My 15 Year Perspective on the Mo-99 Shortage What Did We Learn ?

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The opinions I express today are my own, and do not necessarily reflect the policies of my former employer or companies for whom I have consulted.

An Investigation of Hepatic Pliability as Imaged with a Gamma Camera and Digital Computer – 1972

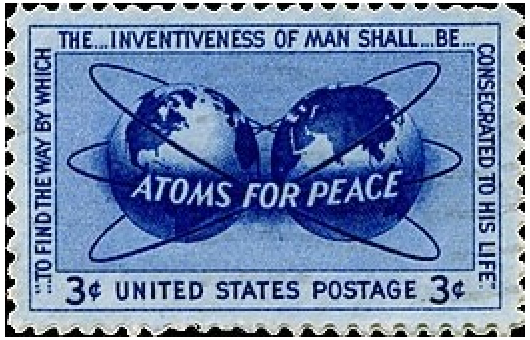
Tc-99m sulfur colloid

PDP 8I Computer

8 K RAM

Tc99m is the major medical isotope in the world

- Represents ~80% of all nuclear medicine exams
- Discovered and developed in U.S. national labs
- Used in over 30 million patient doses annually worldwide, including 14-15 million in the U.S. (50,000 daily)
- Ideal radionuclide
  - Optimal imaging energy (140 keV γ)
  - Practical half-life of 6 hours
  - Good chemical state
  - Easy to manufacture
  - Available!
  - Tc-99m will remain an essential medical isotope

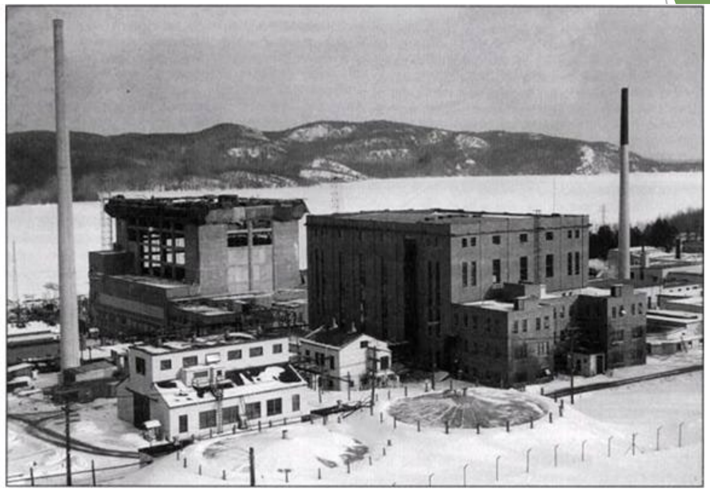


“Atoms for Peace” Speech by US President Eisenhower on December 8, 1953, at the United Nations

- Previously exclusive military use of nuclear technology allowed for schools, hospitals, and research institutions.
- Made nuclear technology, specifically reactors, available to the civilian world.
- Could we have foreseen the potential use uranium fuel by terrorists?

The Canadian Reactors

(Once largest producer of Mo99)



The National Research Universal (NRU) reactor had produced as much as 67% of global Mo99. It became operational in Chalk River in 1956, and was to cease operation in 2005.

The NRU was to be replaced by two Maple reactors, which were cancelled in 2008 due to safety design flaws. Canada eventually decided to exit the global Mo-99 market, but extended the NRU service beyond its original planned 2005 shutdown, finally closing in 2018.

The shutdowns of the NRU in 2007 and 2009 precipitated both a Canadian political crisis and the global Mo99 shortages.

Early Lessons Learned!

- **New technologies, such as nuclear technology, will have unanticipated risks. Difficult to predict.**

- **Don't put all your eggs in one basket!**

  The world depended too much on Chalk River, and did expect the Maple Reactors would not go online.

