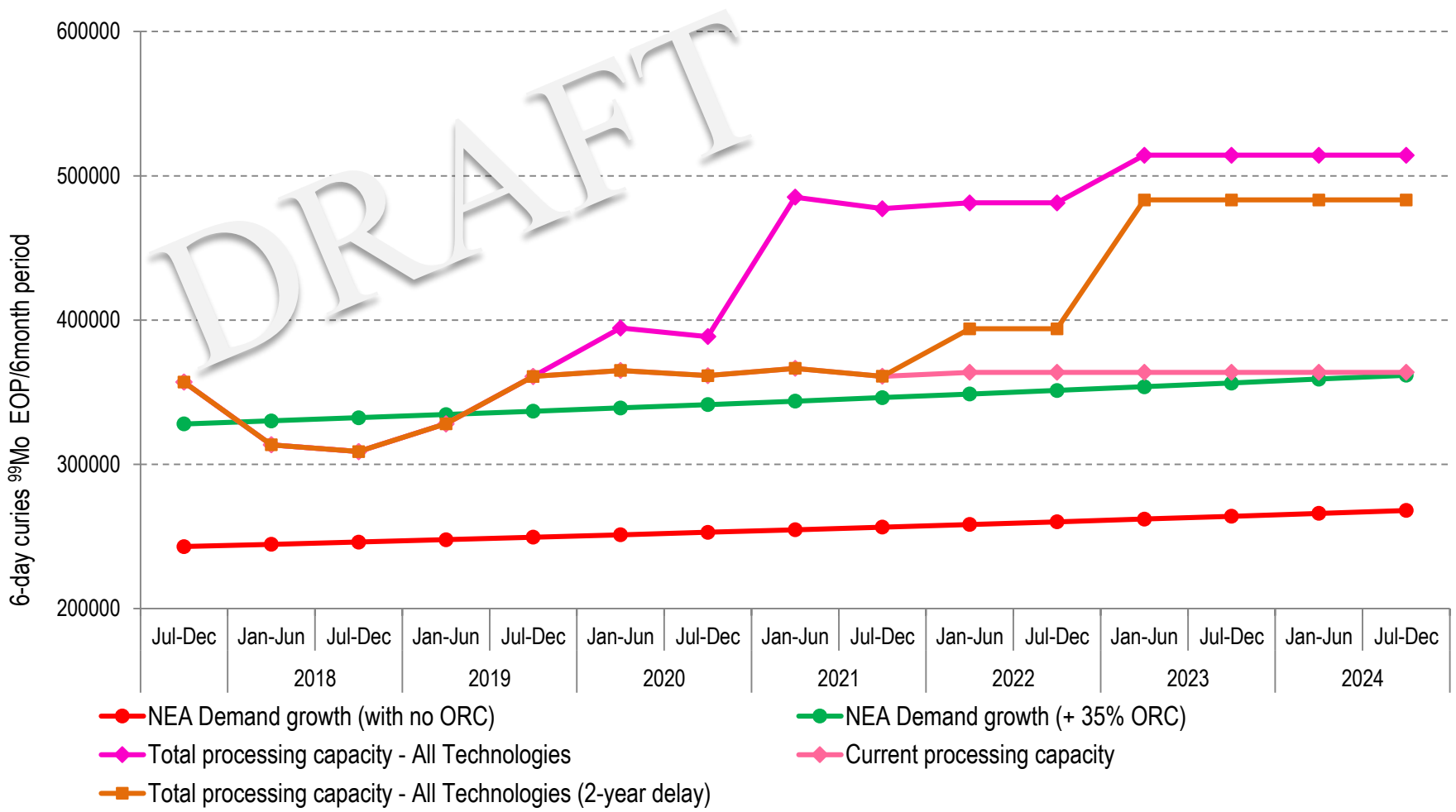

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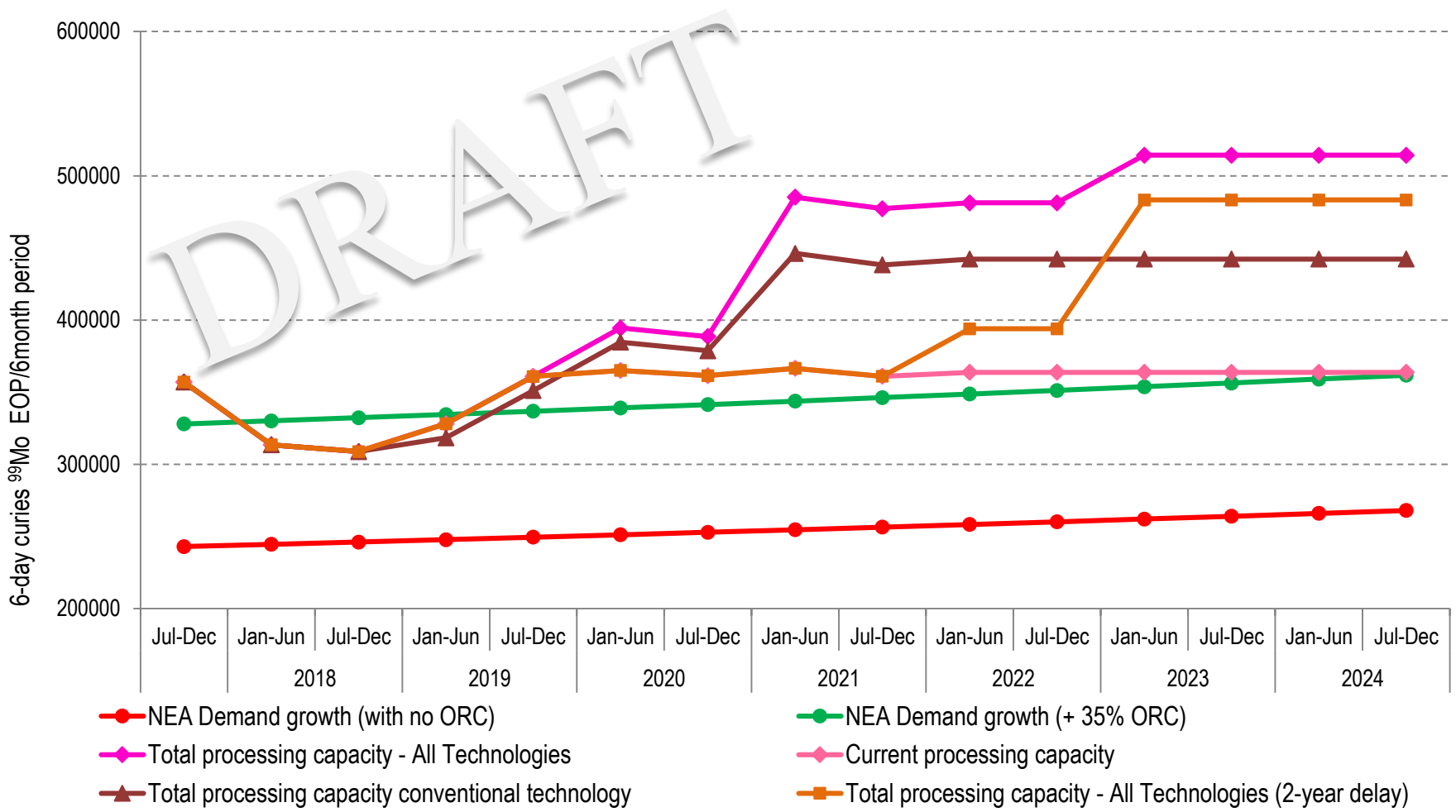

