

Mallinckrodt



Update on Mallinckrodt's Low-Enriched Uranium (LEU) Conversion Project

Mo-99 Topical Meeting
April 2, 2013

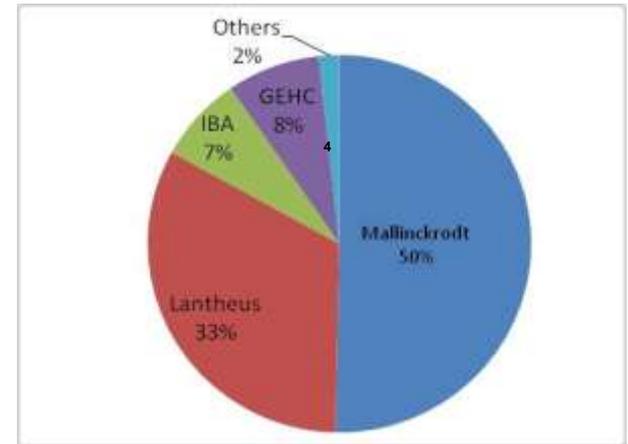
Roy W. Brown
Director, Strategic Alliances



Current Mo-99 Supply Situation

Mo-99 Supply from Mallinckrodt

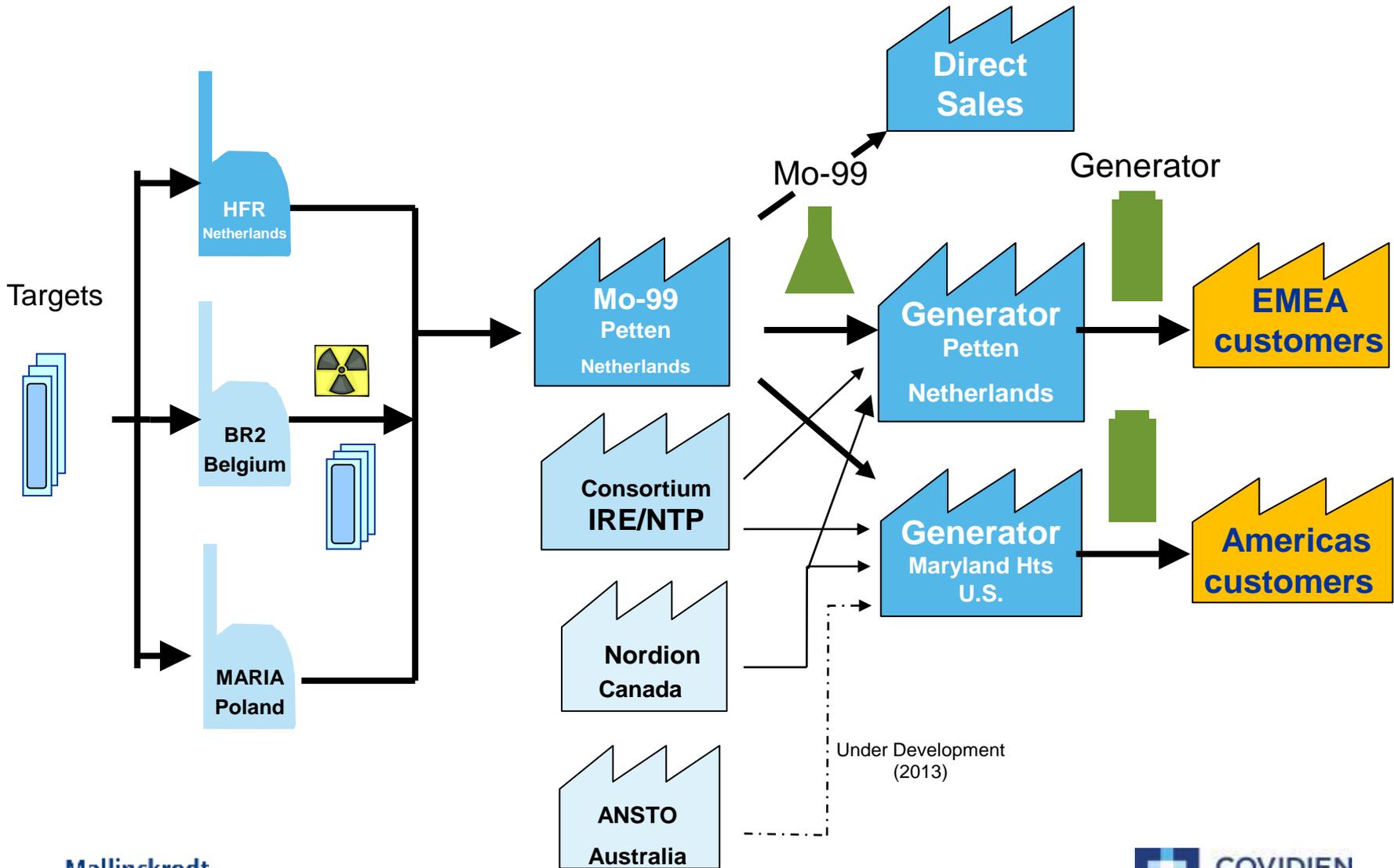
- Mallinckrodt is one of only a few vertically integrated Mo-99 producers/Tc-99m generator manufacturers
 - That vertical integration allows us to better serve our customers
 - We produce much of our own Mo-99 supply, creating significantly greater stability
 - We can and do buy Mo-99 from IRE¹ in Belgium, NTP² in South Africa, and Nordion in Canada when needed
 - We are awaiting FDA approval to use LEU-based Mo-99 from ANSTO³ in Australia
- Mallinckrodt is the world's largest producer of Tc-99m generators
 - We produce more Mo-99 than any other manufacturer globally
 - We use more Mo-99 in the production of Tc-99m generators than any other manufacturer globally



