Establishment of LEU based Mo-99 production capacity at IRE

Valery Host
Mo-99 Topical Meeting 2017, Montreal
Institute for Radioelements

- **175** employees

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

- Continuous investments for **innovation**, modernization and **safety** improvements
One of the most reliable source for the supply of radioisotopes

25% of the world demand of $^{99}$Mo and $^{131}$I

- Outstanding performances (QoS, release dosimetry...)
- without any single day of interruption,
- never out-of-spec for the last 5 years
A worldwide presence in the nuclear medicine field
What we do

Radiochemical products
Mo-99, I-131, Xe-133 for medical use
Non-processed products

Radiopharmaceutical products
Ga-68, Re-188 generators
clinical trials (MA on going for Ga-68)
LEU conversion challenges

IRE LEU

Transport container

Hot cells

Processing

Irradiation

Waste management

Safety improvements

Target manufacturing

Footprint reduction

Customers
IRE conversion: achievements

- Hotcell decontaminated
- Target specifications
- Target manufacturability
- BR2 Qualification
- LVR15 Qualification
- Approval of target transport container...
- Hotcells refurbished
- Process development
- Cold commissioning
- Prelicensing
- 1st S.R. approval
- HFR irradiation
LEU target qualification in European reactors

- Target qualification in BR2, LVR15
- Expected irradiation yield loss confirmed
- Irradiations in HFR for development purpose achieved
Process development

LEU conversion impacts

- Target design
- Target specifications
- Dissolution
- U filtration
- $^{99}$Mo - $^{131}$I separation step
- $^{99}$Mo purification
- $^{131}$I purification

Improved safety
IRE LEU process at a glance

- Target dissolution
- Filtration
- Acidification
- I-131 trapping
- Mo-99 purification
- Xe trapping

- LEU
- HEU
- I-131 solution

IRE LEU process at a glance
Cold commissioning

- Increase progressively the batch size
- Processing on Al plates and non-irradiated uranium targets
- Spike with limited amount of activity
- Check safety features

- Develop new Standard Operating Procedures
- Perform operator training
  - New production environment
  - Process
Cold commissioning outcomes

- Higher impact of target specification on processing
- > 100 tests
- > 200 targets

- Compliant with safety requirements

- Very high impact on process conditions
  - Filtration procedure
  - Equipment modifications
  - Impact on waste production

SUCCESSFUL
Hot commissioning

- Provide safety demonstration of active LEU process
- Ramp-up
  - Increase progressively the batch size
  - Processing of irradiated targets up to full scale
  - Preparing pharmaceutical file modifications with customers
- Pharmaceutical validation
  - Full scale runs
  - Regulatory file modifications
- Obtain GMP certificates and validation by customers
Hot commissioning : status

- Ramp-up phase
- 15 hot runs
- 140 processed targets

- Pharmacopea specifications compliant LEU Mo-99 !!

- Irradiation losses confirmed and high impacts on processing conditions

- Several runs at scale 1:3 achieved and still challenging
Processing authorization

- Pre-licensing
- Safety file submitted
  - Technical modifications
    - Process
    - Processing equipment
    - Hot cells
    - Chiller
  - New operating conditions
  - Environmental impact study
- 2 step approval

✔ Safety file accepted
Planning

Mo-99 timeline

I-131 timeline

Xe-133 timeline

Validation & Approvals

HEU Phase out

Hot commissioning
Conclusions

• Important milestones have been achieved
  • Cold commissioning successfully completed
  • High active hot tests on going
  • Safety file revision approval obtained
• Process LEU conversion is progressing well but still challenging

But no compromise on the security of supply
Excellence dedicated to nuclear medicine, healthcare and environment