



Community of Federal Regulators  
Communauté des régulateurs fédéraux

# *Case Study in Collaboration: The CNSC Response to the Medical Isotope Shortage*

**Peter Fundarek, M.Sc.**

Director,

Nuclear Substances and Radiation Devices Licensing

Division

Canadian Nuclear Safety Commission



Government  
of Canada

Gouvernement  
du Canada

Canada

# CNSC Response to the Medical Isotope Shortage

- Story of collaboration on many fronts:
  - Within CNSC
  - With partner Federal and Provincial Agencies
  - With regulated industry
  - With Canadians



# Nuclear safety means protecting Canadians

## Canadian Nuclear Safety Commission (CNSC)

- Canada's nuclear regulator
  - Federal agency reporting to Parliament through Natural Resources Minister
- Regulates the use of nuclear energy and materials to:
  - protect the health, safety and security of persons and the environment;
  - implement Canada's international commitments on the peaceful use of nuclear energy; and
  - disseminate objective information

*A regulator with 65 years of experience*

# Nuclear Safety and Control Act (2000)

## Modern legislation Establishes the Commission

- Quasi-judicial administrative tribunal
- Up to seven members
- Experts in own fields
- Holds public hearings
- Makes regulations
- Issues licences
- Supported by staff

## Regulatory Philosophy

Licensees responsible for the protection of health, safety, security, and the environment and respecting Canada's international commitments

CNSC responsible for regulating licensees, assessing the qualifications of applicants and whether licensees are compliant with the NSCA, regulations, and international obligations

**Nuclear regulation is a federal responsibility**

# Regulating medical facilities and activities: an exercise in collaboration

## **CNSC regulates**

- production of radioisotopes
- processing of radiopharmaceuticals
- manufacturing of medically used sealed sources
- safe handling and exposure control
- radioactive waste management
- packaging and transportation
- safety to workers and the public

## **Health Canada approves**

- radiopharmaceuticals for human use

## **Provincial jurisdiction**

- licensing bodies of medical professionals
- public hospitals and private medical clinics



# Medical uses of nuclear substances in Canada

- **Nuclear medicine**

- Use of unsealed nuclear substances for diagnosis or treatment of diseases

- **Radiation therapy**

- Use of sealed nuclear substances and prescribed equipment to deliver very high doses of radiation to tumour sites

- **Research**

- Use of unsealed and sealed nuclear substances for medical research



Dual head gamma camera

Radioactive source teletherapy



# Medical radioisotopes are important for many Canadians!

- Approximately 1 million nuclear medicine procedures are performed in Canada annually
- As Canada's population ages, nuclear medicine will continue to play an important role

Radioisotope	Use
<b>Technetium-99 m</b> ( $^{99m}\text{Tc}$ )	- Used in medical imaging and diagnostics - Produced via a generator from Mo-99
<b>Iodine-131</b> ( $^{131}\text{I}$ )	- To diagnose and treat thyroid conditions - Radiolabel antibodies to diagnose and treat cancers
<b>Iodine-125</b> ( $^{125}\text{I}$ )	- Used to treat prostate cancer (brachytherapy seeds)



**CNSC is responsible for safety, not supply**

# Molybdenum-99 ( $^{99}\text{Mo}$ ) supply is fragile

- Parent radionuclide of most widely-used imaging and diagnostic radioisotope, technetium-99m ( $^{99\text{m}}\text{Tc}$ )
- $^{99}\text{Mo}$  supply chain vulnerable to limited number of aging reactors
- $^{99}\text{Mo}$  supply chain also susceptible to other choke points
  - Processing facilities
  - Generator manufacturers
  - Transportation



$^{99\text{m}}\text{Tc}$  Supplies

$^{99}\text{Mo}$  decays into Technetium-99m ( $^{99\text{m}}\text{Tc}$ ), a short-lived medical radioisotope *used in 80% of nuclear medicine imaging and diagnostic procedures*

# Parliamentary Directive

- On December 10, 2007 the Government of Canada issued the following directive to the CNSC:

*“In regulating the production, possession and use of nuclear substances in order to prevent unreasonable risk to the health of persons, the Canadian Nuclear Safety Commission shall take into account the health of Canadians who, for medical purposes, depend on nuclear substances produced by nuclear reactors.”*

- Directive issued pursuant to section 19 of the NSC Act
- Directive is binding on the CNSC



# Regulatory Program Review

- CNSC interpreted the scope to include:
  - Radiation therapy & diagnostic nuclear medicine applications with nuclear substances produced in nuclear reactors and by other means
- CNSC reviewed the Directive with respect to its risk-informed regulatory program
  - Licensing, certification, compliance



# Regulatory Program Review

- CNSC concluded from the program review that:
  - *Health of Canadians* is already taken into account on a case-by-case basis with respect to licensing, certification and compliance activities
  - Integral part of the risk-informed regulatory program
  - Does not require establishment of additional specific programs or measures at the CNSC



