ACCELERATING PRODUCTION:
THE GLOBAL SHORTAGE OF MEDICAL ISOTOPES

by

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Abstract

Closures for unexpected repairs and routine maintenance of the five leading medical isotope producing nuclear reactors leads to worldwide isotope shortages. These shutdowns will re-occur with increasing corrosion of the aging facilities. Medical isotope shortages compromise the health of people across the world.

This study examines why global shortages of medical isotopes come about, their impact on patient care in Canada and what role Canada can play to reduce future shortages. A literature review, case study and expert interviews were used to generate data and develop policy options. The findings indicate Canada should aim for slight redundancy in domestic medical isotope production without employing highly enriched uranium and efficiently use available medical resources. Recommendations are to build a network of cyclotrons across the country, fund R&D into photo-fission technology, increase the Health Technology Assessment Task Group’s role and revise CNSC’s mandate to include consideration of isotope use.

Keywords: Medical isotopes; shortages; Mo-99; Tc-99m; Chalk River; MAPLEs; cyclotrons; health policy; technology policy, nuclear medicine; PET; low enriched uranium; HEU
Executive Summary

Medical isotopes are used in the treatment and diagnosis of diseases such as cancer and heart ailments. Approximately 90 percent of the world’s supply of medical isotopes derives from 5 reactors, located in Canada, Belgium, the Netherlands, South Africa and France. The NRU reactor at Chalk River, Canada, currently has the capacity to supply anywhere from 30 to 70 percent of the world’s supply. All of these reactors are aging and the consequent corrosion results in a continual need for repairs, with scheduled and unanticipated closures resulting in global shortages of medical isotopes.

The shutdowns at the Chalk River reactor have resulted in isotope shortages, most notably in recent years. Although the shortages did not cause health disasters, they constitute a serious recurring problem and could, if not addressed, have serious consequences for Canadian’s health in the future. Without medical isotopes, hospitals are unable to deliver the same level of patient care, resulting in their performing diagnostic tests that require more radiation and are less reliable for an accurate early diagnosis.

Shortages in medical isotopes compromise the health of people in Canada as well as globally and, as such, constitute a serious problem for public health policy makers. This study offers policy options for the medical isotope shortages. Consequently, the research questions in this study comprehensively examine why shortages come about, what impact they have on patient health care and what can be done to reduce shortages in the future. By establishing the reasons for the shortages, the researcher can create policy options which provide guidance on how similar shortages can be avoided in the future.
A multi-methods approach was employed in this study combining elite interviews and case study analysis. In addition, a critical assessment of recently published medical isotope studies is contained in a literature review. The case study examines the policy contexts in 6 countries – Australia, Argentina, Belgium, South Africa, the U.S. and Canada – to determine what factors contribute to barriers for conversion to low enriched uranium medical isotope production.

Elite interviews were conducted with experts in nuclear medicine; academia; industry and federal government. These interviews were necessary to explore expert opinion on the problems posed by shortages, their impact on healthcare as well as possible solutions for the future. Interviews covered issues concerning how patients were affected by the shortages, alternate isotopes to Tc-99m, alternative technologies for future production and what role Canada can play to reduce/prevent future shortages. Where possible, face-to-face interviews took place and provided rich data for analysis. Telephone interviews were conducted when face-to-face interviews were not possible. In total, 2 face-to-face and 6 telephone interviews provided the data which was analysed using a thematic analysis framework. Qualitative thematic analysis was used to capture dominant trends and themes in the interview data.

A surprising finding deals with the effect the shortages have had on patient care in Canada. The findings indicated how detrimental to patient care the medical isotope shortages have been and their respective level of severity across Canada. One might expect that the shortages would cause problems and that those would get more pronounced with each closure, especially when non-production is of a longer duration. However, the shortages in 2007, although lasting only 4 weeks in November affected patients more negatively than the current shortage which has lasted from May 2009 to the present. In 2007, without any guidelines in place to deal with an unexpected shortage, hospitals all over North America cancelled tens of thousands of heart studies and medical procedures. The impact on Western provinces, such as British
Columbia and Alberta, from the current shortages has been reduced as they were receiving isotopes from the High Flux Reactor in the Netherlands. In addition, re-scheduling patients (a costly measure) and using substitute isotopes has enabled doctors and technologists in nuclear medicine to cope with the problem. However, Quebec, Ontario and the Atlantic provinces have experienced serious shortages because they had contracts with the NRU reactor, although they are also coping by performing diagnoses with substitute medical isotopes for tests. However, these alternatives are not as accurate and likely resulting in an increase in morbidity rates. Medical tests which use PET scan compatible isotopes, provide detail at the cellular level. This information cannot be obtained from other non-isotope tests which use equipment like CT, X-rays and ultrasounds. Having the ability to perform tests using the most suitable medical isotopes results in an earlier diagnosis. Early detection of an illness for a patient can result in earlier treatments, a better quality of life and even potentially save a person’s life.

The findings from elite interviews with experts from nuclear medicine, academia, industry and government identified common reoccurring themes. Key issues to be addressed with respect to the production, distribution and use of medical isotopes are: (1) PET technology, although better for imaging, is only utilized on a small scale; (2) there is a need for redundancy in the production system; (3) international cooperation between medical isotope producers and distributors would mitigate shortages; (4) an independent nuclear safety regulator should have a clear mandate from government; and (5) for reasons of global non-proliferation, the use of highly enriched uranium should be eliminated from all future medical isotope production methods.

Thus far, Canada has managed to cope with the medical isotope shortages, albeit with likely increased negative outcomes for patient care, in part by receiving isotopes from other reactors. However, on February 19, 2010, the High Flux Reactor in Petten, Netherlands, the second largest medical isotope reactor, was shutdown for routine maintenance expected to last for 6 months. Due to delays, the NRU reactor at Chalk River will not be operational until at least late
July 2010. This will result in serious shortages from late February to July that will be rightfully characterized as a crisis given that the two largest producers of medical isotopes, together accounting for two-thirds of production, will be simultaneously unavailable.

Currently, the federal government has announced Canada is withdrawing from the isotope business, while simultaneously reviewing proposals for future production. As such, Canada’s role in the medical isotope industry is uncertain and ways to combat future shortages have not been addressed. The status quo position is to extend the NRU reactor’s license until 2016 and make any required repairs until that time. After which, either Canada will have to rely on other countries, such as the U.S., for its medical isotopes or the federal government will need to take action and build a replacement(s) to the NRU to secure domestic supply. This study assumes that the status quo position is that Canada will end the production of isotopes by reactor altogether (since at time of publication, no further action had been taken by the government). The U.S. is starting its own production and is upgrading its MURR reactor which means that Canada’s largest market for isotopes is no longer assured. Canada cannot justify investing in very large production sources if only supplying a small domestic market, unless production has a dual purpose, such as for conducting basic research. Furthermore, the U.S. is also in the process of legislating banning exports of highly enriched uranium. This further limits which policy options are available to Canada since currently Canada receives its HEU from the States.

The alternative policies considered in this study are to (1) withdraw entirely from the isotope production business; (2) establish a panel of experts to examine whether one MAPLE reactor can be re-designed to operate safely and as predicted using low enriched uranium in targets and for fuel; (3) build the Canadian Neutron Source reactor in Saskatchewan using LEU; (4) fund R&D and then build a linear accelerator; and (5) build a national network of cyclotrons spread throughout Canada.
The status quo and alternative policy options were evaluated against the criteria of (1) health outcomes, (2) equity/inclusiveness, (3) reliability, (4) effectiveness/built-in redundancy, (5) government costs, (6) domestic safety, (7) global security, (8) technological feasibility, (9) political feasibility/commitment, (10) stakeholder acceptability, and (11) administrative ease. Governmental cost, reliability and global security are of primary concern as a policy option which cannot successfully meet these criteria is not likely to be implemented. These 3 criteria were given double weighting to reflect their importance.

The recommendations presented in this study are to (1) encourage a national network of cyclotrons; (2) fund R&D into linear accelerator photo-fission technology; (3) assist the provinces and territories with an expanded role for the inter-provincial Health Technology Assessment Task Group; and (4) modify the Canadian Nuclear Safety Commission’s mandate to consider the effects of the production, maintenance and shutdowns of medical isotope production facilities on Canadian patients.
To all the doctors who devote their lives to saving those of others.
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Glossary

Accelerator A device that uses electric fields to propel ions or charged subatomic particles to high speeds containing them in well-defined beams. Two basic types: linear accelerators (linac for short) and cyclotrons.

Cardiac Study The testing of a patient’s heart to evaluate the coronary arteries, in which the patient exercises to increase blood flow to the heart. A scan is taken and compared with heart images taken while the patient was at rest.

Curie The unit of measurement for describing the radioactivity of a quantity of radioactive material. One curie equals the amount of an isotope needed to produce 37 billion disintegrations per second. 1 Ci = 3.7 x 10^{10} radioactive decay per second.

Cyclotron A circular particle accelerator that accelerates charged atomic or subatomic particles in a constant magnetic field. As the speed of the particles increases, so does the radius of their path and the accelerated particles spiral outward.

Fission The process in which a large atomic nucleus splits into two smaller nuclei, resulting in new isotopes.

Gamma Camera Nuclear medicine imaging device optimized to image single photon emission tracers. This camera can perform images acquisition in 2D (planar imaging) or 3D (SPECT).

Gamma Rays Electromagnetic radiation emitted during radioactive decay and having an extremely short wavelength.

Half-life The time required for half of the atoms in a given amount of a radioactive substance to decay.

Heavy water Water which includes the deuterium isotope of hydrogen, 2H2O or D2O. Heavy water itself is not radioactive, but it is slightly toxic to humans. Its increased weight affects the speed of certain important chemical reactions, including cell division.

High Enriched Uranium Uranium-235 (U-235) with a concentration greater than 19.75% by weight. It makes up about 0.7 percent of the uranium found naturally on Earth.