Global Tc-99m Generator Market – 2011*

* Source: Lantheus Medical Imaging Annual Report 2011, IBA Annual Report 2011, Internal Estimates

Diversification of Mo-99 Supply Increases Reliability



Impact of Reactor Maintenance April-May

- HFR has been down since mid Nov – no generator shipments have been missed by Mallinckrodt.
- This has been done by close cooperation with the reactors where Mallinckrodt irradiates targets, and by outside purchases of Mo-99.
- NRU is scheduled to be shutdown mid-April through mid-May for inspections/maintenance.
- This has created supply concerns with the HFR also being down.
- Significant efforts have been made to source additional Mo-99 from other reactors during this time period.
- A new three week cycle was added at BR2, at substantial cost to ensure patients would have access to Tc-99m.
- Planned maintenance was delayed at MARIA, at substantial cost.
- Mallinckrodt believes there may be shortages in late April, and May if the HFR does not come back on-line in early May.

Mallinckrodt's LEU Conversion Update

Mallinckrodt's Support for LEU Conversion

- Mallinckrodt fully supports the conversion from HEU to LEU for the production of medical radionuclides.
- We are making a significant investment in converting to LEU targets for the production of Mo-99.
- Although it has been demonstrated that the use of LEU targets will lower the production efficiency and increase the cost of Mo-99 production, we believe conversion to LEU targets will improve the long-term reliability of Mo-99 supply.
- Conversion to LEU targets has been shown by those already converted that an inherent loss in production efficiency will occur. Conversion is still supported in spite of this loss of efficiency.
- We are still on track to be fully converted by the end of 2015.

LEU Conversion Update

- We have developed a new LEU dispersion target design through a collaboration between Mallinckrodt, NRG and CERCA.
- That new LEU target has already been qualified in the HFR and is scheduled to be qualified in the MARIA and BR2 reactors later this year.
- The new LEU target has been successfully irradiated in the HFR for times considered the outside bounds of typical irradiation time.
- Fabrication of new target rigs and holders is underway.
- Successful radiochemistry processing has been performed on depleted uranium targets.

