



# Safety and Security of Supply of Medical Isotope Production

## The Canadian Regulator's Perspective

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# Canadian Nuclear Safety Commission

Regulates the use of nuclear energy and materials to protect the **health, safety** and **security** of Canadians and the **environment**; to implement Canada's **international commitments** on the peaceful use of nuclear energy; and to **disseminate objective scientific, technical and regulatory information to the public.**

## Canada's nuclear watchdog





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## The CNSC Regulates All Nuclear Facilities and Activities ...

- Uranium mines and mills
- Uranium fuel fabricators and processing
- Nuclear power plants
- Waste management facilities
- Nuclear substance processing
- **Industrial and medical applications**
  - **Isotope production accelerators**
- Nuclear research
- Export/import control

... from cradle to grave



The Gamma Knife is used to treat brain disorders. Ionizing gamma radiation is delivered with surgical precision.



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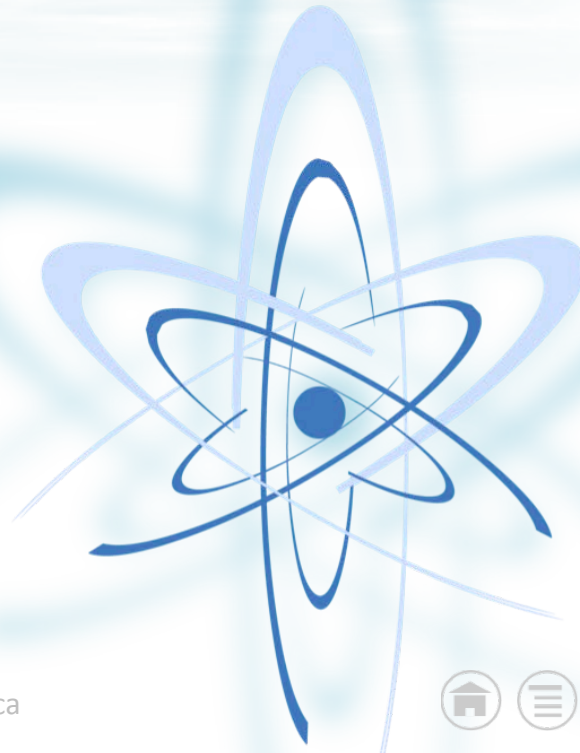
# Shared Responsibility for Isotopes

## Health Canada's mandate:

- To approve the use of technetium on humans
- To issue Good Manufacturing Practices certification of production facilities

## CNSC's mandate:

- To regulate all nuclear facilities and activities





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## Isotope Production Facilities in Canada

Nuclear power reactors - Bruce Power and OPG

- Cobalt-60

Research reactors – NRU at CNL and McMaster

- Cobalt-60
- Iodine-131
- Iodine-125

Isotope Production Accelerators

- Thallium-201, gallium-67, Iodine-123, Iodine-124, Fluorine-18, carbon-11, nitrogen-13, oxygen-15, Technetium-99m



A cutaway model of a technetium generator. The molybdenum/alumina sample is placed in the centre of the device, surrounded by shielding (painted red in this case).





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## Medical Isotopes Research Reactors

- At the end of October 2016, NRU ceased routine Molybdenum-99 production.
- World supply in Molybdenum-99 secured by additional reactor capacity from existing supply chain members
- Cobalt inventory to last 5 to 6 years



NRU currently on “hot standby” NRU reactor as a “supplier of last resort” from November 1, 2016 to March 31, 2018

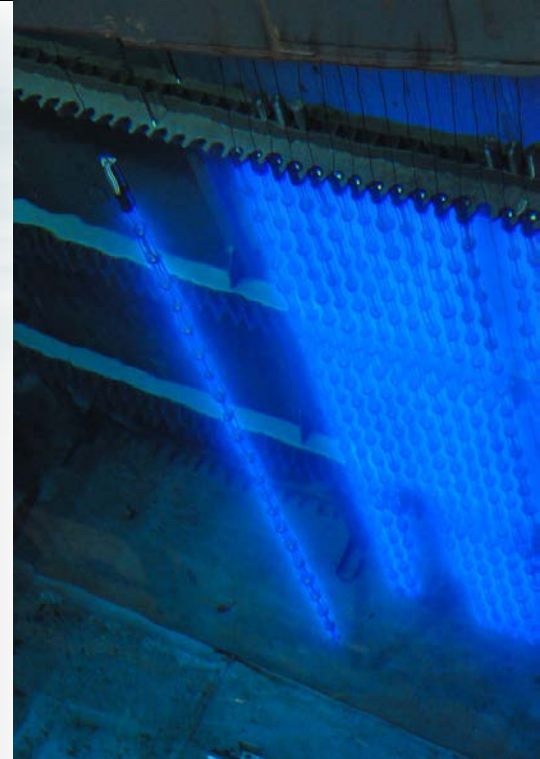


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## Medical Isotopes Nuclear Power Reactors

