Establishment of LEU based Mo-99 production capacity at IRE

Valery Host

Mo-99 Topical Meeting 2017, Montreal

Excellence dedicated to nuclear medicine, healthcare and environment

Institute for Radioelements

- **175** employees

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

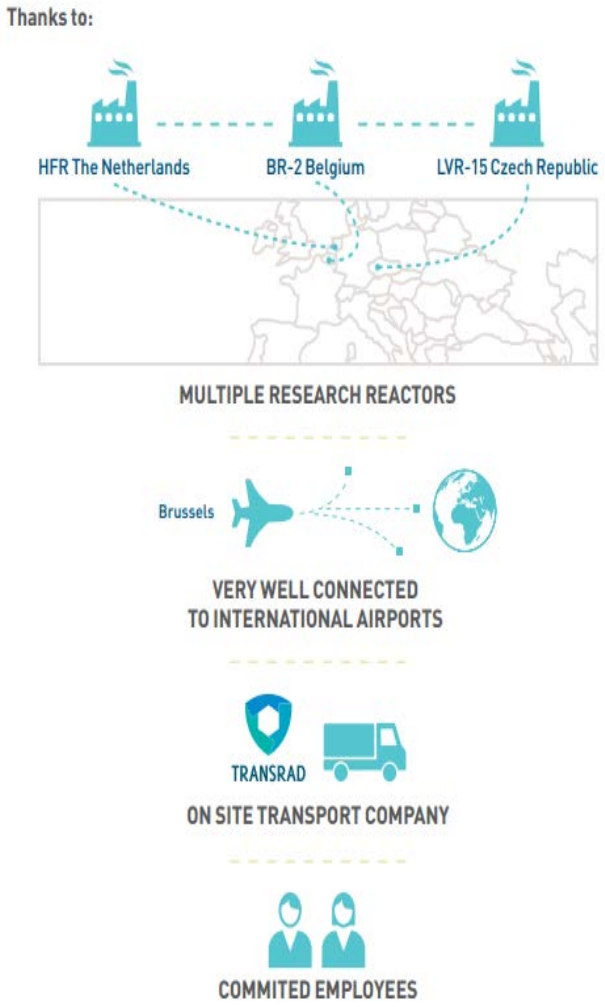
- Continuous investments for **innovation**, modernization and **safety** improvements