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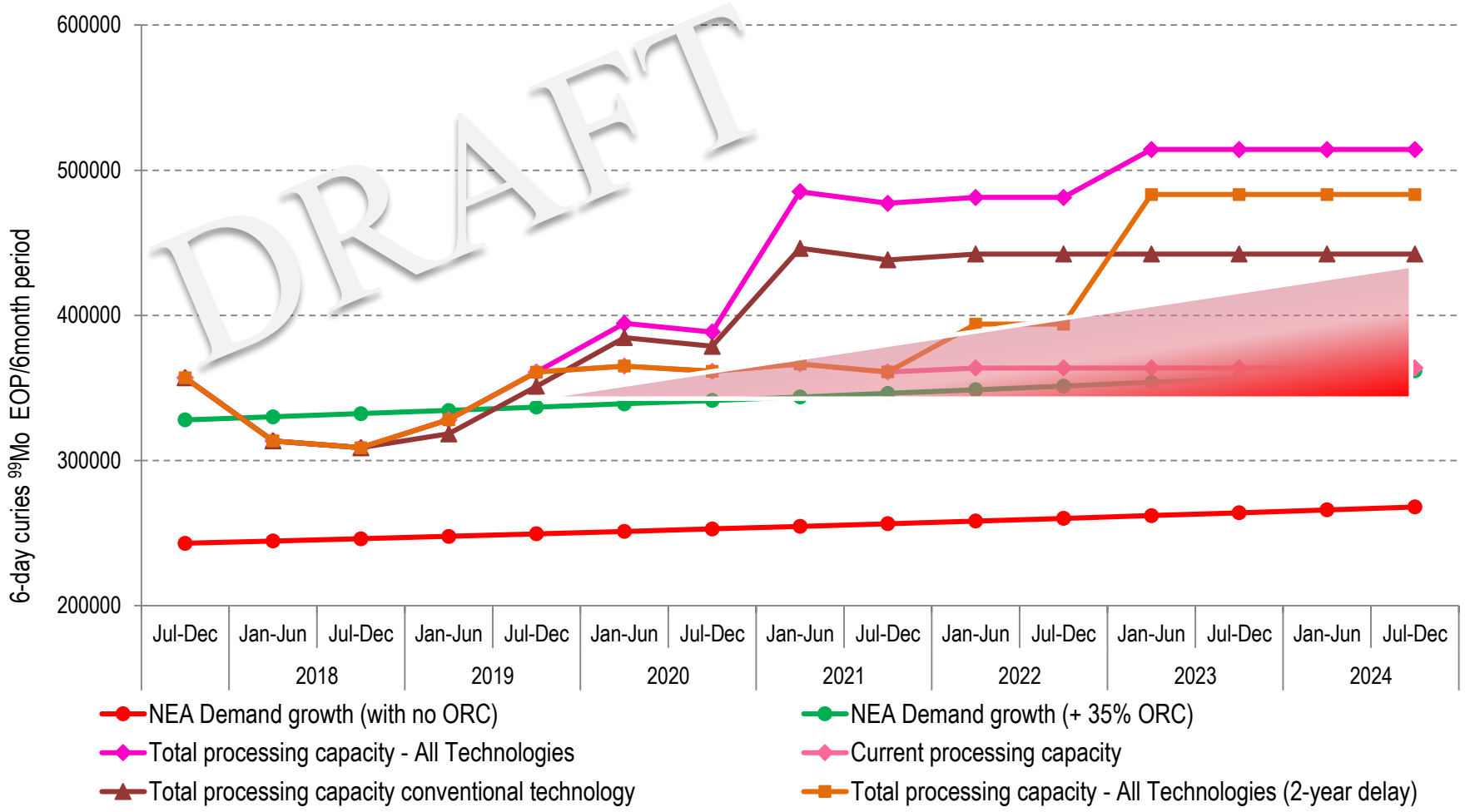
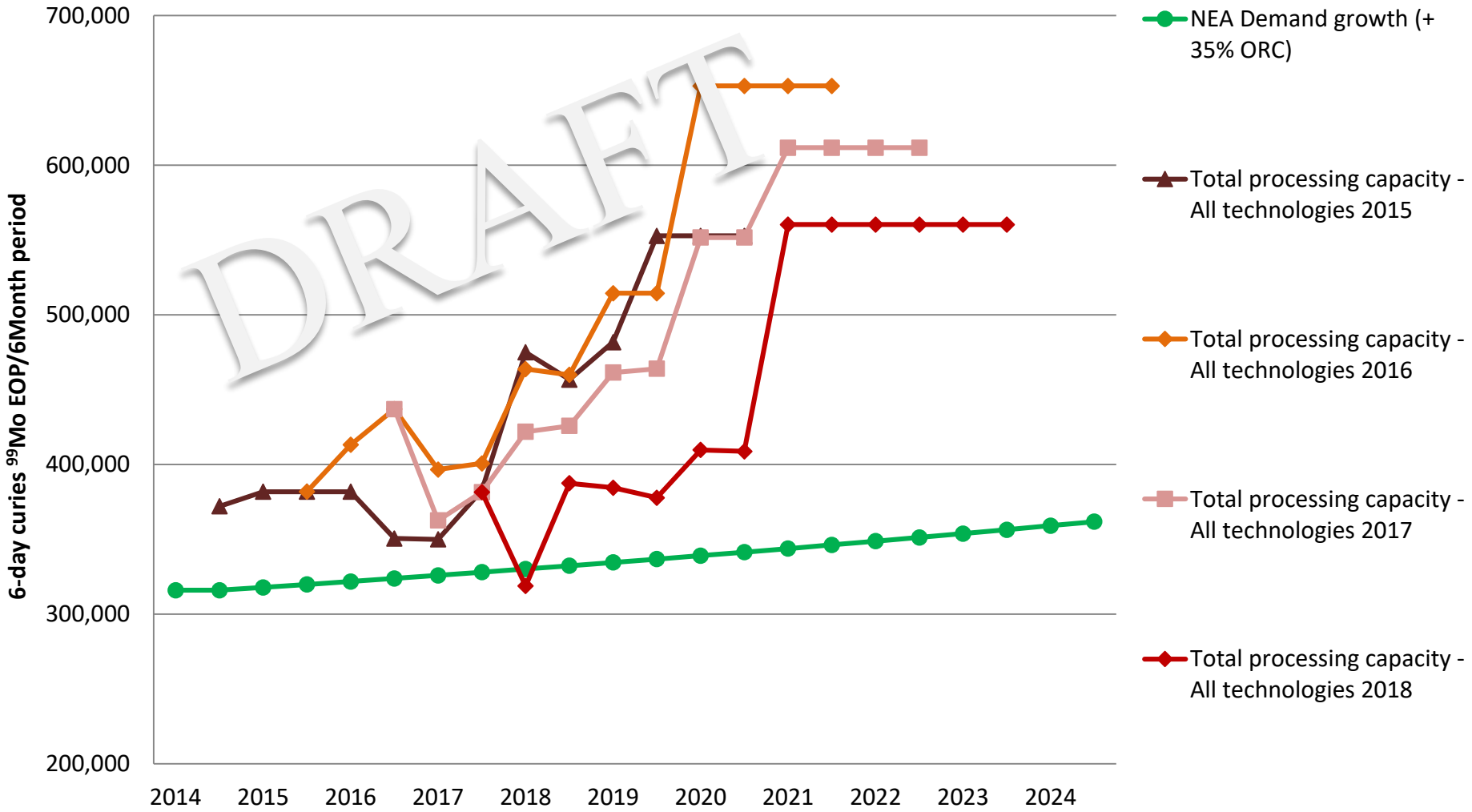