Security and Supply

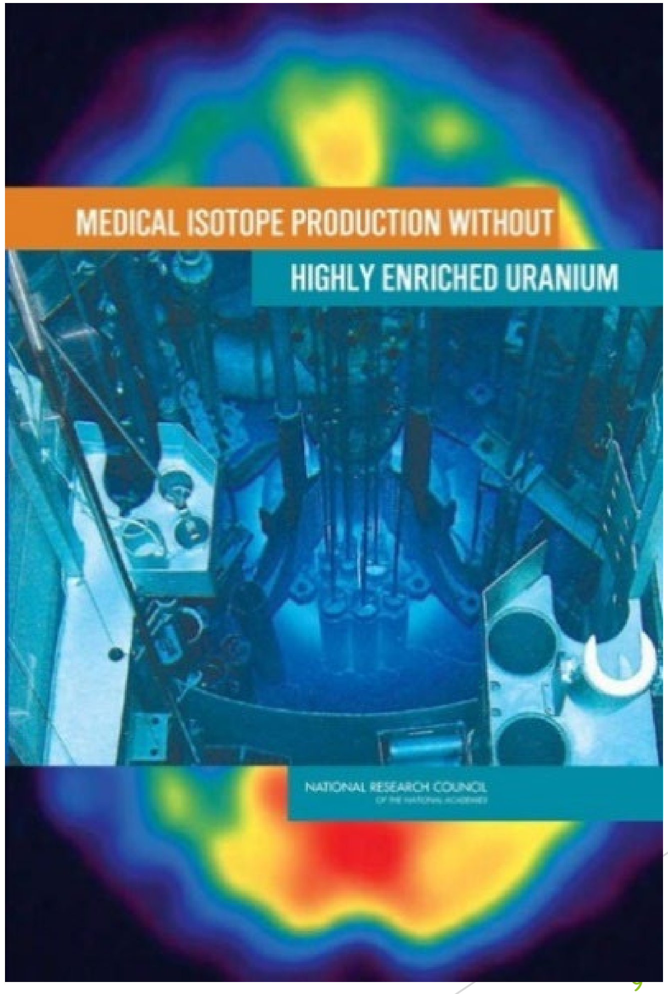
- The Energy Policy Act of 1992.
- The Energy Policy Act of 2005
- The Department of Energy's National Nuclear Security Agency

MEDICAL ISOTOPE PRODUCTION WITHOUT HIGHLY ENRICHED URANIUM

April 11, 2007, I appeared before this committee.

Was HEU to LEU conversion feasible?

National Academy of Sciences 2009 Report



Clear and simple objectives

1. Reduce access to weapons grade uranium (without HEU).
2. Don't impede medicine

These two parallel and independent efforts would soon unite the global community.

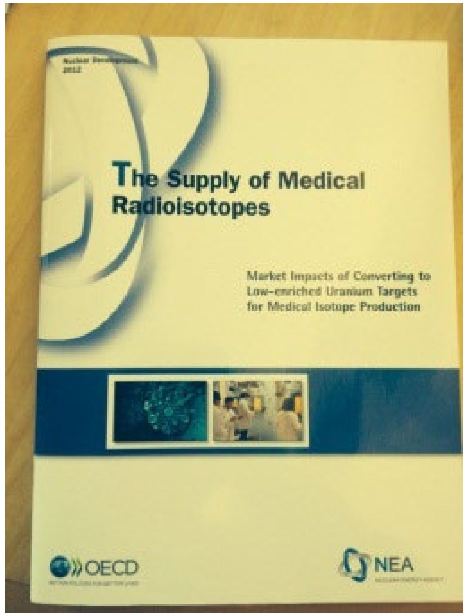
- While the NNSA was working to eliminate HEU, without creating a drug shortage.

- The future of Canada as a Global Supplier Mo-99 was in serious jeopardy due to imminent and unanticipated technical, economic, and political factors.

High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

- In 2009 the Nuclear Energy Agency of the Organization of Economic Cooperation and Development (OECD-NEA) established the HLG-MR.

- Its purpose was to come up with a plan to ensure a (1) secure and (2) adequate supply of Mo-99 by working with 35 member governments.



Knowledge of Reactor Production and Downtime Schedules was Critical Step in Minimizing Risk of Multiple Outages (NAS 2016)