One of the most reliable source for the supply of radioisotopes

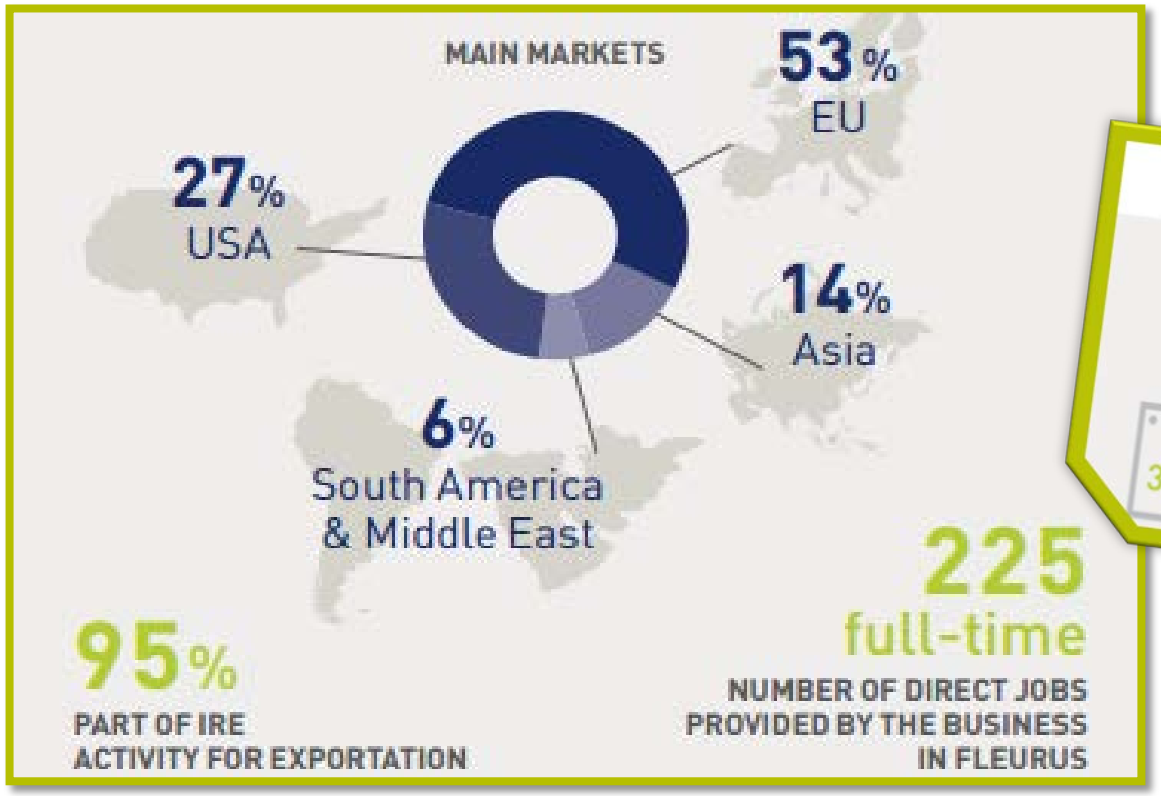
25%

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

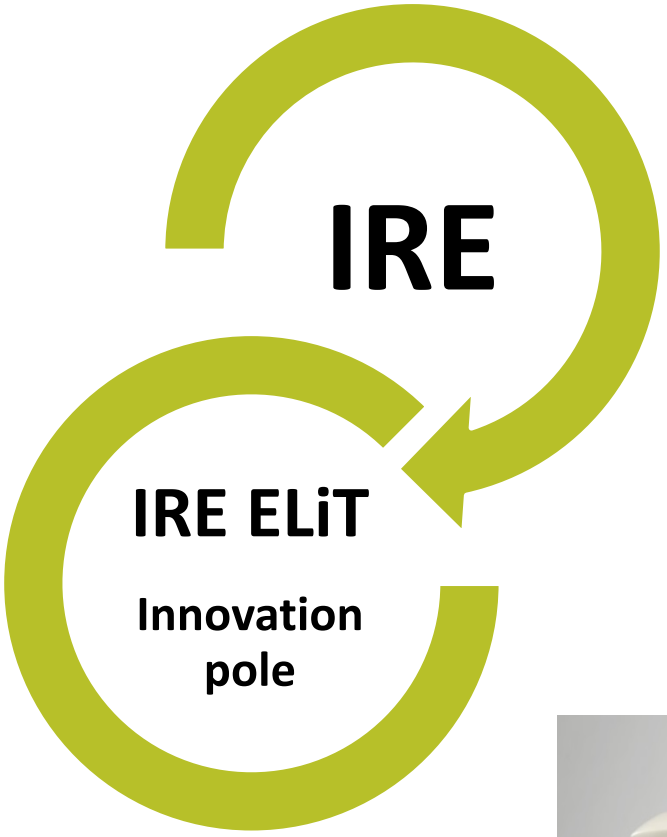
- ***Outstanding performances (QoS, release dosimetry…)***
- ***without any single day of interruption,***
- ***never out-of-spec for the last 5 years***



A worldwide presence in the nuclear medicine field



What we do



Radiochemical products

Mo-99, I-131, Xe-133 for medical use

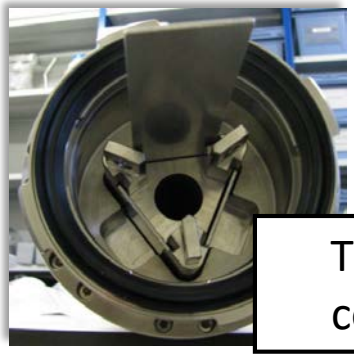
Non-processed products

Radiopharmaceutical products

Ga-68, Re-188 generators

clinical trials (MA on going for Ga-68)

