Safety and Security of Supply of Medical Isotope Production

The Canadian Regulator’s Perspective

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Canadian Nuclear Safety Commission
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.
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

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).
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.
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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 (NISP) 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)

<table>
<thead>
<tr>
<th>Budget 2010 (NISP)</th>
<th>$35 million</th>
<th>2 years, ended 2012</th>
<th>Feasibility of alternative technologies to reactor-based production</th>
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<tbody>
<tr>
<td>Budget 2012 (ITAP)</td>
<td>$25 million</td>
<td>4 years, ended 2016</td>
<td>Demonstrate commercial production and achieve the necessary regulatory approvals</td>
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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.

Vancouver 5*
Edmonton 2
Saskatoon 2
Winnipeg 1
Thunder Bay 1
Montreal 2
Sherbrooke 2
Dorval 1
Halifax 1
St. John’s
London 1
Toronto 4
Hamilton 2
Ottawa 1
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
### Regulating New Technologies in Canada

#### Approach for determining the licensing strategy for novel applications

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<tr>
<th>Understand the nature of the proposed activities</th>
<th>Proposal discussions, document considerations and propose strategy</th>
<th>Discussions with Management</th>
<th>Communicate licensing strategy decision to proponent</th>
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<tr>
<td>Proposal is evaluated on hazards, complexity and novelty aspects</td>
<td>Licensing strategy provides recommendation on the most appropriate regulations, application guides, REGDOCs and lead licensing service line.</td>
<td>Applicants are informed on expectations regarding information to be submitted in support of this process</td>
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<td>Recommendations for scope and depth of licensing review for each SCA</td>
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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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