The Target Qualification Process

slides courtesy of NRG

Steps for the irradiation qualification



To qualify the use of LEU targets for irradiation in the HFR:

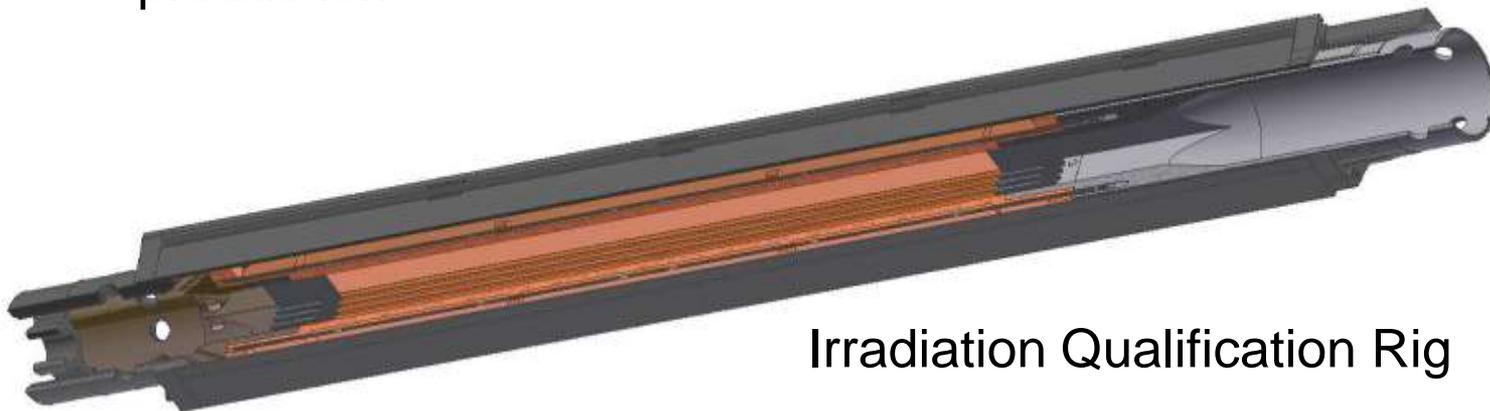
1. Set irradiation conditions & acceptance criteria
2. Irradiation testing at defined qualification conditions
3. Post Irradiation Examinations
4. Check if irradiation damage / target degradation is within acceptance criteria
5. Positive advice by NRG Safety Committees
6. Statement of 'no objection' by (Dutch) authorities



Irradiation qualification for LEU targets



- The qualification irradiations were performed on various LEU targets
 - In a dedicated irradiation facility in-core at HFR
 - Irradiation conditions overlapping most severe irradiation conditions experienced during production
 - **For example:** peak heat flux significantly higher than maximum during production
 - Extra safety measures as compared to regular production



Irradiation Qualification Rig

Post Irradiation Examinations

- Post Irradiation Examinations (PIE) are performed to check the irradiation behaviour
- To qualify an LEU target, a number of techniques can be used
 - Visual inspection
 - Swelling behaviour
 - Oxide layer growth
 - Gamma scanning
 - Destructive testing
- All non-destructive PIE were performed in a dedicated scanning device