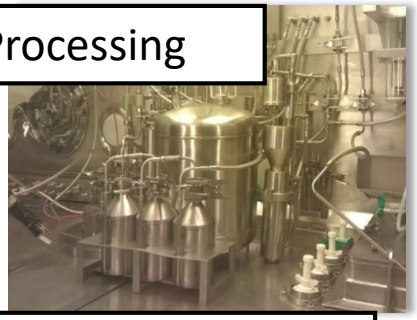
LEU conversion challenges



Transport container

Hot cells

Processing



Waste management

Irradiation

IRE LEU

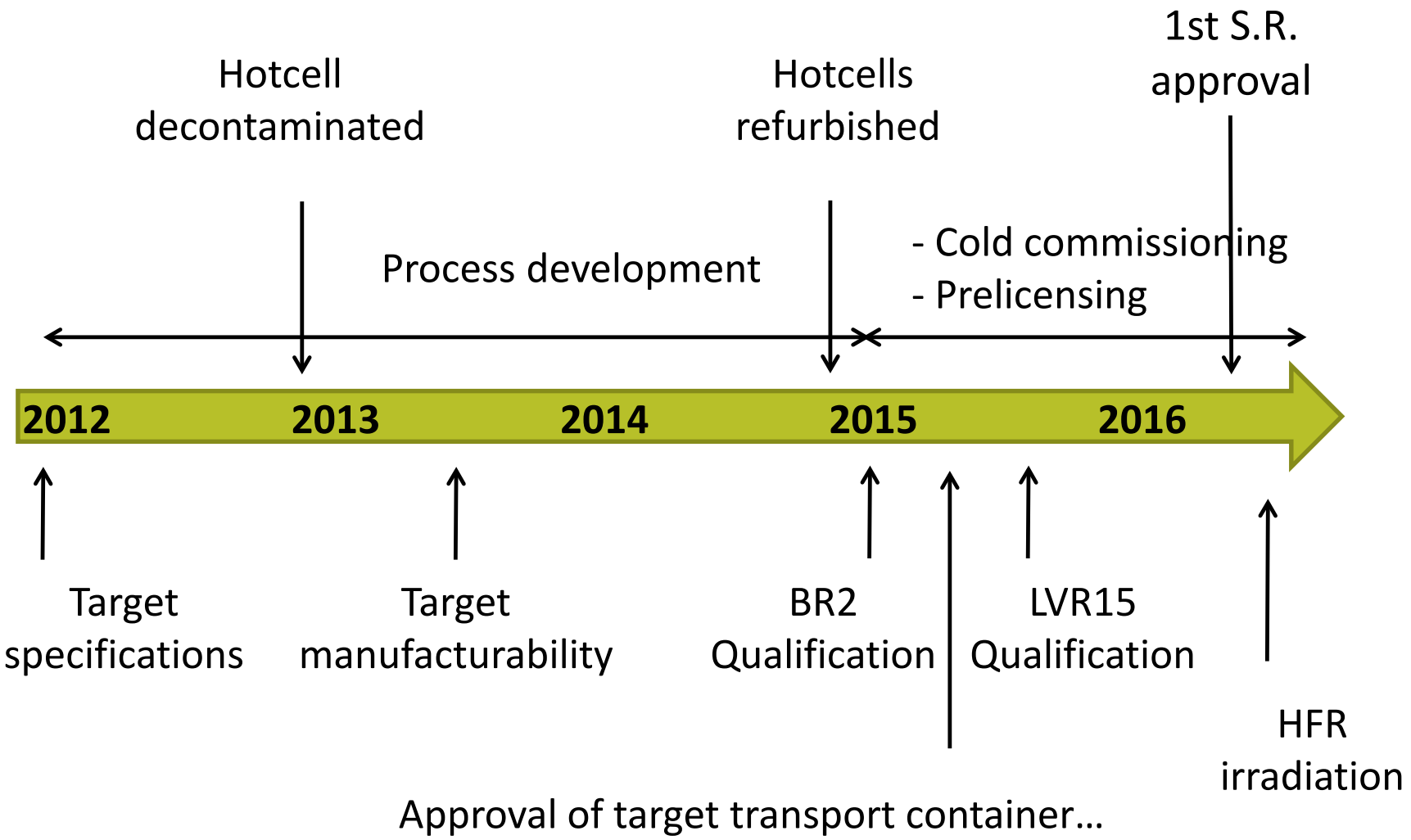
Safety improvements

Footprint reduction

Target manufacturing

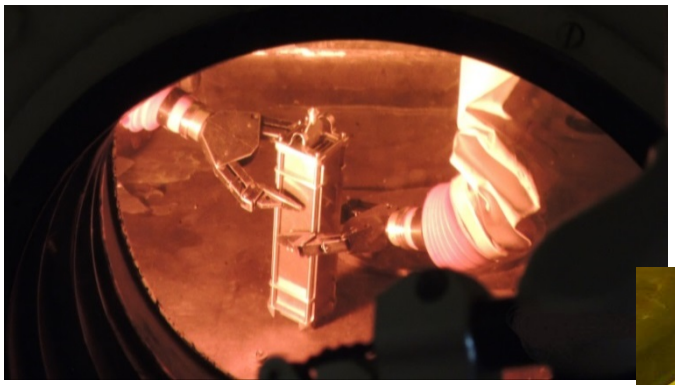
