



WOSMIP REMOTE

IRE LEU CONVERSION UPDATE

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Institute for Radioelements

- Missions
 - ***Contribute to public health***
 - ✓ First producer of fission I-131
 - ✓ Major producer of Mo-99 for Europe
 - ✓ Xe-133 producer
 - ***Environmental protection***

institute for
radioelements **IRE**



IRE LEU conversion challenges

Safety improvements required

- Chemical process modifications
- Production equipment modifications
- Production environment updates : hot cells and ancillaries

3 processes to convert

- Mo-99 I-131 Xe-133

Important modifications of target specifications



Target manufacturing



Irradiation



Transport container

LEU Conversion

- New impurity profile
- Unique specification

- Reactors to accommodate new specifications
- Lower yield

- Modifications of design
- Revision of Transport License

- **Modified chemical process**
- **Hydrogen risk management**
- **Uranium filtration**
- **Iodine trapping**

- **Increased quantities**

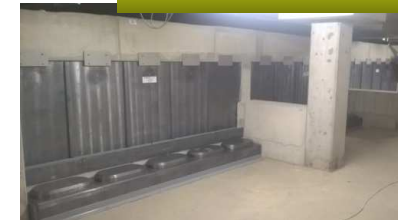
**LEU
Conversion**

- **Post Fukushima stress tests**
- **New processing equipments**

Processing



Waste management



Hot cells

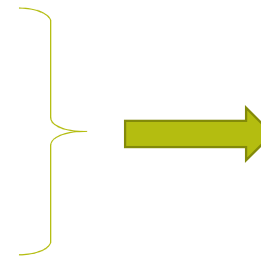


Xe-133 Process modifications

☼ HEU Xe-133 is recovered on liquid nitrogen traps

☼ Trapping of LEU Xe-133

- New process at room temperature
- Below the atmospheric pressure
- Closed passive system with decay tanks



Safety improvements

Recent achievements

- ☼ May-July 2019 Mo-99 pharmaceutical validation runs – stability
- ☼ August 2019 Drug Master File submitted to FDA
- ☼ October 2019 Drug Master File submitted to European Medicines Agency
- ☼ November 2020 FDA approval for Mo-99
- ☼ January 2020 Xe-133 Approval by FDA
- ☼ March 31, 2020 Final safety demonstration achieved

First LEU Mo-99 commercial production achieved on April 30rd !



EXCELLENCE FOR LIFE

IRE supplies a first commercial batch of LEU-based Mo-99

Fleurus, Belgium – April 30th, 2020 - The Institute for radioelements (IRE), one of the leaders in the production of Molybdenum-99 (Mo-99), the most widely used radio-isotope in nuclear medicine for diagnosis, announced today that the company produced its first commercial Mo-99 Low Enriched Uranium (LEU) batch for the US market.

This conversion to LEU represents a key milestone for IRE in the global commitment to end the civil use of High Enriched Uranium (HEU) for the production of Mo-99 medical isotopes. This demonstrates its unique capacity to carry out advanced R&D activities while maintaining during the last two years its highest production output to serve the global market during temporary or unplanned outages of some alternative suppliers of medical radioisotopes. It achieves the first step of the complex development of an entirely new industrial process to supply healthcare professionals with Mo-99. This conversion will include very soon the production process for Iodine -131 (I-131), essential and irreplaceable radionuclide for thyroid cancer treatments, based on LEU. Despite the additional burden induced by the lockdown caused by the COVID-19 crisis, our teams could maintain and complete their planning to receive the authorization from the FANC, the Federal Agency for Nuclear Control in Belgium. Conversion to LEU will positively impact Safety and Security on site, two components inseparable of our IRE activity, since this new LEU production flow takes place in refurbished installations that bring many advantages in terms of nuclear safety and nuclear security for our teams.

This first production was completed with uranium targets irradiated in the BR-2, the Belgian research reactor located at SCK CEN in Mol, a key partner of IRE in the production of radioisotopes.

IRE will conduct this conversion in progressive steps, in the coming months with a dedicated part of the produced volumes of Mo-99 to supply the US market, and will later increase its volume to allow the supply of LEU-based Mo-99 to all regions, until the full conversion is achieved, at the latest by 2022. IRE will do its best to maintain until then a sufficient level of HEU-based production to validate its final industrial process for the purification of I-131 LEU and at the same time allows all its clients to convert their regulatory files for I-131 based products.

Mrs. Marie-Christine Marghem, Minister of Energy, Environment and Sustainable Development and Minister responsible for IRE, stated: *"Despite the restrictions related to the health crisis, IRE has continued its efforts and has made it possible to collaborate in the implementation of our national strategy for the production of medical radioisotopes. I intend to maintain Belgian expertise in this area while respecting our international commitments to fight proliferation. Moreover, the completion of this project underlines the importance of funding research dedicated to medical solutions."*

I-131 and Xe-133

☼ I-131 production process still in development. High active tests on going.

☼ Xe-133

- Emissions are verified for each LEU tests and compared with similar HEU production conditions
- Xe-133 emissions are lower
- Must be confirmed when the production rate will increase

Summary

- ✿ Project started in 2011
- ✿ A lot of technical and radiochemical challenges were overcome
- ✿ All LEU high active tests were performed without any interruption of Mo-99 supply
- ✿ Loss of efficiency is confirmed with additional waste produced
- ✿ Mitigation actions are taken to ensure a reliable and high quality supply of radioelements from LEU

Thank you !