The Effect of Multiple Project Delays



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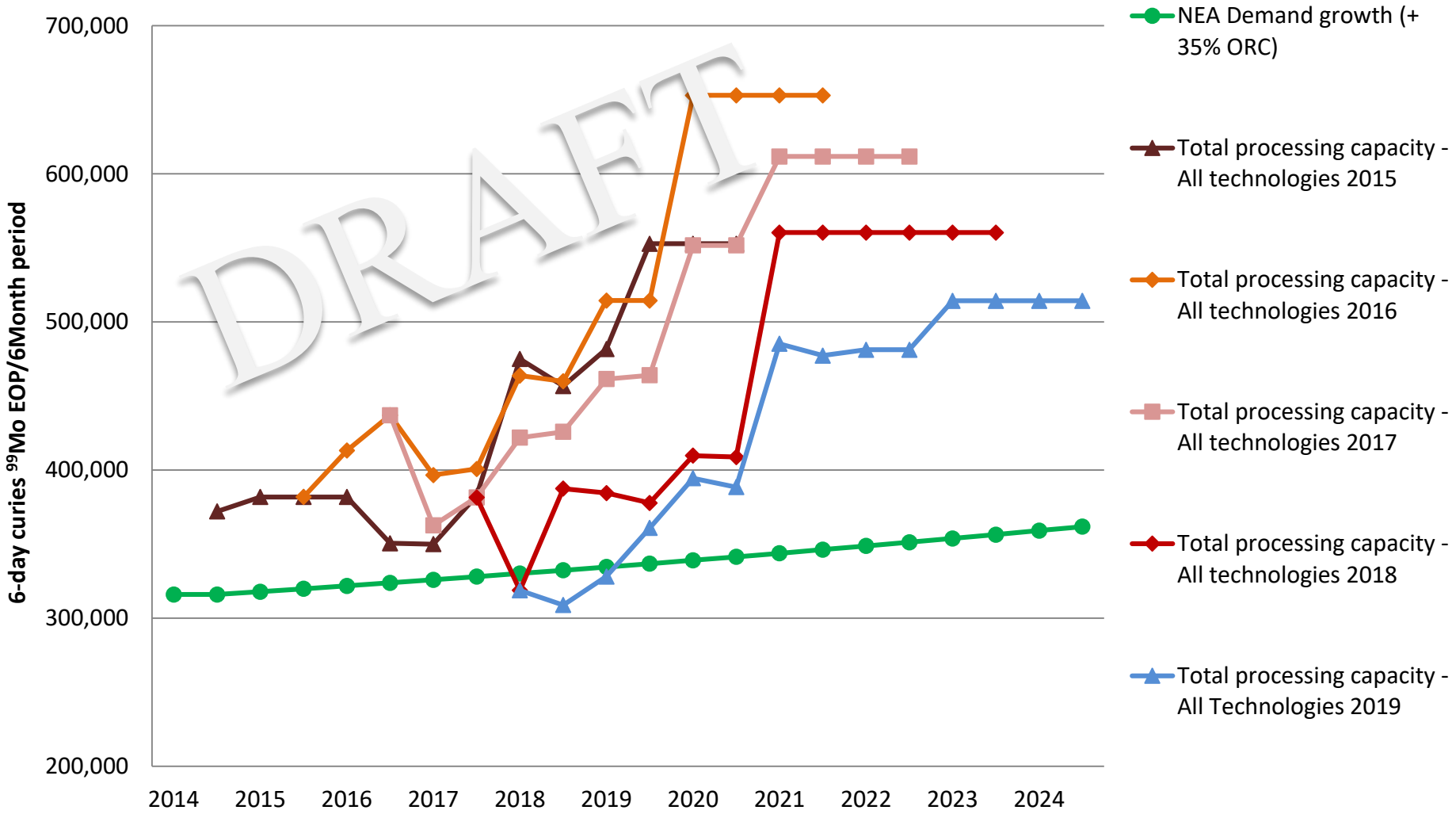