Customers

IRE conversion : achievements



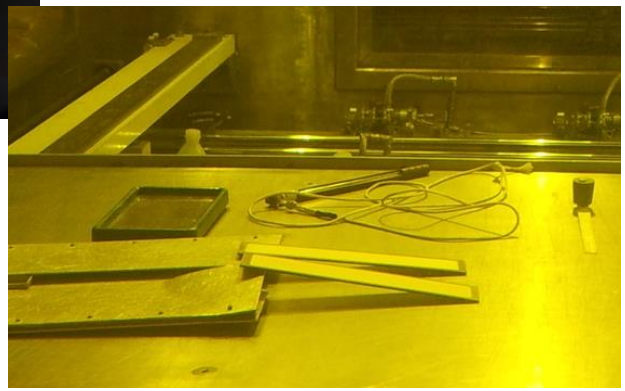
LEU target qualification in European reactors

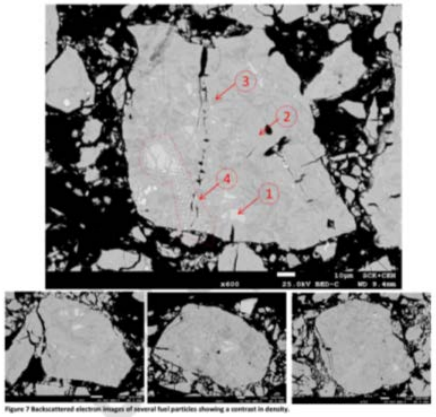
- Target qualification in BR2, LVR15
- Expected irradiation yield loss confirmed
- Irradiations in HFR for development purpose achieved