Hot cell A shielded workspace for working with highly radioactive materials.
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<th>Term</th>
<th>Definition</th>
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<tr>
<td>Isotope</td>
<td>Any of two or more forms of the same chemical element, having the same number of protons (or the same atomic number), but each having a different number of neutrons (or different atomic weights). Isotopes can be stable (non-radioactive) or unstable (radioactive).</td>
</tr>
<tr>
<td>Low Enriched Uranium</td>
<td>Uranium-238 (U-238) enriched with a concentration less than 19.75%. It makes up 99 percent of the uranium on Earth and has a half-life of 4.5 billion years.</td>
</tr>
<tr>
<td>Medical Isotope</td>
<td>Tiny radioactive particles that can be safely injected into the body to be used in the medical imaging, diagnosis and treatment of diseases.</td>
</tr>
<tr>
<td>Molybdenum-99</td>
<td>Molybdenum-99 (Mo-99) is a commercially produced radioactive isotope. It is the parent isotope of Tc-99m.</td>
</tr>
<tr>
<td>Neutron</td>
<td>A subatomic particle with no net electric charge and a mass slightly larger than that of a proton.</td>
</tr>
<tr>
<td>Nuclear Fission</td>
<td>Nuclear fission is the splitting of a large atom’s nucleus, creating two products of roughly half the mass of the original. During the process, some neutrons and a substantial amount of energy are released. In a controlled fission reaction, this energy can be harnessed and coaxed into establishing a chain reaction which encourages the rest of the fissionable element to break apart. An uncontrolled chain reaction creates a nuclear bomb.</td>
</tr>
<tr>
<td>Nuclear Reactor</td>
<td>A device in which the process of fission is used to initiate nuclear chain reactions, which are then controlled and sustained at a steady rate. Nuclear reactors can be used commercially to generate electricity or for basic research as research reactors.</td>
</tr>
<tr>
<td>Nucleus</td>
<td>The centre of an atom composed of neutrons and protons.</td>
</tr>
<tr>
<td>PET Scan</td>
<td>A positron emission tomography (PET) scan is an imaging test used in nuclear medicine allowing doctors to see how certain tissues and organs within the body are functioning. Tissue function is imaged – damaged tissues have reduced metabolic activity indicated by reduced or absent gamma radiation from these areas.</td>
</tr>
<tr>
<td>Photon</td>
<td>A particle that travels at the speed of light.</td>
</tr>
<tr>
<td>Power Coefficient of Reactivity (PCR)</td>
<td>A power coefficient of reactivity is a measure of how the overall amount of neutrons in a reactor will respond as the power goes up. If the overall neutron population increases as the power goes up, then there is a positive power coefficient of reactivity. If the overall neutron population tends to go down as the power goes up, then the power coefficient of reactivity is negative.</td>
</tr>
<tr>
<td>Radioisotope</td>
<td>A naturally or artificially produced radioactive isotope of an element.</td>
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<tr>
<td>Term</td>
<td>Description</td>
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<tr>
<td>Specific Activity</td>
<td>The activity of a particular radioactive element per unit mass of the material. It is calculated by the number of decays per unit of time divided by the mass of material in which it exists. Units are usually expressed as curies per gram (Ci/g).</td>
</tr>
<tr>
<td>SPECT Scan</td>
<td>A single-photon emission computerized tomography (SPECT) scan integrates CTs and tracers. A patient is injected with a tracer and two-dimensional cross-section images are taken and then added together to form 3D images. The images show how blood flows to tissues and organs and through arteries and veins in the brain - show the function of internal organs.</td>
</tr>
<tr>
<td>Target</td>
<td>A radioactive substance designed to be irradiated in nuclear reactors, cyclotrons or accelerators to produce medical isotopes.</td>
</tr>
<tr>
<td>Technetium-99m</td>
<td>Technetium-99m (Tc-99m) is a meta-stable radioactive isotope with a 6 hour half-life, used in 80% of nuclear medicine procedures. It is the daughter of Molybdenum.</td>
</tr>
<tr>
<td>Tomography</td>
<td>The technique of using rotating X-rays to capture an image at a particular depth in the body, bringing those structures into sharp focus while blurring structures at other depths.</td>
</tr>
<tr>
<td>Tracer</td>
<td>A substance, usually radioactive, injected into patients (that emits gamma rays detected by scanners) which can be followed to gain information about metabolic processes.</td>
</tr>
<tr>
<td>Uranium</td>
<td>Uranium is a common element on Earth. It can be used as targets and fuel in various technologies, such as reactors and accelerators, for producing isotopes.</td>
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Acronyms

AECL  Atomic Energy of Canada Ltd.
ANSTO Australian Nuclear Science and Technology Organization
CNSC Canadian Nuclear Safety Commission
CT  Computed tomography
HEU High enriched uranium
IEA International Energy Agency
LEU Low enriched uranium
MAPLE Multipurpose Applied Physics Lattice Experimental
MURR Missouri University Research Reactor
MRI Magnetic Resonance Imaging
NRCan National Resources Canada
NRU National Research Universal
OPAL Open Pool Australian Lightwater
PCR Power coefficient of reactivity
PET Positron emission tomography
SAFARI South African Fundamental Atomic Research Installation
SPECT Single-photon emission computerized tomography
TRIUMF Tri-University Meson Facility
VGH Vancouver General Hospital
1: Introduction and Policy Problem

1.1 Introduction

Reactors use the nuclear fission of highly enriched uranium (U-235) to produce products such as molybdenum-99 (Mo-99) and technetium-99m (Tc-99m). Mo-99 is used as the ‘parent’ to produce Tc-99m – the latter is the most widely used isotope in nuclear medicine (World Nuclear Association, 2009), used in four-fifths of all medical imaging procedures (Ruth, 2009). Since it does not occur in nature, but rather is artificially produced in radionuclide generators, hospitals rely on the production of Mo-99 to generate it. The half-life of Mo-99 is sixty-six hours, making it possible to transport over fairly long distances to hospitals. Tc-99m, on the other hand, has a half-life of six hours – long enough for a medical examination, but short enough to avoid radiation damage to bodily organs.

Medical isotopes – tiny radioactive particles that can be injected into the body – are used in the imaging, diagnosis and treatment of diseases. Tc-99m is used for imaging of the brain, heart, skeleton, thyroid, lungs, liver, kidney, spleen, gall bladder and bone marrow (World Nuclear Association, 2010). Approximately 90 percent of all diagnostic nuclear medicine procedures in Canada require Mo-99 to generate Tc-99m (AECL, 2009). Over 10,000 hospitals worldwide use radioisotopes in medicine (World Nuclear Association, 2009). In Canada, about 1.5 million nuclear medicine procedures are performed per year (Kondro, 2009), compared to 20 million in North America and 40 million globally (TRIUMF, 2008). The fundamental difference between nuclear medicine imaging and other imaging techniques, such as X-rays, ultrasound, CT scans or MRI, lies in the positioning of the radiation source within the body. While imaging tests such as X-rays can show what the structures inside your body look like, nuclear medicine scans
can produce 3D images that show how your internal organs function. Mo-99 radioactively beta decays into Tc-99m which once injected inside a patient, further decays releasing gamma photons that are detected by a gamma camera enabling the imaging of organs from multiple angles (World Nuclear Association, 2009).

Five reactors worldwide produce over 90 percent of the raw material for medical radioisotopes. These reactors are in Canada, Belgium, France, the Netherlands and South Africa. All of these reactors raise security concerns because they all employ highly enriched uranium in their production process in a form relatively easy to convert into the metal required for a nuclear bomb (Hansell, 2008), are more than 40 years old and are in regular need of repair. Mo-99 is currently produced in at least nineteen countries, but more than 95 percent of the world’s supply comes from these five reactors and over a third of the world’s supply of Mo-99 comes from Canada. The National Research Universal (NRU) Reactor in Chalk River Laboratories, Ontario, is the oldest and largest of these reactors producing the majority of the entire global supply of medical isotopes as it frequently increases production to meet 70 percent of the world’s needs. The many problems at Chalk River and its frequent shutdowns have resulted in global shortages of medical isotopes.

1.2 Policy Problem Definition

Shortages in medical isotopes compromise the health of people in Canada and across the world.

1.3 Research Questions

The main research questions to be investigated are: why do global shortages in medical isotopes come about and what can be done to prevent/reduce them? And what role can Canada play in ensuring domestic supply while reducing global isotope shortages and contributing to better health outcomes for people in Canada and throughout the world?
1.4 Purpose of Study

The purpose of this study is to investigate why there are shortages, what impact those shortages have on patient care in Canada, possible alternatives to the isotopes currently used and what role Canada can play to reduce/prevent future shortages. Policy alternatives are developed and analyzed based on the information ascertained in the study.

The intended audience for this study is a policy analyst working in government, although science and technology consultants along with academics will be able to use its critical assessment of the literature, findings and subsequent policy analysis.
2: Background

In order to properly address the policy problem, we need to have a clear understanding of what medical isotopes are, how they are used and produced because knowledge of the scientific and technological aspects of production along with the medical diagnostic technologies is essential to making sound policy decisions in this multi-disciplinary topic.

2.1 Medical Isotopes in Modern Medicine

Medical isotopes are commonly used in modern medicine. Detailed information on forty such isotopes, their respective half-lifes and specific uses in diagnostics and the treatments of various diseases is provided in Appendix A. Although, there are large amounts of radioisotopes utilized, technetium-99 (Tc-99m) is the most widely used due to its functionality in a vast range of medical procedures. See Figure 1\(^1\) below showing a breakdown of the various medical procedures using Tc-99m.