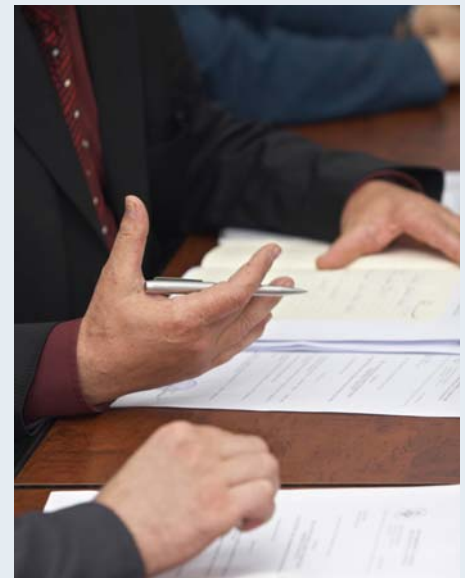
# Specific staff instructions

- **Licensing and Certification**

- Prioritize work to ensure licensing changes handled with due diligence
- Prioritize licence/certification applications for nuclear substances and radiation devices by considering urgency level of patient care
- Communicate and explain CNSC requirements and expectations in advance
- Provide licensing guidance to licensees and applicants

- **Compliance Verification**

- ALARA principle enforced to reduce dose to public
- Inspection plans discussed in advance to ensure no interference with patient treatment hours and medicine dept remains open during inspection
- Pre-compliance inspection meetings with licensees to ensure CNSC requirements are met without causing negative impact on health of Canadians



# Compliance enforcement

- Compliance enforcement actions can be escalated to the highest level if there is an immediate threat to health, safety, security or the environment
- Order may be issued by Inspector or Designated Officer, requiring the licensee to correct the problem, without shutting down patient treatment activities



# NRU Shutdown – what happened?

## 52 year old reactor

Major worldwide source of isotopes

## Shutdown May 14, 2009

- Heavy water leak detected from reactor vessel following day
- Ten sites required repair
- Repairs complicated by space constraints and radiation fields
- Extensive preparation and practice
- Most work done remotely
- Quality control evaluation of repairs



# NRU Shutdown – what happened?

- **Complications**
  - Repairs more difficult than initially considered
  - Other supply reactors shut down for maintenance
  - Prolonged nature of the shutdown
- **Opportunity**
  - Conduct other reactor maintenance activities during same period



# CNSC response: effective collaboration and regulatory control

- **Worked closely with AECL to monitor progress on NRU repairs and return to service**
  - Intensive on-site verification and monitoring
  - CNSC confirmed effectiveness of repairs
- **CNSC/AECL protocols**
  - Protocol for the Restart of the NRU Reactor
  - Protocol for NRU Licensing Activities
    - October 2011 - Licence renewed for 5 years
    - New approach to future operations



*Returned to service in August 2010 with no risk to the public, workers or the environment*

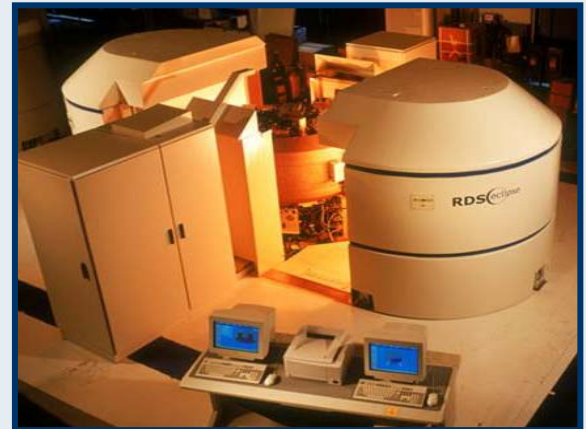
# CNSC response: working to ensure effective control

- **Monitored reports on availability of isotopes**
  - Ready to respond to requests for licensing action
- **Highest priority given to patient care licensing requests**
  - Many hospitals added Thallium-201 and other isotopes
  - Amendments to allow other isotopes, higher quantities processed within 24 hours (usually the same day)
  - Import of depleted uranium shields
- **Regulation of the radioisotope, not the source**
  - Health Canada responsible for approving the medical device



# Ongoing Collaboration - continuing our efforts

- Non-reactor based Isotope Supply Contribution Program
  - Four projects - \$35M funding
- Evaluation of project proposals
  - Licensing implications
  - Unique hazards
  - Time constraints



# Summary

- CNSC responded as an effective regulator to a high-profile issue
  - Received praise from medical community
  - No compromise of regulatory control
- Timely collaboration is essential to managing critical issues
- Constant communication with all stakeholders is key



# For more information on the CNSC

Visit our Web site  
[nuclearsafety.gc.ca](http://nuclearsafety.gc.ca)



Annual Report 2010-2011



# Thank You

[nuclearsafety.gc.ca](http://nuclearsafety.gc.ca)



Canada 

Canada 