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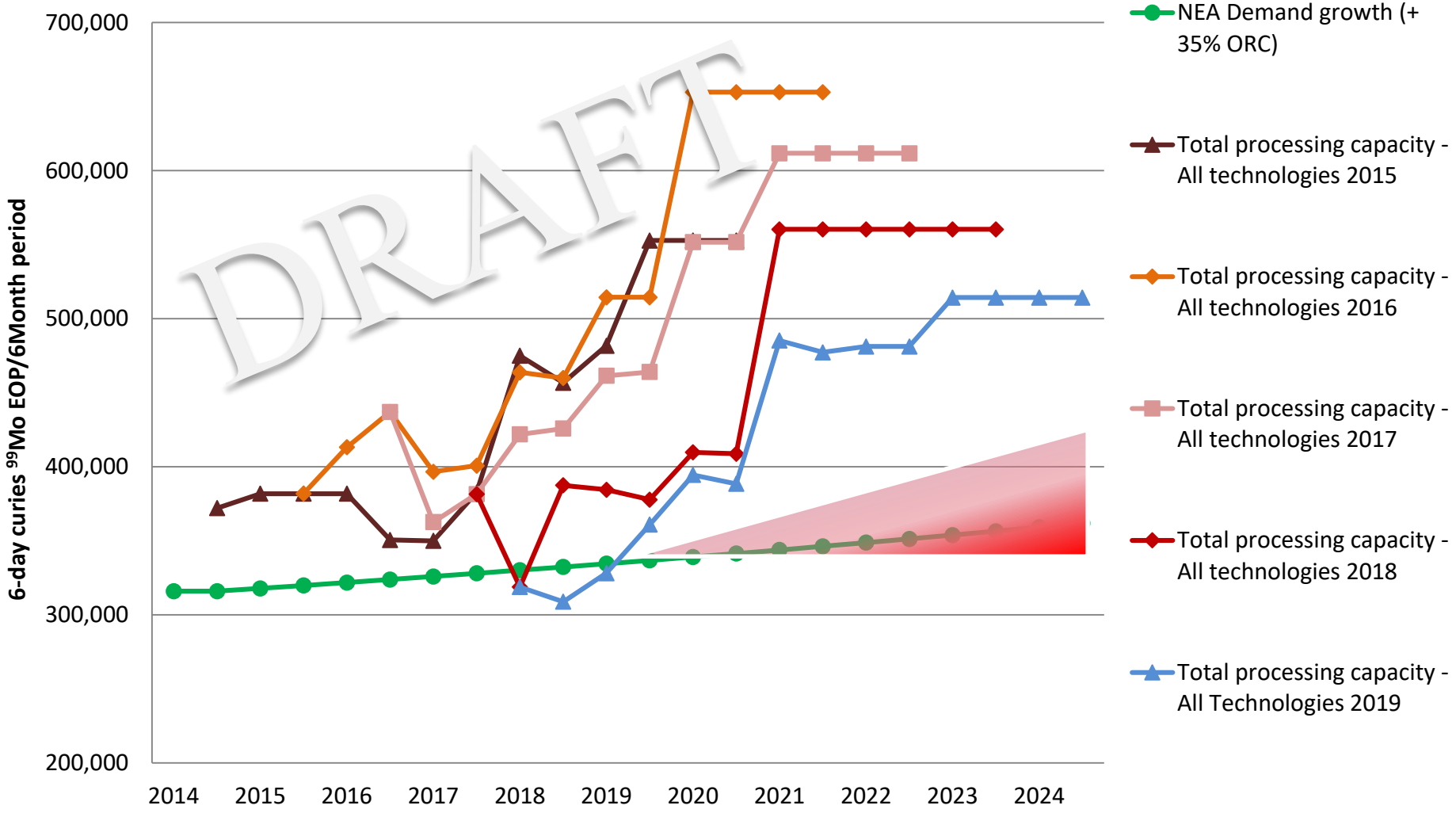