\(^1\) Breakdown of procedure percentages from Library of Parliament PRB 09-04E, “The Medical Isotope Shortage: Cause, Effects and Options.” The original document was presented to the House of Commons Standing Committee on Natural Resources at a meeting held on June 2, 2009.
Medical isotopes are used in medicine in three distinct ways:

(1) Radioactive isotopes can be injected into a patient and their emitted energy can then be captured on film. The resulting image is an important diagnostic tool;
(2) Gamma rays emitted from a radioactive source can be directed onto a tumour, destroying the cancerous cells and (3) Radioactive isotopes can be manufactured into drugs. Once injected into a patient, the drug will accumulate in a certain part of the body, such as a tumour. As the isotopes decay and release energy, that energy destroys the tumour (AECL, 2009).²

In a nuclear medicine imaging test, a patient is injected with a radioactive substance (tracer) that emits gamma rays which can be detected by a special camera to create pictures of the organs. In the case of a single-photon emission computerized tomography (SPECT) scan, the computer collects the information emitted by the gamma rays and translates them into two-dimensional cross-sections. These cross-sections are added back together to form a 3D image. A SPECT scan is primarily used to view how blood flows through arteries and veins in the brain. Tests have shown that it might be more sensitive to brain injury than either MRI or CT scanning because it can detect reduced blood flow to injured sites (Mayfield Clinic, 2010).

² Direct quotes from news articles, press releases and websites are not cited with a page number as there are none. However, page numbers for direct references from numbered documents are provided. All references are provided in the bibliography.
Figure 2 clearly shows how a radioisotope-based technology is preferable. While an MRI (far left photo) shows abnormalities in the brain’s structure, a PET scan (second photo on left) shows abnormalities in the brain’s functioning (Danko, 2009). The last two images in Figure 2 display the striking contrasting images for detection and diagnosis with a patient with a normal brain (photo second from right) and another patient with Alzheimer’s (photo on far right). PET scans provide information about the body’s cell function at a molecular level rather than just pictures of the body’s anatomical structure as shown by an imaging technique like a CT scan or ultrasound. As a result, PET scans can reveal abnormalities or tumours that would otherwise remain undetected. Furthermore, a tumour detected with CT can be confirmed as malignant (cancerous) or benign with PET eliminating the need for diagnostic surgical procedures (UCLA, 2010). It can also show how a patient’s body is responding to treatment and by imaging all the organ systems of the body in a single exam, it eliminates the need for redundant tests while saving money (UCLA, 2010). Early detection and accurate treatment of diseases requires the use of medical isotopes for PET imaging than with any other imaging modality.

Figure 2  MRI and PET Scans

Another advantage of using nuclear imaging over X-rays is that both bone and soft tissue can be imaged very successfully (World Nuclear Association, 2009). For example, when radioactive material is injected into the bloodstream, it travels, eventually settling in the bones. The resultant information on cell activity shows whether cancer has spread to the bones from
another part of the body. Bone scans can detect problems months before X-rays because cellular imaging at the molecular level looks at “cells before the actual structure of the organ changes” (Kirkey, 2009). Dr. Christopher O’Brien, president of the Ontario Association of Nuclear Medicine, states that bone scans can also be used to assess whether a child suspected of abuse has bone fractures. He goes on to say that nuclear medicine has “a very low level of radiation exposure, it’s safe, there’s no side effects – no one dies from a nuclear medicine scan, whereas you can have an allergic contrast (reaction) to an X-ray dye and die on the table” (Kirkey, 2009). Nuclear medicine procedures are safe since the amount of radiation that a patient is exposed to is too low to affect the normal processes of the body (Mayo Clinic, 2009). Isotopes also provide more information than an ultrasound. By providing information on what is happening at the cellular level, medical isotopes are the most effective (as well as the cheapest) way to diagnose cancer and heart ailments (CBC, 2009b).

2.2 The (Burden of) Production of Medical Isotopes

Over two dozen medical isotopes are made in nuclear reactors, fewer in cyclotrons. Generally, neutron-rich isotopes and those resulting from nuclear fission are made in reactors, while neutron-depleted ones are made in cyclotrons. Altogether, there are about 40 activation product isotopes (where neutron bombardment on stable isotopes can form radioisotopes) and five fission product ones made in reactors (World Nuclear Association, 2010). The latest findings from the OECD for 2005 report that there are 54 research reactors producing isotopes in 36 countries and 273 accelerators producing isotopes in 41 countries (OECD, 2005). Yet, the burden of production resides mainly with only five reactors because select reactors have the power range to produce isotopes generally – the larger the reactor’s power, the greater the capacity for isotope production due to the greater availability of neutrons and the larger physical volume for target sites available (OECD, 2005). Also, neutron flux defines the isotope production capabilities of reactors; it determines the types of isotopes that can be produced. Since only five can produce at
the levels necessary for large-scale medical isotope production, they have a monopoly on production. This is a problem because if one of the five goes down this leads to shortages.

Figure 3 below shows the global medical isotope market share, with 95 percent coming from the five largest suppliers as well as various small producers together accounting for the remaining 5 percent. The NRU reactor can increase production, thereby producing up to 70 percent of global supply, but usually supplies nearly half of the world’s medical isotope requirements (AECL, 2009). The combined production of the High Flux Reactor (HFR) in the Netherlands and the NRU reactor in Canada accounts for a minimum of two-thirds of the world’s supply.

![Figure 3 World Market Share of Moly by Reactor]

Only a handful of companies process and distribute the medical isotopes from the reactors. Figure 6 in Appendix B shows the production and distribution links from the reactors to the companies which market and sell them to hospitals worldwide.

The Canadian isotope supply chain is illustrated in Figure 7 in Appendix C starting with production at the NRU reactor at Chalk River. MDS Nordion is the supplier of Canadian isotopes; it sells them to international manufacturers and buyers which in turn supply hospitals and other nuclear medicine facilities. The U.S. is its single biggest market with half of all of the world’s isotopes going into the States (Hansell, 2008) and demand there is rising by 10 percent.
each year (Collier, 2008). The distribution chain of Tc-99m is more complicated than illustrated in either figure. For Canada, the distribution begins with the Chalk River reactor which makes Mo-99, then the bulk Mo-99 is taken to a Tc-99m generator, then to a hospital and finally ends up in the patient (see Figure 4 below).

**Figure 4  Canadian Mo-99 Supply Chain**

Concentrating medical isotope production for 95 percent of supply with five production facilities with a handful of processors and distributors creates a situation in which there is a high degree of vulnerability to shortages, only to be further intensified by reactor shutdowns occurring without warning. For instance, given that two producers account for the majority of production, when one of these reactors shuts down, especially unexpectedly, the result is shortages. Although there have been shutdowns in the past several years, usually for maintenance, the most recent unexpected shutdowns of the NRU reactor at Chalk River, in 2007, 2008 and 2009 for repairs, has led to concerns of reliability of isotope supply and its subsequent effect on patients. Such shortages are examined next in greater detail.

### 2.3 The Isotope Shortages

This section examines the various causes of medical isotope shortages and their impact on patients. The primary reason for the shortages of recent years is reactor shutdowns. These
shutdowns have been the result of various factors, such as the forced closure by the Canadian nuclear regulator and ever more frequent heavy water leakages. The lack of alternative production facilities capable of production levels on a similar scale is due to the expectation that the Canadian MAPLE reactors were going to be built and commissioned. Moreover, there are major impediments to entering this market, particularly high upfront costs that are usually borne by governments.

First, we examine Chalk River Laboratories and the problems which ensued from the 2007 closure, followed by the various physical problems at the NRU itself. The section ends with an examination of the impacts of shortages on hospitals which have had the effect of reducing hospitals’ capacity to deliver appropriate patient care.

2.3.1 Shortages – Aging Facilities, Regulatory Obligations and Contracts

Leakages at the NRU in Chalk River Laboratories and at the HFR in Petten, Netherlands along with scheduled maintenance has resulted in shortages, both anticipated and unexpected.

The NRU reactor had heavy water leakages in 2008 – a problem attributable to the age of the reactor. Leaks are caused by corrosion. Heavy water itself is not radioactive, but is slightly toxic to humans. However, small amounts do not have potential for human and environmental damage. There have been two leakages in 2008 starting with 47 kg of heavy water containing tritium leaking from the NRU reactor. It was contained and the leak stopped before the source could be identified (CNSC Report, 2009). Also, 7,000 litres of light water per day were later leaking from a crack in a weld of the reactor’s reflector system which was also collected. There were further heavy water leakages the following year, in 2009, but none posed a public health concern or environmental threat. The reactor was shutdown once again in May 2009 and was reported would be reopened after a few months as refilling, refuelling and restarting the reactor takes many months (AECL Status Report, 2009). However, the source of the leaks were not
identified until January 2010 and the reactor is now set to reopen in July over a year later, after several delays occurred.

The 2009 isotope shortage was further exacerbated by routine maintenance of another reactor. The second largest isotope producer, the HFR in the Netherlands, accounting for approximately 30 percent of global supply, shutdown for a few days in June 2009 and then again in July for an additional four weeks for required maintenance and refuelling (Covidien, 2009). The scheduled shutdowns had been synchronized with the other four major Mo-99 producing reactors, prior to the unexpected Chalk River closure. However, “[r]egulatory obligations demand maintenance schedules occur as planned – even in situations where global supply would be further challenged” (Covidien, 2009). Regulatory obligations are a public policy issue and could be changed to meet concerns about the public good. For example, if a reactor is scheduled for maintenance during a sudden shortage due to another reactor being offline, the maintenance can possibly be postponed until the repairs are complete. The HFR will also be shutdown for 6 months in 2010 beginning February 19, 2010, for “extensive planned maintenance work by government directive” (Covidien, 2009). This will result in the largest and longest shortage to date. Hospitals will have medical isotope shortages for a minimum of five months, provided that the Chalk River reactor resumes production in July.

