

NNSA MO-99 STAKEHOLDERS MEETING

# CURRENT SUPPLY STATUS

Roy W. Brown May 16, 2018

CONFIDENTIAL

## **INTRODUCING CURIUM**

## CURIUM – UNITING IBA MOLECULAR AND MALLINCKRODT NUCLEAR MEDICINE LLC

- CUCIUM™ LIFE FORWARD
- January 27, 2017 Mallinckrodt Pharmaceuticals completed the sale of its Global Nuclear Imaging business to IBA Molecular.
- 100 years of combined experience in the nuclear medicine industry.
- Singular focus to develop, manufacture and supply SPECT, PET and therapeutic radiopharmaceuticals.
- More than 1,600 dedicated employees work to provide nuclear medicine products for over 14 million patients worldwide each year through 6,000 customers in 70 countries.
- Largest vertically integrated radiopharmaceutical manufacturing network with one global Mo-99 production facility, three large SPECT manufacturing facilities, and more than 40 SPECT and PET radiopharmacies.

## **CURIUM'S LEU CONVERSION PROJECT**



- Curium began its LEU conversion project in 2010.
- Since that time we have resolved several technical development challenges in the radiochemistry and analytical testing.
- We have established arrangements with a diverse network of reactors to irradiate targets for our Mo-99 production process.
- Curium has taken steps to steadily increase reliability and capacity of Mo-99 production to account for loss of older reactors and for the loss of efficiency due to LEU conversion.
- All regulatory filings for LEU conversion were completed during 2017.

## **CURIUM IS NOW FULLY CONVERTED TO LEU Mo-99 PRODUCTION**



- Curium burned the last of our HEU targets in late 2017.
- As of January, 100% of North American generators are from LEU-produced Mo-99.
- We have already seen the lower yield and higher cost associated with producing LEU Mo-99.
- We appreciate the technical and financial assistance provided by the U.S. Department of Energy during our conversion effort.



Curium is the world's largest supplier of Tc 99m generators and the largest user of Mo-90 in the world. This milestone helps satisfy the goals set forth by the Department of Energy's (DOE) National Nuclear Security Administration (NNSA) and confirms our support for the NNSA project to eliminate the use of weapons-grade uranium in the production of medical isotopes. We are eager to see others follow our lead and comply with the government's call for full conversion as soon possible' says Curium North American CEO, Dan Brague.

This project is the culmination of more than seven years of work, requiring close collaboration with Curium's irradiation partners: the Dutch High Flux Reactor, the Polish MARIA reactor, and BR2 in Belgium, as well as, the DOE and NNSA. Roy Brown, Vice President, Government Affairs for Curium North America, states, "Our 100 percent LEU conversion helps Curium generator customers eliminate the inefficiency of balancing the availability of both HEU and LEU generators in their inventory and helps them to control costs better. Something that is especially important when you consider the special reimbursement guidelines surrounding LEU versus HEU patient doses."

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## **CURIUM HAS BEGUN LEU Xe-133 GAS PRODUCTION**



• Curium (Mallinckrodt) previously manufactured Xe-133 gas from an HEU process.

- During the Mo-99 HEU conversion project Curium also developed a method for separating LEU produced Xe-133 from our process in Petten.
- Curium has now re-entered the Xe-133 market utilizing LEU produced Xe-133, used for pulmonary function, lung imaging, and cerebral blood flow scans..
- Curium's Xe-133 provides customers with the only 100% Low Enriched Uranium (LEU) offering.



## **CURIUM Mo-99 SUPPLY METRICS**



- Curium Mo-99 production began in the Netherlands in the late 1990s.
- Production capacity has steadily increased since then.
- Additional capacity has been recently added.
- Capacity added to account for loss of the OSIRIS and NRU reactors.
- Capacity has been added to account for loss of efficiency due to LEU conversion.



## **CURRENT Mo-99 SUPPLY OUTLOOK**



- Curium has increased the number of Mo-99 production runs in Petten from four days per week to five. We have the ability to add a sixth production.
- Those extra production days coupled with the increased Outage Reserve Capacity creates even more reliability for Curium.
- We increased Mo-99 production during the recent NTP operational challenges in S. Africa, enabling Curium to provide additional coverage to patients.



#### **PRODUCTION OF LEU Mo-99 DURING MARKET TRANSITION**



- Production of Mo-99 with LEU versus HEU is less efficient and generates significantly more radioactive waste.
- IRE reported at the EU Observatory meeting last month they may not be fully converted to LEU until late 2020.
- This higher cost of LEU production of Mo-99 impacts Curium in making Tc-99m generators at its plants in Petten, the Netherlands, Maryland Heights, MO and Saclay, France.
- Curium is now at a competitive disadvantage because we are producing LEU-based Mo-99, while our principle competitor in Mo-99 production continues to produce HEU-based Mo-99 at lower cost.

Mo-99 PRODUCERS WHO HAVE ALREADY CONVERTED TO LEU ARE AT A COMPETITIVE DISADVANTAGE