Supply Status Summary

- Many technical problems have actually been solved and a range of alternative production technologies demonstrated
  - the first alternative technology is now being used in the US market
- Supply was stabilised as a result of the actions of existing supply chain participants and the co-ordination activities of the Nuclear Medicine Europe organisation (NMeu formally AIPES), but challenges remain
  - supply has been stressed since mid-November 2017 due to an unplanned outages at NTP (South Africa)
    - the NMeu Emergency Response Team convened almost weekly during 2018 and continue to monitor the situation closely
    - still some “chronic” supply shortages in 2019

Supply Status Summary

- LEU targets (market externality determined by governments)
  - >70% market conversion recently achieved
  - but less efficient, more waste and a higher unit cost
- Self-Assessment: 6-policy principle - slow implementation
  - 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
  - security of supply risks remain
  - continued risk of project delay or cancellation of new investment

Ad-hoc "Lite" Meeting

- One day meeting 9 July 2019
  - primarily held in "Open" session.
- Main discussion points
  - supply status
  - 2019 Demand and Capacity Forecast
  - some project updates
  - OECD Health Division report
  - advice from participants to the NEA NDC

Focus of this presentation

Outline of draft Health Division / NEA report

1	Use of Tc-99m in health care	Discussed before
2	Variations in use of Tc-99m across countries	Discussed before
3	Health care provider payment for NM diagnostic scans	Discussed before
4	Supply chain analysis	Focus of this presentation
5	Policy options to increase reliability of Tc-99m supply	Focus of this presentation

- *Draft report circulated with HLG-MR on 3 July 2019*

Policy options

- *Policies need to tackle the issue within the supply chain*

Policies to move towards full-cost recovery within the Mo-99/Tc-99m supply chain

1. Phased and coordinated discontinuation of NRR funding by governments of producing countries
2. Increasing price transparency in the supply chain
3. Direct price regulation in the supply chain
4. Introducing a commodities trading platform for bulk Mo-99
5. Direct funding of Mo-99 production by end-user countries

Policies to reduce the reliance on the current Mo-99/Tc-99m supply chain

6. Increasing use of substitute diagnostic imaging modalities or substitute isotopes
7. Move towards alternative methods to produce Mo-99/Tc-99m

Forward Plan Beyond 2018

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  - continued preparation and publication of the Mo-99 Demand and Capacity Projection report series – in publication process
  - retain the ability to arrange ad hoc meetings of stakeholders (up to two per year) – held 9 July 2019
  - ability to coordinate communications among the current members of the group should the need arise – communication has been essential
  - follow-up work/analysis on the OECD Health Division project – report released for review

Advice from 9 July 2019 Ad-hoc meeting

- Maintain the activities that transferred to the NTE Programme of Work for the 2019-2020 period:
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Thank you for your attention