Currently, Canada is receiving isotopes from South Africa’s SAFARI reactor and Australia’s OPAL reactor, but foreign suppliers do not have the capacity to keep Canada fully supplied with isotopes (Collier, 2008) and are not without problems of their own. Australia, for instance, is reported to only produce 4 percent of the world’s isotopes (Standing Committee on Natural Resources, 2009) and although its OPAL reactor recently opened in 2007, it was shutdown for 8 weeks due to dislodged plates in the fuel assemblies and heavy water dilution (ANSTO, 2007). Its actual isotope contribution is about 1 percent.
MDS Nordion’s agreement with Atomic Energy Council Ltd. (AECL) – the owner of the NRU – does not stipulate that any of the isotopes must be reserved for Canadian patients. AECL’s CEO, Hugh MacDiarmid, acknowledged that “there never has been” the requirement to supply Canadians with isotopes from the Chalk River reactor (Galloway and McCarthy, 2010). “The intent was that the isotopes would be distributed by Nordion into the commercial marketplace,” he said, “And when you do that there is really very little ability to impose constraints” (Galloway and McCarthy, 2010). He further added that AECL was not to blame, “…our job is to produce the isotopes and supply them to Nordion” (Galloway and McCarthy, 2010). The privatization of Nordion stipulated that AECL would supply isotopes to Nordion for processing, but allowed Nordion to market them on a fully commercial basis to companies for distribution to customers.3 Given where Nordion and AECL fit in the supply chain, they cannot dictate where the product is ultimately shipped. Canadian taxpayers funded an estimated $70 million to repair the aging NRU reactor (Galloway and McCarthy, 2010), but there are rising costs for the isotopes in times of shortages. A nuclear medicine doctor commented that, it “is unfortunate because Canada, as it stands now, has no plan, no organized structure, to safeguard Canadian patients from these cost increases” (Galloway and McCarthy, 2010).

2.3.2 Impact of Shortages on Hospitals and their Capacity to Deliver Healthcare

Whenever a reactor is shutdown, there is a potential for isotope shortages. Hospitals are unprepared for emergency shutdowns as there is no pre-warning. If the NRU reactor goes down for more than seven days, the other reactors cannot fully supply hospitals since together they supply only 65 percent of the world’s current isotope requirements (Hansell, 2008). Obtaining back-up supplies from other producers also requires planning ahead to buy irradiation time at

3 Until the recent NRU closure, MDS Nordion was sending isotopes to Lantheus Medical Imaging in the U.S. It is reported that Nordion is demanding a high price for the isotopes and that Lantheus has been unwilling to sign a new contract for their distribution. The month-long production halt in 2007 cut MDS’ profits by $9 million (Steenhuysen, 2009).
other reactors and preparing staff at alternate production facilities (Hansell, 2008). This will become even more problematic as demand increases.

The result is that some patients are denied access to essential tests, while others are exposed to higher doses of radiation as doctors switch to alternate medical procedures (Kirkey, 2009). It is reported that about half of all the nuclear medicine procedures performed in Quebec are done on an emergency basis (Kirkey, 2009) which displays the need for continual supply of isotopes as they cannot be stockpiled and their time of use cannot always be predicted. All this would seem to indicate that the current situation is a far worse problem for health than the 2007 month long shutdown of the NRU which the Canadian government called a “national and international medical crisis” (Lunn, 2008).

Although the NRU shutdown for only a few weeks, the 2007 closure threatened a health crisis on a global scale. For example, because the NRU reactor supplies about half of the clinics and hospitals in the U.S., isotope stocks in North American hospitals decreased by about 80 percent resulting in the cancellation of 50,000 medical procedures (Ruth, 2009). Recall that Mo-99 has a half-life of 6 days. This means that if hospitals are supplied by Chalk River on Monday, by the end of six days they will have half of that total supply remaining. The isotopes need to be re-stocked within the 6 days to maintain regular, consistent supplies for use. If a reactor is down for more than a week, then medical isotope stocks are depleted.

The next two sub-sections examine the impact on mortality, morbidity, quality of life and the pressure on governments from the shortages.

2.3.3 Impact of Isotope Shortages on Health Experience

The Journal of Nuclear Medicine (2008) reports that for each month of disrupted supply, 50,000 to 90,000 patients in Canada and as many as 200,000 patients in the U.S. will be affected.
In addition, about 8 million U.S. studies are imperiled for the Society of Nuclear Medicine alone (Steenhuysen, 2009).

A patient unable to undergo a routine medical diagnostic procedure may be given an alternate medical procedure. If a CT is done in lieu of a PET scan due to unavailability of medical isotopes, the patient could be misdiagnosed, not diagnosed at all or have to undergo an otherwise unnecessary procedure.

With respect to a patient with a shadow on his X-ray indicating lung cancer, without a PET scan the patient would need to have a needle biopsy or a portion of his lung removed just to determine if his cancer was benign or malignant (UCLA, 2010: 4). For a patient with a history of rectal cancer and an increase in serum CEA levels indicates she might have colon cancer. If medical isotopes are unavailable, CT scans would be taken until the tumours are large enough to be detected. Without waiting for the disease to get worse, a PET scan would show the extent of the disease, indicating to doctors which surgical, radiation or medical treatment should be used (UCLA, 2010: 5). A patient with breast cancer who had a lumpectomy and is experiencing symptoms would have a CT scan of her chest, a mammogram and a bone scan to look for possible recurrent disease. Unfortunately, many of the imaging tests may not show recurrent disease at that stage; whereas one PET scan of the entire body would show where the recurrent disease was presently located and could be immediately treated (UCLA, 2010: 6). A last case to consider is a child who had a brain tumour surgically removed. An MRI scan taken later showed that there was a change in the brain’s structure near the surgical site; however, an MRI does not show if it is due to scar tissue or tumour re-growth. A PET scan, able to detect the cause, determined that it was merely scar tissue. This “saved [the] child from unnecessary surgery, and his family was spared the emotional trauma of further diagnostic evaluation” (UCLA, 2010: 13).

A patient’s quality of life can be negatively effected if medical isotopes are not used in diagnosis. The patient will experience greater anxiety while either waiting for isotopes to become
available, or at her doctor’s suggestion will undergo an otherwise unnecessary procedure resulting in greater exposure to radiation. One of the worst effects to a patient’s health is a disease which could have been diagnosed earlier and treated, but by waiting for a tumour to become large enough to spot on a CT scan, it becomes much more difficult to treat. This could result in an earlier death than if treatment had been provided immediately upon symptoms.

There is a greater cost for the health service of delaying assessments and treatment. If a patient’s condition worsens by not treating a disease, it can worsen into a more severe and even chronic condition requiring more treatment, more costs to the patient, a longer recovery period, more pain, discomfort and stress for the patient. There are costs to health services and consequential costs such as paying for technologists to test patients more worse off more frequently. Medical costs include paying more for doctors and technicians to work overtime, and higher treatment costs as the patient’s condition worsens resulting in poorer health. Patient costs include pain, death and longer recovery times. In addition,

[dealing on a daily basis with the distress of suffering patients who must endure long waits for critical imaging procedures created emotional stress and tension at every level of the health care system. Unless one has had this experience, it is difficult to appreciate the extremely deleterious effect of this type of uncertainty on individual patients, their families and their health care providers (Ad Hoc Health Experts Group, 2008: 4).

2.3.4 CNSC, AECL and Governance

The National Research Universal (NRU) reactor at Chalk River is owned and operated by Atomic Energy of Canada Ltd. (AECL) which was established by the government over fifty years ago. AECL is responsible for designing productive applications of nuclear energy. Chalk River operates under the supervision of the Canadian Nuclear Safety Commission (CNSC) which is the quasi-judicial regulation, safety and licensing agency. CNSC’s mandate is to protect the health, safety and security of Canadians as well as the environment and to respect Canada’s international
commitments on the peaceful use of nuclear energy (CNSC website, 2009). The CNSC reports to Parliament through the Minister of Natural Resources.

**Lack of Cooperation Between CNSC and NRCan**

The relationships of the CNSC, AECL and Minister of Natural Resources are currently strained. The NRU reactor has faced many problems in recent years. The reactor was shutdown by the Canadian Nuclear Safety Commission in November 2007 due to safety concerns and non-compliance with their 2006 operating license requirements – two of the reactor’s cooling pumps were not connected to seismically-qualified emergency power supplies (Hansell, 2008). Its prolonged closure caused an international isotope shortage and ended with the government forcing the plant to reopen the following month. Under political scrutiny, Parliament using a rare, emergency legislative process (Committee of the Whole) authorized AECL to restart the NRU reactor with Bill C-38, bypassing the Canadian Nuclear Safety Commission’s regulatory authority and against its advice. The Chairman of AECL resigned. The country’s nuclear regulator (the head of the CNSC), Linda Keen, was fired soon afterwards creating widespread concern about political interference in a regulatory body.

Gary Lunn (2008), the Minister of Natural Resources during the 2007 isotope shortages, stated before the House Standing Committee on Natural Resources that “the extended shutdown of the [NRU] reactor threatened a national and international health crisis…[w]ithout these isotopes, many patients were faced with delays in essential treatment.” Experts consulted confirmed that a continued shortage of isotopes “would have meant life or death for some patients.” Lunn testified that the Minister of Health’s department consulted with nuclear medicine specialists (close to 800 health care facilities, including nearly 250 nuclear medicine facilities) across Canada to assess how to manage the growing shortage of isotopes as well as the extent and impact of the shortage. A nuclear medicine specialist advising Lunn said that the
situation reminded him of his time in Uganda, having to decide who would receive medical care and who would not based on that day’s shortages.

**Need for Medical Advice for CNSC**

Until 2001, the CNSC maintained external advisory councils, including a medical advisory council, which facilitated communication between the medical community and the commission. Council members provided CNSC staff with insight into how their operational and policy decisions would affect patient care throughout the country. The councils were disbanded in 2001, “effectively isolating CNSC from physician input and marginalizing an important source of knowledge concerning radiation safety and patient care” (Ad Hoc Health Experts Group: 2004: 6-7). In 2007, “the lack of input from qualified nuclear medicine specialists and inadequate consideration of the health needs of Canadians in the assessment and decision making processes exacerbated the situation caused by the extended shutdown of the Chalk River reactor” (Ad Hoc Health Experts Group: 2004: 7).