### Bruce Power

- Supply arrangement to secure long-term supply of High Specific Activity (HSA) Cobalt-60 until 2064
- Harvests Cobalt-60 from its Bruce B reactors during planned maintenance outages.
- Next HSA Cobalt-60 to be harvested in 2018



Cobalt-60 is stored in water in the Secondary Fuel Bay until transported for processing. Source: Bruce Power



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## Securing supply How Stable Is the Supply Chain?

- Market demand of Mo-99 is lower
- Capacity is highly dependent on technological challenges and project delays
- Contingency capacity from NRU, extra irradiation capacity from OPAL late 2017, entry of FRM II (Germany) in 2019







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## Canada's Approach Accelerators and Cyclotrons

Projects funded under the Non-reactor-based Isotope Supply Contribution Program (NISIP) and Isotope Technology Acceleration Program (ITAP)

- Cyclotron production of Tc-99m
- Linear-accelerator-based production of Tc-99m via the transmutation of molybdenum 100 (Mo-100)
- Administered by Natural Resources Canada (NRCan)

Budget 2010 (NISIP)	\$35 million	2 years, ended 2012	Feasibility of alternative technologies to reactor-based production
Budget 2012 (ITAP)	\$25 million	4 years, ended 2016	Demonstrate commercial production and achieve the necessary regulatory approvals



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# Non Reactor Based Isotope Production National Cyclotron Network for Tc-99m Production