Courtesy LVR15

All reactors involved





Courtesy SCK-CEN

Process development

LEU conversion impacts

- Target design
- Target specifications

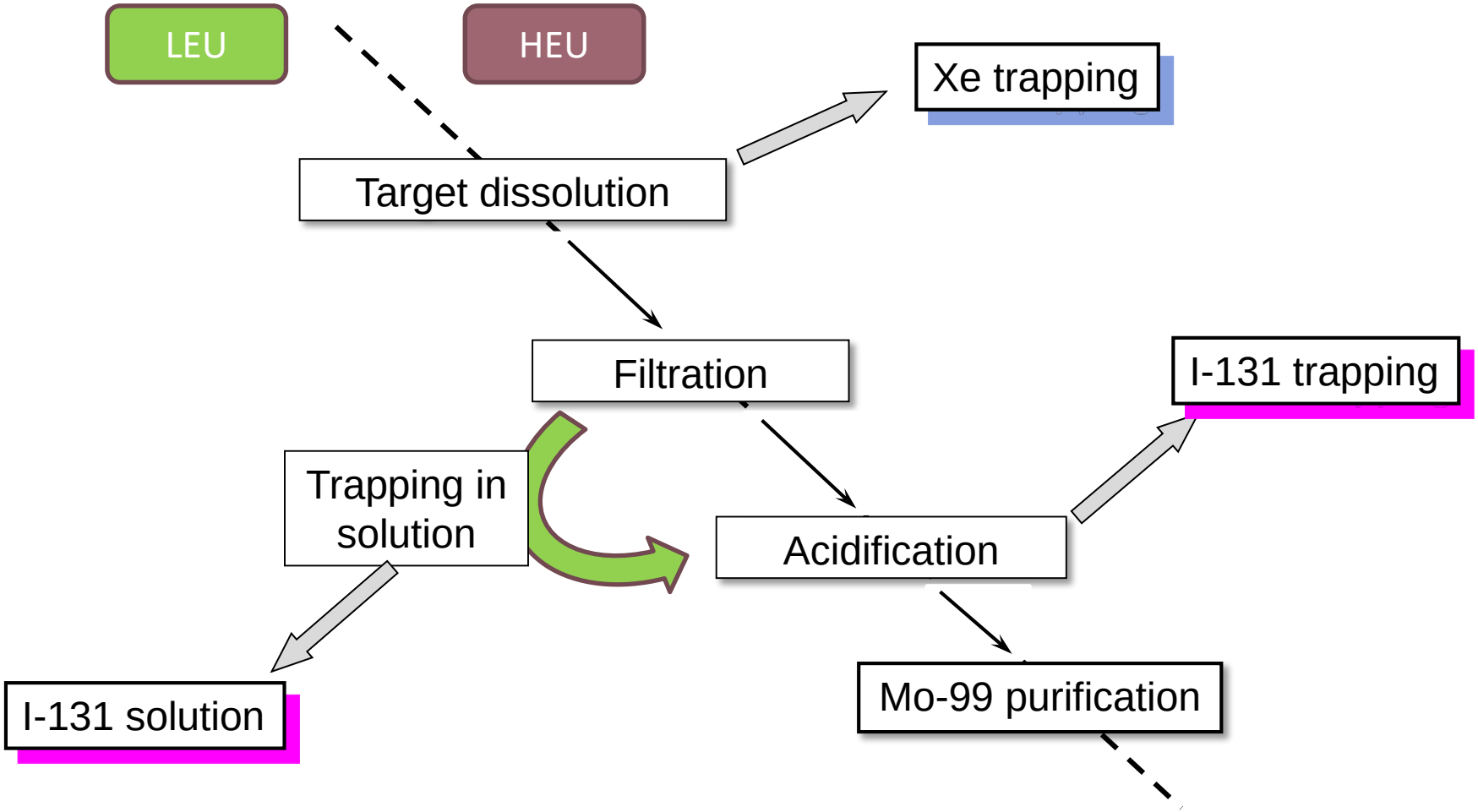
- Dissolution
- U filtration

- ^{99}Mo - ^{131}I separation step

- ^{99}Mo purification
- ^{131}I purification

Improved safety

IRE LEU process at a glance



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

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SCIENCE MEDICINES HEALTH

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

FANC AFCN
federaal agentschap voor nucleaire controle
agence fédérale de contrôle nucléaire

BEL V
filiaal van het FANC | filiale de l'AFCN

- 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**

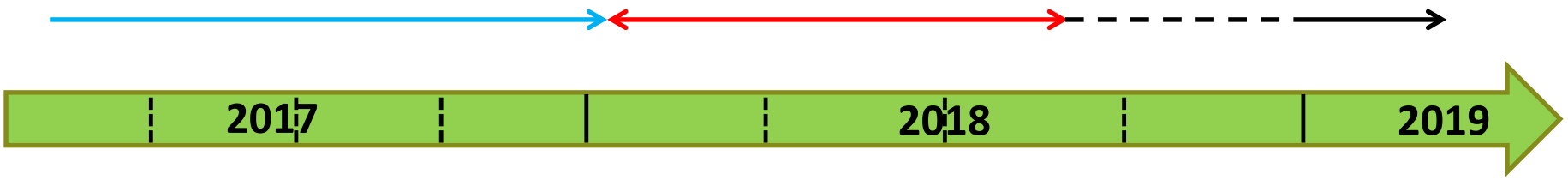
Planning

Hot commissioning

Validation & Approvals

HEU Phase out

Mo-99 timeline



I-131 timeline

Xe-133 timeline

Conclusions

- Important milestones have been achieved
  - Cold commissionning 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

RE

RE Elit
Environment & Lifescience Technology

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