**PM Harper Announces Canada is Leaving the Medical Isotope Business**

Due to safety concerns and rising costs, there is currently funding for the Chalk River reactor to 2016 after which it will be permanently shut down. Its current licence expires in 2011, but is expected to be renewed to 2016. In June 2006, the federal government began a five-year cleanup of “nuclear legacy liabilities” at Chalk River with costs of more than half-a-billion dollars allocated. Over half of these “nuclear legacy liabilities” result from research and development activities from the Cold War, the rest are from the research and development of medical isotopes and from nuclear reactor technology, as well as national science programs (NRC, 2009a). Over $45 million was provided in the last Supplementary Estimates to address regulatory and health and safety needs at Chalk River (Lunn, 2008). In late May 2009, the federal government announced plans to sell AECL whereby restructuring includes private-sector
management for AECL’s Chalk River research facility (Rennie, 2009a). Two weeks later, in June 2009, Prime Minister Harper announced that Canada plans to leave the isotope business by 2016 (Alberts, 2009) and production of medical isotopes will be left to other countries (Akin, 2009a). Without new production sources, the closure will result in a continuous shortage of medical isotopes which is concern, not only for the health of Canadians and patients worldwide, but is a major issue for public policy.

2.3.5 MAPLE Project Cancellation

In 1996, AECL and MDS Nordion formed a partnership to design and construct two reactors and a new processing facility to replace the old Canadian NRU reactor. The sole purpose of the Multipurpose Applied Physics Lattice Experimental (MAPLE) reactors was to produce medical isotopes. They were “designed to fully support the world’s demand of the nuclear medicine community and the patients they serve. While there are other reactors in the world, none of them alone or together can meet the world’s needs reliably” (Standing Committee on Natural Resources, 2009: 1). The two reactors were supposed to be online by 1999 and 2000 respectively, but were never finished and the MAPLE project was abandoned in 2008 due to design flaws and excessive delays in commissioning (Rennie, 2009a) as well as being “eight years behind schedule and hundreds of millions of dollars over budget” (The Economist, 2009). AECL was not able to “satisfy the Canadian nuclear regulator that it would be possible to accurately predict how the MAPLEs would operate under certain conditions” (Akin, 2009a). Dr. Labrie, the manager of Reactor Physics and Systems Behaviour (at the Office of the Chief Engineer) for AECL, asserts that “there are significant technical and regulatory hurdles that require, in the best-case scenario, at least five to six years of intensive research and analysis before we can even consider bringing the MAPLE reactors on-line” (Labrie, 2009).

The reactors were licensed by CNSC to operate with a small negative power coefficient of reactivity (PCR), meaning that core reactivity was to decrease as power increased, but test data
analysis in 2003 indicated the reactor has a small positive PCR. This means that after being
started up, “as the power level increased, the reactors had a tendency to run faster and
faster…That is a highly undesirable characteristic in a reactor” (Wald, 2009). Consultations with
experts from the Korea Atomic Energy Research Institute, Brookhaven National Laboratory,
Idaho National Laboratory and Argentinean INVAP from 2003 to 2008 could not determine the
cause or resolve the PCR issue (Labrie, 2009).

AECL president Hugh MacDiarmid asserts that the MAPLE reactors “…have never
produced an isotope that could be used for a patient” (Rennie, 2009b). This failure led the federal
government to say, “[W]e can’t spend hundreds and hundreds of millions of dollars and never
produce an isotope…Atomic Energy was not able to make that project work and there was no
prospect that it would work. What we decided to do instead is invest money in repair of the
(NRU) while other sources come online” (Akin, 2009a). The Harper government did not state at
the time of the comment what the other sources would be or whether they would be a result of
Canadian production. This again occurred in 2010, in response to the issue of whether Canadians
would receive isotopes whose material originates from Chalk River. MacDiarmid commented
that the Canadian government “is committed to ensuring there is an adequate supply of isotopes
for global markets. If the global market is properly supplied, “there is no reason that Canadians
wouldn’t have access to the supplies that exist’” (Galloway and McCarthy, 2010). This seems to
indicate that the federal government is waiting for other countries to start large-scale production.

Executives from MDS Nordion testified at a House of Commons committee arguing the
case for continuing with the MAPLE project. Although the MAPLE reactors had operated as part
of its commissioning and some of the commissioning tests were done with targets, none of those
targets were processed, i.e., no radioisotopes were ever produced (Standing Committee on
Natural Resources, 2009). It was implied that those targets would have been processed if the
processing facility had been commissioned.
The effect of the announcement of the MAPLEs is important for why there are shortages today. International stakeholders could have advocated for reactors to be built in their countries, but they avoided investment since they were relying on the completion of the MAPLE project to secure global supply (Collier, 2008). The benefits from this strategy are many given the impediments to production. For example, consider the U.S. When the reactor in Tuxedo, New York closed over a decade ago due to tritium leaks, the problem of not having a domestic supply of medical isotopes was considered. However, when the plans to build the MAPLEs were announced, entering a market that has low profit margins and high upfront costs was not a viable business plan. If just one MAPLE reactor could supply all of world demand, it was not reasonable to go into the reactor isotope producing business. Canada was subsidizing the production. Private enterprises from the U.S. could not compete against this and so decided not to produce isotopes, relying on Canada to supply them instead. Similar decisions were made by other countries.

Supply of Mo-99 is in danger with the Chalk River shutdowns and the cancellation of the MAPLE project. Canada has one unreliable reactor and no backup source, which Dr. Urbain, president of the Canadian Society of Nuclear Medicine, referred to being “extremely dicey” (Collier, 2008).

Impediments to Production

Though the world market for radioisotopes is rapidly expanding, “…high up-front costs, low profit margins and difficult licensing processes mean that the establishment of new facilities is extremely difficult without government intervention” (Hansell, 2008). In addition, there are further “…deterrents to entering the industry – the scarcity of nuclear technology experts, high infrastructure costs [and] the challenge of distributing decaying-by-the-minute radioactive material” (Collier, 2008). These challenges exist despite the global nuclear imaging and therapeutics market being estimated at $3.7 billion (Collier, 2008).
2.4 Current Policy Context

2.4.1 Health Policy

The Canadian Constitution largely determines the organization of Canada’s health care system, in which roles and responsibilities are divided between the federal, provincial and territorial governments. The provincial and territorial governments bear most of the responsibility for delivering health services; they have primary jurisdiction in the administration and delivery of health care services, including setting their own priorities, administering their health care budgets and managing their own resources. The federal government’s role in health includes setting and administering national principles under the Canada Health Act, providing financial support to the provinces and territories and funding for health research and health information activities, and is responsible for some direct delivery of services for certain groups of people, such as the First Nations living on reserves, Canadian Forces members, veterans and inmates (Health Canada, 2006).

In December 2002, the Federal, Provincial and Territorial Deputy Ministers of Health created the Advisory Committee on Information and Emerging Technologies (ACIET). The Committee’s mandate is to provide policy development and strategic advice on health information issues and on the effectiveness, appropriateness and utilization of emerging health products and technologies to Federal, Provincial and Territorial Deputy Ministers of Health (Health Canada, 2006).

One initiative identified by ACIET Deputies was a Emerging Technologies Assessment. Health Ministers approved a new Canadian Health Technology Strategy. This development arose from the 2003 Accord on Health Care Renewal’s commitment to develop a comprehensive

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4 ACIET has a Provincial and Federal Co-chair and is comprised of representatives from the federal, provincial and territorial governments as well as external members from Canada Health Infoway Inc., Canadian Coordinating Office on Health Technology Assessment, Canadian Institute for Health Information, and other external experts are added as the Committee deems necessary.
strategy to assess the impact of health technologies and provide advice on how to maximize their
effective utilization. The Strategy represents a collaborative approach towards ensuring that
Canadians have ongoing access to appropriate health care technology.

Technological change is a major cost in Canada’s health systems, estimated at one-quarter of health expenditure growth. Technological change is a primary source of escalating costs, which threaten the financial sustainability of Canada’s health systems. Changing technology is the cause of the rising costs and the speed of health technology development is outpacing the ability of the health system to effectively use it. Health technology and its management are therefore leading priorities for policy makers and academic researchers (Health Canada, 2006). Although updating technology can be expensive, so too is providing medical care coverage for individuals who have expensive chronic illnesses which could have been diagnosed or treated at an earlier stage with better technology.

Technological innovation is important as it holds the promise of new treatments, ways to improve patient care and better tools for managing and improving the overall health systems quality. Furthermore, health technology innovation can be a driver of economic benefits to Canada. To realize clinical and economic benefits, health technology needs to be better managed.

There are many common health technology management issues facing federal, provincial and territorial jurisdictions so a coordinated approach to formulating specific policy advice to be made available to all jurisdictions is required. Health Canada has identified the need for a means for developing shared policy advice to aid health technology investment decisions in all jurisdictions. This policy advice needs to be clear, concise and timely. A Task Group for health technology (coined the term Health Technology Strategy 1.0), to give a name to the first version of this comprehensive strategy. In years to come subsequent versions of this strategy will be created to address new health system realities created by rapidly evolving health technologies.
The Health Technology Assessment Task Group (HTA Task Group) found that “[n]o single jurisdiction has the evidence and policy development capacity to match all the technologies entering Canada’s health systems” (HTA Task Group, 2004: 5). “The Task Group recommends that CCOHTA evolve its role and mandate to become the National Health Technology Agency…move away from traditional HTA to a broader, yet more granular evidence and policy advice model” (HTA Task Group, 2004: 8).

Currently, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) is an independent, not-for-profit organization funded by Canadian territorial, provincial and federal governments. “CCOHTA’s mission is to encourage the appropriate use of health technology by influencing decision makers through the collection, analysis, creation and dissemination of information concerning the effectiveness and cost of technology and its impact on health” (HTA Task Group, 2004: 14).