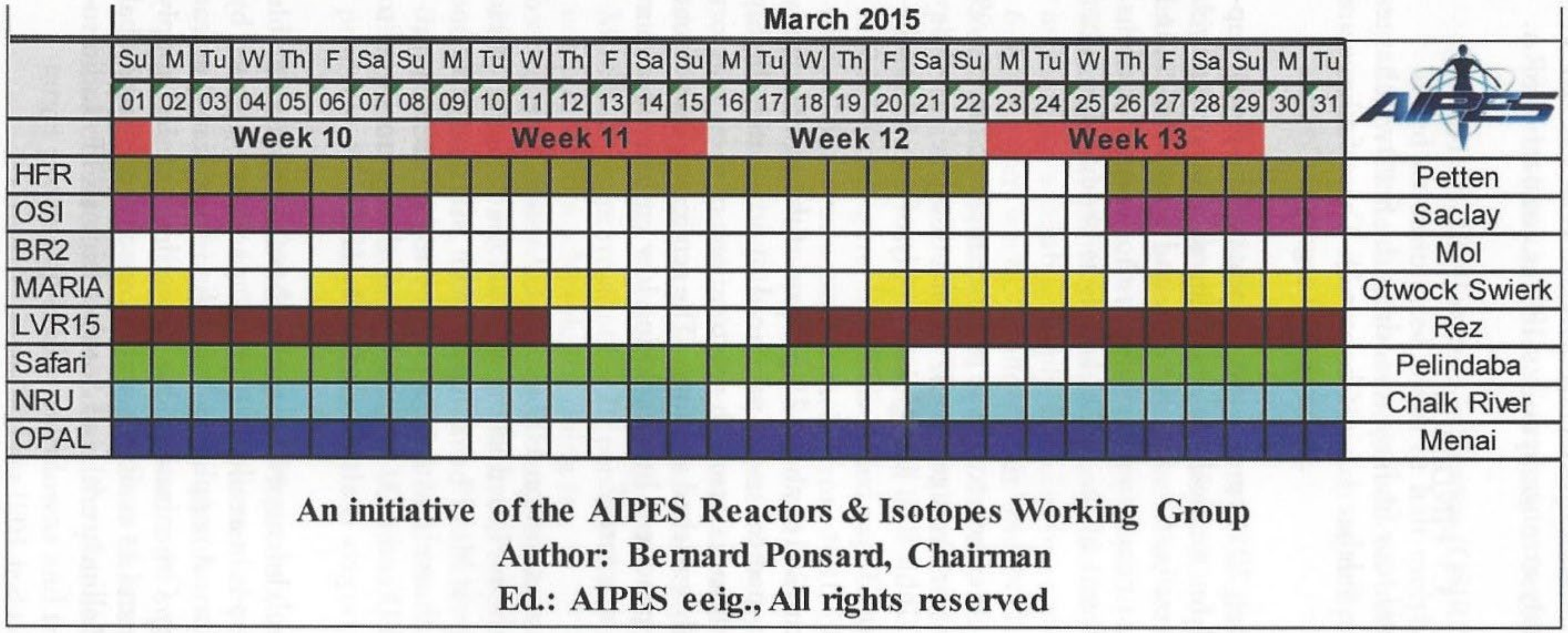


FIGURE 3.4 AIPES Reactor Schedule, first trimester, 2015. NOTES: BR-2 = Belgian Reactor 2; HFR = High Flux Reactor; NRU = National Research Universal; OPAL = Open Pool Australian Lightwater reactor; SAFARI-1 = South African Fundamental Atomic Research Installation 1. SOURCE: Bernard Ponsard, SCK•CEN, written communication, February 11, 2016.

Leadership and Partnerships were important to Forge a Solution

Canadian and United States Government

Organization of Economic Cooperation and Development's (OECD) Nuclear Energy Agency (NEA)

White House Office of Science and Technology Policy (OSTP)

Department of Energy's NNSA and the National Labs

Nuclear Regulatory Commission (NRC)

Department of Transportation (DoT)

Department of Health and Human Services' (DHHS)

Food and Drug Administration and the

Centers for Medicare and Medicaid Services (CMS)

Department of State

Office of the U.S. Trade representative

International Atomic Energy Agency (IAEA)
National Academies of Science, Engineering, and Medicine
Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Council on Radionuclides and Radiopharmaceuticals (CORAR)
Association of Imaging Producers and Equipment Suppliers (AIPES)
Northstar
SHINE
Lantheus
Mallincrodt
Cardinal Health
Nordion
Chalk River
MURR
Petten
OPAL
And others……….

What did we learn? (1)

Future risks must be periodically reviewed!

- Strategic goals, long term by definition, need constant attention!

  We cannot predict the future, except for Tc-99m, but we have to be constantly **vigilant** of risks associated with new technologies.

- **We have to adapt** as the scenarios change. e.g. nuclear power and nuclear threat, petroleum based engines and pollution (climate change).

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What did we learn? (2)

We must work together.

- We need to work together, with some degree of control to prevent chaos.
  - Leadership, or lack of leadership makes a big difference.
  - Objectivity difficult to maintain
  - International Organizations “least” political.
  - There is bias by Industry, professional organizations, and governments

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What did we learn? (3)

Keep goals simple.

Security - Reduce nuclear threat, eliminate HEU

and

Stable Supply – ensure stable supply of medical isotopes

Do not make it overly complex

HLG 6 mandates included FCR which involved economic variables, different governments, and private companies.

Difficult to separate research, healthcare, and different types of government support such as tax law benefits, financing, direct subsidies, grants, and credits.

What did we learn? (4)

Difficult to create alternate technologies

- North American Solutions slow….

  Canadian Efforts at accelerator produced Tc-99m

  US government efforts used grants – Northstar only online today.

  Conventional businesses, without government support, have also been stakeholders.

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What did we learn? (5)

Minimize distractions from main goals!

All important Issues were not necessarily part of the main objectives. Diluted the effort at times.

Reimbursement was an exclusive United States issue.

Some of the problems were simply poor business practices. Contracts needed to be based on both fixed and flexible costs, e.g. electricity costs.

Contracts between suppliers of generators and customers were really not a priority for the HLG.

Progress Report as of September, 2022?

- We have essentially eliminated the use of HEU in the civilian sector.

- There is a “ somewhat stable” source of Tc-99m for the world.

The supply stability for Mo-99m is probably as good as the supply stability of other “essential” supplies like food (wheat); energy (gas, oil, and electricity); medicines, and computer chips.

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Thank you!