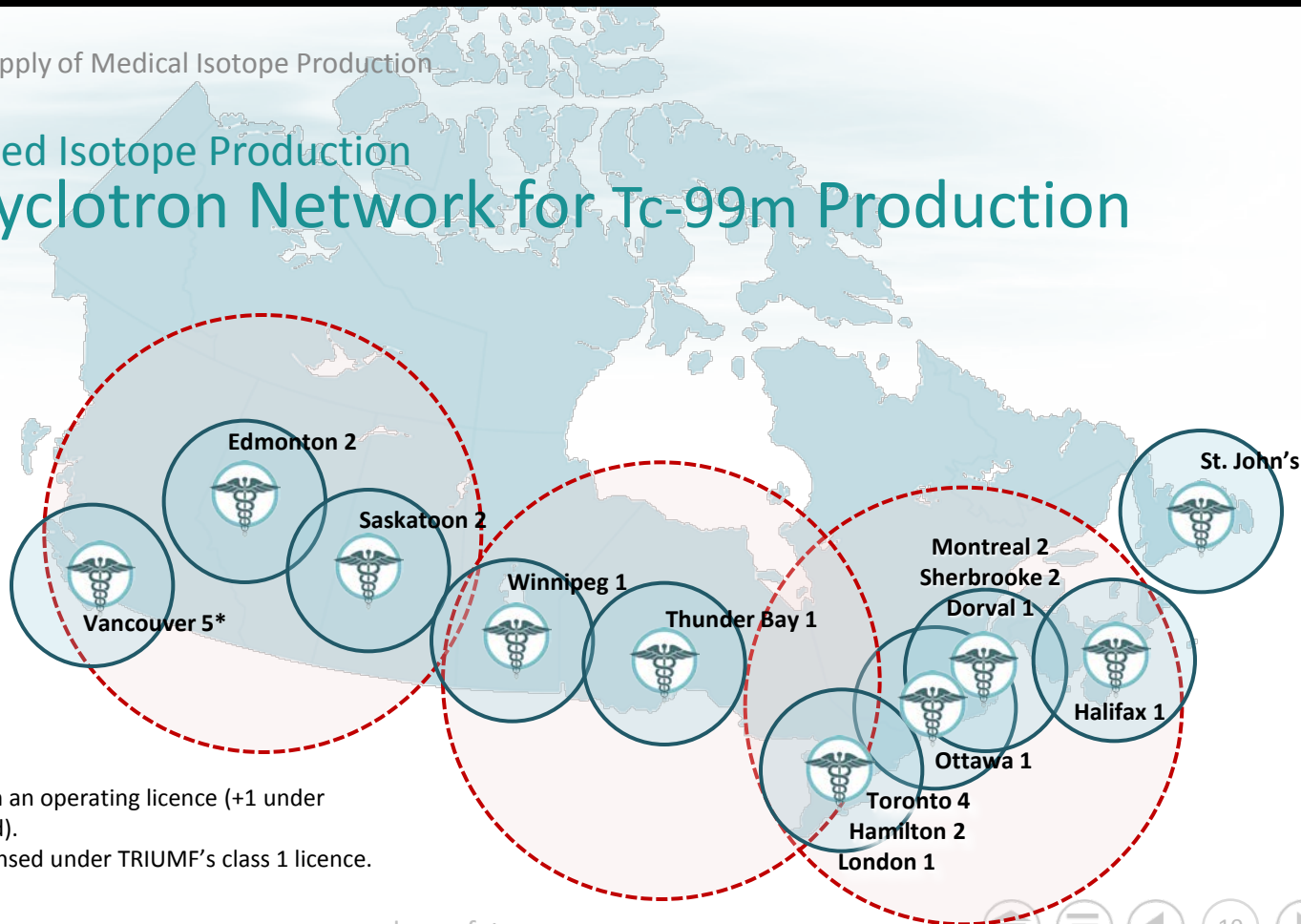
Isotope Producers



Plane 2 hours



Car 4 hours



\*There are 25 class II IPAs with an operating licence (+1 under construction in St. John's Nfld).  
Note that 4 of the 25 are licensed under TRIUMF's class 1 licence.



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## Regulatory Considerations

- Clarity with respect to regulatory requirements
- CNSC has published regulatory requirements for non-reactor production of Mo-99 and Tc-99m
- Implementation of government policies  
– without compromise to safety
- Life extensions for existing reactors and processing facilities

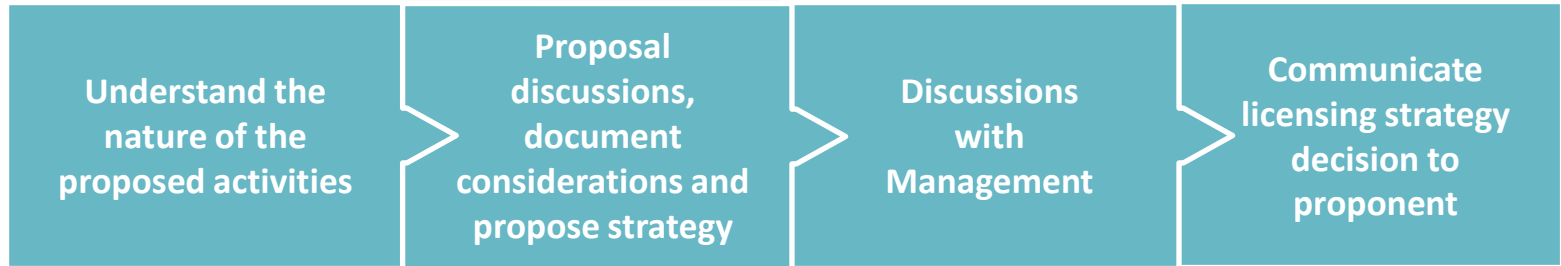




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# Regulating New Technologies in Canada

## Approach for determining the licensing strategy for novel applications



Proposal is evaluated on hazards, complexity and novelty aspects

Licensing strategy provides recommendation on the most appropriate regulations, application guides, REGDOCs and lead licensing service line.

Recommendations for scope and depth of licensing review for each SCA

Applicants are informed on expectations regarding information to be submitted in support of this process



# Safety and Security Consideration in Canada

- Commensurate with conversion of HEU to LEU
- Alternate technologies
- Waste management – short and long term
- Repatriation of HEU
- Transportation of generators, unit doses to users
- Changes in radiopharmaceutical practices – radiopharmacy, hospital or clinic – handling and safety training
- Communicating benefits to the public to gain their trust and educating political decision makers





## Conclusions

- Canada is leading with alternate and non-reactor technology to secure medical isotopes to Canadians
- Regulatory collaboration internationally is a must to ensure safe, reliable supply of medical isotopes
- Producers are to work together and engage early with the safety and health regulators to understand their requirements
- Conversion from HEU to LEU can be done safely in order to mitigate security concerns



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