With respect to a product of medical technology – medical isotopes, Health Canada/FDA approvals are required for isotopes generated from new production technologies or from older ones that have not supplied Canada and the U.S. previously.

2.4.2 Energy Policy

Canada’s energy policy is guided by a series of principles, agreements and accords emphasizing the importance of competitive market behaviour and encouraging investment in Canadian energy markets. The main principles of its energy policy are: (1) a market orientation (markets are the most efficient means of determining supply, demand, prices and trade while ensuring an efficient, competitive and innovative energy system that is responsive to Canada’s energy needs); (2) respect for jurisdictional authority and the role of the provinces; and (3) where necessary, targeted intervention in the market process to achieve specific policy objectives.
through regulation or other means (these policy objectives include issues of health, safety and environmental sustainability) (NRCan, 2009c).

Over time, numerous federal decisions have also contributed to the energy policy: (1) the creation of the Canadian Nuclear Safety Commission to regulate all aspects of the nuclear power industry in Canada; and (2) the creation of Atomic Energy of Canada Limited to foster the advancement of nuclear energy and nuclear technology.

2.5 Security and Nuclear Non-Proliferation

Nuclear non-proliferation and security concerns have led to discussions around the world about moving away from the use of highly enriched weapons-grade uranium (HEU) as reactor fuel and in targets for producing Mo-99 (Hansell, 2008). Canada has signed on to a number of international non-proliferation agreements, but approved AECL’S design of the MAPLEs which use highly enriched uranium. Aside from the issue of high cost, HEU poses security and terrorist risks. The possibility of converting to low enriched uranium (LEU) is examined succeeding explanations for how uranium is necessary for 95-98 percent of current medical isotope production, the issues of safety associated with such production and recent American legislation.

2.5.1 Reactor-Based Production – Nuclear Fission

Currently, 95-98 percent of all medical isotopes are the result of fission products from the use of a nuclear reactor. Despite the fact that there are at least 273 accelerators producing isotopes in 41 countries (OECD, 2005). The five largest producers of medical isotopes all rely on reactor-based technology.

Nuclear fission is the process in which heavy elements split into lighter ones and release energy. The five major reactors responsible for producing medical isotopes generate nuclear chain reactions with highly enriched uranium as the target material. In the reactors, a neutron strikes a target, a uranium (U-235) atom, and is absorbed by the nucleus of the uranium atom.
That extra neutron causes the uranium atom to destabilize and split into other elements, one of which is Mo-99. Kinetic energy, gamma radiation and free neutrons are also released, collectively known as fission products. When other neutrons are released, some of those are absorbed into other uranium nuclei and those in turn split and that liberates even more neutrons and so on. One neutron ejected from each fission causes another fission to occur. That is the chain reaction and it becomes self-sustaining. If each neutron releases two more neutrons, then the number of fissions doubles each generation (Atomic Archive, 2008).

Nuclear reactors use the process of fission to convert atomic energy into heat. In a controlled fission reaction, this energy can be channelled into establishing a chain reaction encouraging the remaining fissionable products to break apart as well. An uncontrolled (run-away) reaction creates a nuclear bomb. The heat from a reactor can be used to generate electricity. Some reactors are designed for both research and electrical generation.

2.5.2 Safety Measures/Global Security – Run-Away Reactors, Terrorism Risks, Nuclear Weapons and Uranium Enrichment

The process of nuclear fission may be controlled as in the case of nuclear power or uncontrolled as in nuclear weapons. To sustain a controlled nuclear reaction, only one for every two or three neutrons released must strike another uranium nucleus. If this ratio is less than one, then the reaction will die out; if it is greater than one it will grow uncontrolled in an atomic explosion. The neutrons have too much kinetic energy and need to be slowed with a moderator such as heavy water. To control the reaction, i.e., the amount of free neutrons, a neutron poison in the form of a control rods (made of a strongly neutron-absorbent material such as boron or cadmium) can be placed inside the reactor core with the fuel (Atomic Archive, 2008). There they absorb neutrons which slows or stops the fission process.

The point at which a chain reaction can become self-sustaining is referred to as critical mass. Only about 5 kilograms of nearly pure or weapons-grade plutonium 239 or about 15
kilograms of uranium-235 is required to achieve critical mass (Atomic Archive, 2008). In terms of global security risks, if a terrorist were to obtain 15 kilograms of the uranium used in reactors to produce medical isotopes, that would be enough to sustain an uncontrolled chain reaction resulting in a weapon of mass destruction. In 2007, four of the main producers of Mo-99 used enough U-235 to make multiple nuclear bombs (Hansell, 2008).

Four of the five main medical isotope producing reactors in Canada, Belgium, France and the Netherlands all use 93% (highly) enriched uranium targets, while South Africa uses 36-45% enriched uranium targets. The U.S. supplies highly enriched (weapon-grade) uranium to Canada (von Hippel and Kahn, 2006). Roughly 85 kg of HEU is used for making Mo-99 per year in Canada, Europe, and South Africa (von Hippel and Kahn, 2006). Of this, MDS Nordion “imports about 20 kilograms of weapon-grade uranium from the U.S. per year” (von Hippel and Kahn, 2006: 153). The European producers are currently using weapon-grade uranium that was acquired from another nuclear-weapon state (France, Russia, or the U.K.) or was exported by the U.S. prior to the Schumer Amendment. South Africa uses highly enriched uranium that it produced prior to 1991 (von Hippel and Kahn, 2006).

When highly enriched uranium is used as a target in a reactor, only 6 percent of the fission products result in Mo-99. This means that there is HEU in the waste product and it is still weapon-usable. Enough “has accumulated in the Mo-99 producing countries in amounts that would be sufficient to make many Hiroshima weapons” (von Hippel and Kahn, 2006: 152).

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5 Uranium-238 (low enriched) is not suitable for a nuclear weapon since its high probability that an incident neutron would be captured to form uranium 239 instead of causing a fission (Atomic Archive, 2008). Uranium-235 (highly enriched), on the other hand, has a high fission probability and can be converted into metal and then used for a nuclear bomb (Hansell, 2008). Only 0.7% of natural uranium is highly enriched. A by-product of using LEU is plutonium, which could be used for a bomb, but less likely than if U-235 was used.

6 As a comparison, the bomb dropped on Hiroshima during WWII used 60 kg of HEU resulting in a blast equivalent to about 12 kilotons of TNT even though only 1.38% of its material fissioned. The total destruction area was about 13 km in which two-thirds of Hiroshima’s 76,000 buildings were reduced to rubble and destroyed by fire. Almost all of those directly the bomb’s explosion died. 60% of people within 2 km of the explosion died, three-quarters of them in the first 24 hours. In total, 70,000–80,000 people (30% of Hiroshima’s population) were killed immediately and another 70,000 injured (Holdstock and Barnaby, 1995).
Recently, the South African reactor was twice broken into, once in 2006 and then again in 2007 (Hansell, 2008). In 2007, armed attackers defeated the South African reactor security personnel, but luckily were only seeking computers, not uranium (Hansell, 2008).

2.5.3 Legislating Change, Conversion to LEU

In 2005, a lobbying campaign by MDS Nordion and Mallinckrodt resulted in the Burr Amendment to the U.S. National Energy Policy Act. This amendment exempts HEU as target use by medical isotope producers in Canada, Belgium, France, Germany and the Netherlands from the Schumer Amendment’s requirements (von Hippel and Kahn, 2006). The U.S. National Energy Policy Act (2005) states it will pursue domestic LEU production of isotopes if international manufacturers will not convert from HEU production. Despite strong U.S. persistence for this shift, there has yet to be any attempt by the U.S. to legislate any sort of preferences – tax breaks, direct financial assistance, etc. to LEU producers or to the producers of HEU willing to convert to LEU. With the recent unexpected Chalk River closures and the MAPLE project failure, domestic American medical isotope production now seems a viable option for the U.S.

South Africa, which currently supplies 15 percent of the world’s Mo-99 (and is the only producer with a fully independent source of enriched uranium), recently suggested that it has been exploring LEU-based technologies, viewing them as a possible competitive edge if countries were to adopt policies favoring imports of LEU-based Mo-99 production (Hansell, 2008).

2.6 Alternative Technologies for Medical Isotope Production

The technological production methods for producing medical isotopes is presented because “[t]he ability to develop sensible policy regarding the adoption and use of emerging technologies…[requires]… assessment of new technologies…to better inform the process of policy formulation” (Wiktorowicz and Deber, 1997: 117).
2.6.1 Linear Accelerators – Findings of the TRIUMF Task Force

TRIUMF\textsuperscript{7} is Canada’s national laboratory for particle and nuclear physics and is also used for materials and molecular science as well as life sciences (nuclear medicine) projects. Much innovative research is done here such as the three alternative production methods for isotope production using accelerators which will now be examined.

The Task Force on Alternatives for Medical-Isotope Production (composed primarily of TRIUMF, UBC and Advanced Applied Physics Solutions, Inc. with support from Natural Resources Canada) has examined 3 alternative production methods: (1) the neutron-capture process where an intense neutron beam generated by a nuclear reactor adds one neutron to a Mo-98 target to produce Mo-99; (2) the photo-neutron process in which an intense photon beam generated by an electron accelerator removes a neutron from a Mo-100 target to produce Mo-99 and (3) the photo-fission process where a very intense photon beam generated by an electron accelerator causes a uranium target to fission to produce Mo-99. These are shown in Figure 5 below, with the current process shown first.

\begin{figure}[h]
\centering
\includegraphics[width=0.8\textwidth]{figure5.png}
\caption{Four Processes to Generate Mo-99}
\end{figure}

Diagrams courtesy of The Task Force on Alternatives for Medical-Isotope Production

\textsuperscript{7} Owned and operated by 14 Canadian universities, TRIUMF provides research infrastructure and tools to over 350 scientists, engineers and staff as well as research opportunities to 150 students and postdoctoral fellows annually.
An advantage of the first two alternative production processes is that there would be nearly no waste stream. The second alternative is ‘scalable’ meaning it can be built as a small (low power) or large facility. A disadvantage of neutron capture is that it requires a major change in the generator technology to separate Mo-98 from Mo-99. The key disadvantages of photo-neutron are that it also requires a major change in generator technology because of the different target, while also needing Health Canada/FDA approvals for new product and lastly the cost of manufacturing Mo-100 targets and the cost of separating Mo-100 from Mo-99 would likely be quite high since Mo-100 comprises less than 10 percent of naturally occurring molybdenum. The Task Force recommended the photo-fission process. The process and the decision making surrounding this recommendation is discussed next in greater detail.