NRG Hot Cell Laboratory

PIE results

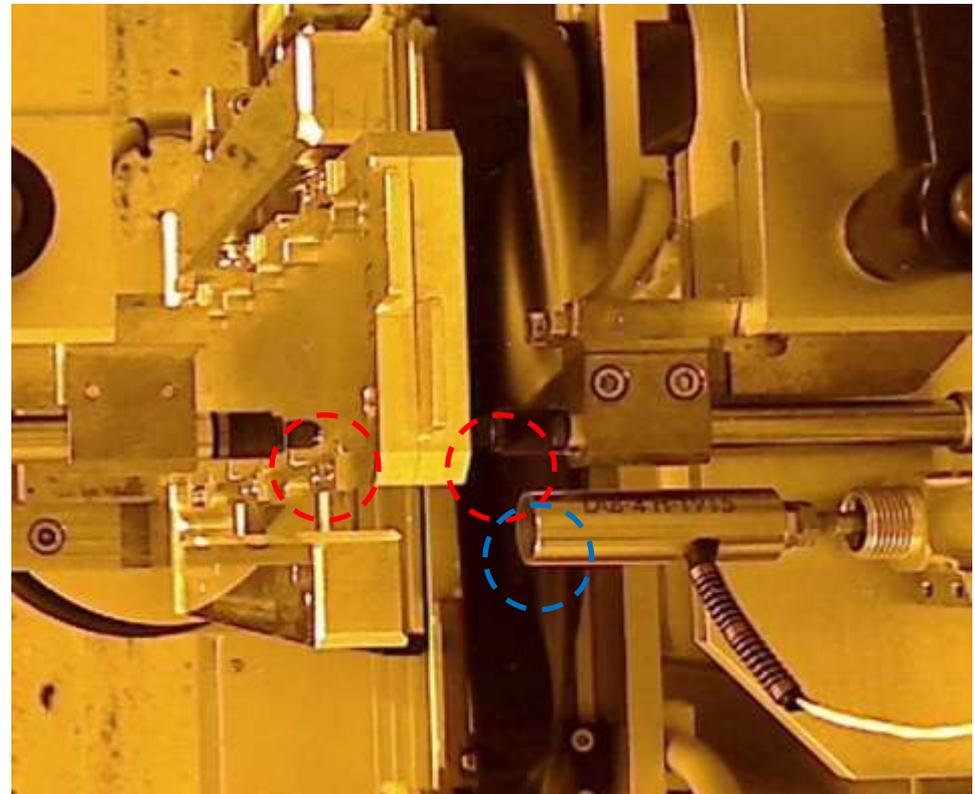
- Visual inspection ✓
- Swelling ✓
- Oxide layer growth ✓
- Gamma scanning ✓

Conclusion:

All acceptance criteria
have been met

At RRFM 2013, NRG will
present the results of the
qualification in more detail

Scanning device, with thickness sensors to
measure swelling (red) and eddy current
probe (blue) to measure the oxide layer



Mallinckrodt's Experience with CMS' Preferential Reimbursement for LEU Tc-99m Procedures

U.S. Experience with LEU-based Mo-99

- The new U.S. preferential reimbursement system for LEU-based generators went into effect for Medicare Hospital Outpatients on January 1.
- We are set up to produce LEU-based generators which qualify under the Center for Medicare and Medicaid Services program.
- Although initially there was some interest in the LEU-based generators, that has not translated into orders or sales.
- Our customers are concerned about the impact of this new rule, driving loss of efficiencies in the nuclear pharmacy, additional costs associated with LEU-based generators, and the additional paperwork required in the hospital to use LEU generator Tc-99m.
- Demand for LEU-based generators may increase with additional availability of LEU supply.

Ways to Increase Non-HEU Mo-99 in U.S.

- Mallinckrodt will continue with its educational efforts for hospital and nuclear pharmacy customers.
- Moving to more conducive scenarios, such as blending of HEU & non-HEU Mo-99 by the generator manufacturers may pull more non-HEU Mo-99 into the U.S.

Summary

- Mallinckrodt is working hard to increase worldwide stability of the Mo-99 supply.
- We are making significant investments in the conversion from HEU to LEU production of Mo-99.
- We are actively implementing the recommendations of the OECD High Level Working Group, which will lead to long term stability of Mo-99 supply.
- All measures taken to improve long-term supply reliability will drive higher cost of Mo-99.