**Accelerator-driven Photo-fission of U-238 for Generating Mo-99**

The TRIMUF Task Force (2008) found that there are many advantages for using linear accelerators (or linacs for short), and specifically photo-fission technology, for producing medical isotopes, namely Mo-99.

A main feature is that there is a higher predictability of schedule, cost and licensing than for a reactor. Second, there is a low probability of impurities in a photo-fission-derived medical isotope. The third feature, and one of the most important, is that linacs eliminate security issues of transporting, storing and disposing of HEU, obviating questions of security and nuclear proliferation concerns because linacs can achieve similar yields from either natural (highly-enriched, U-235) or depleted uranium (low-enriched U-238) targets. Furthermore, a linear accelerator does not produce radioactive waste disposal from its operation, although waste from chemical processing of irradiated targets to recover and extract the Mo-99 would be similar to a reactor-based approach. In addition, they can be easily turned on and off as needed, whereas a reactor cannot. Also, linacs are scalable – additional accelerators of varying power can be built as needed – and can be set up anywhere nationally, at universities or private enterprises. This is an
important factor since it means that the accelerators “could be centrally located or distributed geographically as a coordinated production network” (TRIUMF, 2008: 38). Linacs could be built at universities and with corporations thereby attracting additional funding whereas a reactor would have to be associated with a crown corporation, AECL, ultimately resulting in taxpayer funding. Finally, at end-of-life, an accelerator is comparatively inexpensive to decommission as major components are less prone to become radioactive over time than in the high neutron environment of an operating reactor.

The construction costs including labour amount to $125 million CAD and the manufacture of targets for irradiation, storage of radioactive waste from target processing and hot-cell facilities to recover and refine Mo-99 cost $50 million (TRIUMF, 2008); in contrast reactors cost between $500 million to $1 billion USD (Ruth, 2009). This makes linacs a more cost effective technology. For the price of one reactor, a half-dozen multi-megawatt accelerators can be constructed throughout the country thereby meeting 30 to 50 percent of North American demand (TRIUMF, 2008). Just one linac can produce enough medical isotopes for all of Canada. Multiple units can ensure a high reliability of supply, but they require 3 years to build.

In April 2009, MDS Nordion and TRIUMF announced a partnership to study the feasibility of producing a viable and reliable supply of photo fission-based Mo-99 using linear accelerators to account for isotope shortages due to reactors (namely, Chalk River) being temporarily shut down (Meyer, 2009a). In addition, TRIUMF submitted a 5-year (2010-15) funding proposal to the National Research Council in February 2009 in order to secure funds for the construction an electron linear accelerator.

2.6.2 Cyclotrons

Cyclotrons are a proven, safe technology that is both environmentally friendly and does not pose concerns over global security as it “does not require highly enriched weapons-grade
uranium…and does not generate nuclear waste” (ACSI, 2010). By using lead as a target to obtain Tc-99m, this eliminates the need for Mo-99 and uranium of any kind. Direct production is done on 24 MeV cyclotrons at Advanced Cyclotron Systems Inc. (ACSI).

Another advantage of ACSI’s TR24 cyclotron, it that is can produce PET and SPECT isotopes including Tc-99m and I-123 (ACSI, 2009a). This is important if in the future Canada decides to implement more PET and SPECT scanning medical equipment. Their imaging is better than that done with CT’s, ultrasound and X-rays, resulting in more accurate diagnoses which allow for the recognition of illnesses sooner.

One of the recommendations of the Natural Resources Canada appointed Expert Review Panel on Medical Isotopes was to explore cyclotron technology. Their finding was that if R&D proves successful, cyclotrons would be an important means to ensuring security of supply over the long-term because they have built in all of the elements needed for security such as capacity, redundancy and diversity (Expert Panel Report, 2009). Since the publication of their report, cyclotron technology for medical isotope production has been demonstrated to work.

In January 2010, researchers at the CHUS’s Centre de recherche clinique Étienne-Le Bel (CRCELB) and the Université de Sherbrooke, in collaboration with ACSI demonstrated that Tc-99m can be produced from a cyclotron. Researchers from the Molecular Imaging Center of Sherbrooke (CIMS) performed diagnostic testing which shows that it produces the same results as nuclear reactor-based Tc-99m (ACSI, 2010).

Advanced Cyclotron Systems Inc. has proposed to collaborate with 5 Canadian universities and research centres for the establishment of a National Cyclotron Network. This would require a “one-time capital investment of $52.5 million…with no need for annual federal subsidies” (ACSI, 2009b) resulting in a financially self-supporting model with a low initial investment. A network of 8 strategically placed cyclotrons would provide reliability and a scalable source of isotopes. Operations could begin within 18 months by leveraging existing
cyclotron technology and distribution centres (ACSI, 2009a). Furthermore, a network of this sort would meet virtually all Canadian medical isotope needs in two to three years (ACSI, 2009a). Such a Network would be a viable solution to solving Canada’s current medical isotope shortage since it also ensures supply-chain redundancy and flexibility (ACSI, 2010). The Network would limit the possibility of future shortages since it is unlikely that all Canadian production would simultaneously halt with multiple cyclotrons, as is the case when the only reactor for medical isotope production is shutdown. The Expert Panel report (2009) also recommended that a secure supply of Tc-99m would avoid the “single point of failure” risk associated with a linear supply chain – a network of cyclotrons ensures secure supply in this respect.

ACSI’s TR-24 launched commercially just last year has been licensed by the Canadian Nuclear Safety Commission (ACSI, 2009a).

The disadvantage of creating technetium directly is that due to the 6-hour half life of Tc-99m, the cyclotrons have to be fairly close to hospitals and so many of them are needed. They work well to supply urban centres, but are not effective for supplying rural areas. Five cyclotrons are currently being used in Canada in BC, Quebec and Ontario, and more recently in the U.S.

2.7 Possible Solutions for Medical Isotope Production

Currently, the Canadian government is evaluating solutions for medium and long-term isotope supply. It asked the OECD Nuclear Energy Agency to initiate a workshop in January 2009 entitled, the Security of Supply of Medical Radioisotopes, with the goal of addressing current and future challenges to a reliable supply of Tc-99m “and to identify[ing] measures that should be taken to help ensure supplies in the short, medium and long-term” (Nuclear Energy Agency, 2009). Natural Resources Canada, the federal department responsible for nuclear energy policy, established an Expert Review Panel on June 19, 2009 to study the most viable options for securing Tc-99m for the medium and long-term for Canadian patients. The government
established the panel to review 22 proposals from the private and public sectors for new sources of key medical isotopes (Meyer, 2009b) and will be investing $6 million into research for replacements to Tc-99m (Spears, 2009). Favoured proposals were submitted from Saskatoon and McMaster University for the creation and funding of nuclear reactors, along with TRIUMF located at the University of British Columbia for linear accelerator production.

2.7.1 Canadian Reactor-Based Solutions – McMaster and Saskatoon

It is possible that McMaster University’s facility, which produced Mo-99 in the 1970s, could be ramped up (increased) to supply four times the Canadian demand (about 20 percent of the total North American demand) for isotopes derived from Mo-99 provided it receives $30 million over the next five years, can acquire new non-weapons-grade uranium fuel that would likely come from France, and hire and train staff (Akin, 2009b). However, “it will take up to 18 months and millions of dollars in upgrades before that reactor can make isotopes, which won’t help solve the current shortage crisis” (Rennie, 2009b).

A proposed research reactor in Saskatoon, called the Canadian Neutron Source, could come online in 2016, with estimated costs between $500-750 million and would use low enriched uranium capable of producing half the isotope volume of the Chalk River facility (White, 2009). It is expected that the province would pay for 25 percent of the construction with the federal government paying for the rest as well as 60 percent of the annual operating costs which are estimated between $45-70 million. Saskatchewan is the source of one-quarter of the world’s uranium (White, 2009).

2.7.2 American Reactor-Based Solution – MURR

Health officials in the U.S. are seeking an American supplier of medical isotopes, having decided that Canada is no longer a reliable source of Mo-99 with the cancellation of the MAPLE project (The Economist, 2009). In response to the latest NRU shutdown, on July 10, 2009 a U.S.
Senate committee approved $20 million in spending for the start of domestic production of medical isotopes (Alberts, 2009). This is the first commitment of the U.S. government to meet American demand for Mo-99. Furthermore, the U.S. Department of Energy recently commissioned an independent panel (in a recent National Academy of Sciences study) to examine American options for the production of Mo-99 ending the reliance on foreign suppliers. Specific findings of the study with respect to LEU production were attained with an interview of the Chair of the study as well as another participant and are presented in the interview findings chapter.

The University of Missouri is pursuing low enriched uranium-based Mo-99 production with its high-powered MURR research reactor (Hansell, 2008) and it is the most likely production facility in the U.S. even though it would take 3 or 4 years before it would be ready for large-scale production (Collier, 2008). However, MURR will have difficulty meeting its goals without government financial and regulatory support (Hansell, 2008). Most facilities throughout the world are subsidized in some way by their governments (Ruth, 2008). If built it could supply 30 to 50 percent of current U.S. demand for Mo-99 (Hansell, 2008) going a long way to solving the isotope shortage problem, providing a reliable source for the U.S.

These findings are important with respect to which options Canada pursues. For example, if the U.S. is likely to have two reactors up and running by 2015, then Canada has no market to justify building multiple linear accelerators throughout the country, when one would be sufficient to meet Canadian demand.

2.8 Summary

The literature review has provided pertinent information for understanding the various issues surrounding medical isotope shortages, including technological issues for production,
security concerns over the use of highly enriched uranium, and the political and regulatory issues in Canada over the NRU reactor’s performance.

The recent shortages in medical isotopes have compromised patients’ health on a global scale. The research questions examine the three causes for isotope shortages, namely the repeated shutdowns of the largest producers for required maintenance or to repair leakages caused by corrosion on the aging reactors, the inability of the MAPLEs to function as designed, and the lack of large scale international production facilities due to various impediments to production. The 2007 global medical isotope shortages can be explained, at least in part, by a disagreement between Canada’s federal government and its nuclear regulatory body.

Shortages in medical isotopes compromise the health of people in Canada and across the world. By identifying the underlying issues for how global shortages in medical isotopes come about and their subsequent impact on patient care, the researcher examines ways to reduce future shortages. A reduction in shortages will ensure that the quality of care remains at an acceptable level.

The Chalk River reactor is nearing its end of life. Future medical isotope production can be based on reliable and trusted technology such as another nuclear reactor, or newer ones such as linear accelerators and cyclotrons.

Nuclear non-proliferation is an important consideration for future production. This means moving away from the use of HEU in the long-term. The U.S. is insisting all nations move away from the use of high enriched uranium in reactor fuel and targets, currently used for making Mo-99. Canada receives its HEU from the U.S. There is currently an American bill that passed Senate, but is in the House for consideration which will ban exports of HEU. It is likely to pass, which means that all future Canadian production of Mo-99 using uranium will need to use LEU if Canada would like to continue to supply the American market. This stipulation will effect potential policy options that can be proposed. Since reactors must use uranium, it can be in the
form of low enriched. Linacs can make molybdenum with LEU or without any uranium, while cyclotrons are the only technology that creates technetium-99m directly and it does so without uranium of any kind.

The researcher has established that the isotope shortages negatively impact patient’s health, and that future shortages are likely to occur unless something is done to ensure reliability of supply and increase production. The severity of these impacts on hospitals and their capacity to deliver healthcare is uncovered by the data gathered from elite interviews along with the limits and advantages of technologies such as nuclear reactors and linear accelerators to produce isotopes as well as the types of alternatives to their use. These findings and the methods used to generate them are discussed next.
3: Methodology

3.1 Introduction

The policy problem that guides this study’s research concerns shortages in medical isotopes which compromise the health of Canadians. A multi-methods approach was taken to address this problem building from a review of the existing literature, and involving elite interviews with experts in nuclear medicine, industry, academia and government along with a case study with Australia, Argentina, South Africa, Belgium, Canada and the U.S. examining various reactor-based production of medical isotopes. The use of qualitative methods for a study concerning health is appropriate as they can “be used as part of the process of dissemination of research evidence, and may be especially helpful in making findings relevant to patients and care providers” (Pope, van Royen and Baker, 2002: 151). Moreover, in terms of public policy, “[q]ualitative methods can provide insights to the process of policy implementation, identifying where and why this is successful, uncovering initial “teething problems,” and suggesting solutions” (Pope, van Royen and Baker, 2002: 150).

3.2 Multi-Method Research Design

Using a multi-methods approach is useful in this context because it attempts “to legitimate the use of multiple approaches in answering research questions, rather than restricting or constraining researchers’ choices…It is an expansive and creative form of research, not a limiting form of research” (Johnson and Onwuegbuzie, 2004: 17). A critical review of the literature, including similar studies conducted in Canada and the U.S., was taken in order to establish the scope of the problem and examine the issues surrounding medical isotope production. This pointed to the need for further information on the impact of the shortages on
patient care, how hospitals have coped with a limited amount of reactor-produced isotopes and what industry is currently developing for the production of medical isotopes. Elite interviews were chosen as a way to generate this information since they allowed the researcher to discover projects currently under way and with little if any published information. Also, the extent of the shortages’ impact across Canada was established by speaking with nuclear medicine specialists in different provinces. The case study provides findings on Canada’s aversion to LEU conversion which could not be exclusively derived from the other methods employed.

Findings from all of these methods are presented in the Analysis section of this study. Policy options and recommendations were derived from discussions held in interviews. The types of data and how they were attained are discussed next.

3.3 Elite Interviews with Experts (Primary Data Collection)

In general, data collected from elite interviews is used to acquire expert insight into the nature of the policy problem, confirm the research findings, test the viability of potential policy options and fill in any information gaps still present after reviewing the literature. The interview data collection “begins the process of verification in the research process. Data collection and verification become inextricably intertwined” (Johnson, 2001: 112).

**In-depth Semi-Structure Design**

Researchers use in-depth interviewing to check out and verify theories as well as “explore multiple meanings of or perspectives on some actions, events, or settings” (Johnson, 2001: 104). The individuals selected for interviews are experts and knowledgeable stakeholders with respect to medical isotope production and usage. “[I]f one is interested in questions of greater depth…where different individuals or groups involved in the same line of activity have complicated, multiple perspectives on some phenomenon, then in-depth interviewing is likely the best approach” (Johnson, 2001: 105).
The interviews were semi-structured allowing the researcher to guide the conversation, while simultaneously allowing the participant to discuss any given issues on the interview schedule and related concerns as they arose. This format allows the researcher to modify or add to the existing set of interview questions depending upon the direction of the conversation, thereby resulting in a richer interview data set. Furthermore, “[b]ecause this method elicits people’s own views and accounts, it can have the additional benefit of uncovering issues or concerns that had not been anticipated or considered by the researchers” (Pope, van Royen and Baker, 2002: 148-149).

“Semi-structured interviews are typically based on a flexible topic guide that provides a loose structure of open ended questions to explore experiences and attitudes” (Pope, van Royen and Baker, 2002: 148). A semi-structure method allows the researcher to build a rapport with the interview participant by engaging in discussion, rather than merely posing questions, resulting in more, detailed data collection as the participant wants to aid the researcher and help contribute to the findings.

The participants engaged in face-to-face or telephone interviews in which discussions were held on a series of topics relating to medical isotope production – why there are global shortages, their impacts on patient care, alternative technologies for the production of medical isotopes, alternatives to the isotopes themselves and also to test policy options and what would need to occur to reduce such global shortages. An interview schedule is attached in Appendix E.
3.3.1 Participants and Fields of Expertise

In order to gain knowledge from key fields of expertise, interview participants were drawn from four broad areas: nuclear medicine, industry, academia and government. Table 1 provides the list of the organizations and the respective fields of expertise. See Appendix F for a summary of participant biographies.

<table>
<thead>
<tr>
<th>Title</th>
<th>Organization(s)</th>
<th>Field(s) of Expertise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Researcher</td>
<td>TRIUMF, BC Cancer Agency, BC Cancer Research Centre, Vancouver Hospital</td>
<td>Nuclear Medicine; PET; Industry; Radioisotope Production; Academia</td>
</tr>
<tr>
<td>President</td>
<td>Ontario Association of Nuclear Medicine</td>
<td>Nuclear Medicine; PET</td>
</tr>
<tr>
<td>Senior Vice-President</td>
<td>MDS Nordion</td>
<td>Industry</td>
</tr>
<tr>
<td>Former Federal Deputy Minister of Industry</td>
<td>Federal government</td>
<td>Government</td>
</tr>
<tr>
<td>Consultant; Engineer</td>
<td>ENVIRON International Corporation (Environmental consulting firm)</td>
<td>Industry; Academia</td>
</tr>
<tr>
<td>Doctor</td>
<td>Vancouver Cancer Agency; Vancouver General Hospital</td>
<td>Nuclear Medicine; PET</td>
</tr>
<tr>
<td>Special Advisor to Minister of Health on Medical Isotopes; Adjunct Professor; Associate Director of Research</td>
<td>Federal government; University of Alberta, Dept of Radiology and Diagnostic Imaging; Dept of Oncologic Imaging at the Cross Cancer Institute</td>
<td>Government; Nuclear Medicine; Industry; Radioisotope Therapy; PET; Academia</td>
</tr>
<tr>
<td>Engineer</td>
<td>Advanced Cyclotron Systems Inc.</td>
<td>Industry; Radioisotope Production</td>
</tr>
</tbody>
</table>

One interview participant was an expert in the field of accelerator technology and worked on the TRIUMF Task Force to evaluate alternative technologies; another is an engineer who

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8 The leading research on medical isotopes, their viability and alternatives to their use was addressed in the recent reports: TRIUMF’s “Task Force on Alternatives for Medical-Isotope Production” (2008), the Ad Hoc Health Experts Working Group on Medical Isotopes’ report “Lessons learned from the shutdown of the Chalk River reactor (2008), the Committee on Medical Isotope Production Without Highly Enriched Uranium, National Research Council’s report prepared for the National Academy of Sciences in the U.S. (2009) and the Report of the Expert Review Panel on Medical Isotope Production (2009). The researcher was fortunate to speak with a member from each of these groups with the exception of the Expert Review Panel (their study was started and conducted privately during the course of this study’s investigation). The Expert Review Panel comprised of an energy expert, a member of the Canadian Cancer Agency, a condensed matter physicist and a doctor specializing in nuclear medicine. This study collected data from experts in similar fields.
chaired the National Academy of Sciences study; a former Deputy Minister was interviewed for his insights on Canadian S+T policy and the inter-departmental workings of government. In addition, nuclear medical specialists from BC and Ontario were consulted for their knowledge on the impacts of the shortages on Western Canada and the Central and Atlantic provinces. An Advisor to the Government, known informally as the ‘Isotope Czar’ provided both medical and governmental perspectives. Vice-President of Strategic Technologies at MDS Nordion provided insight into the MAPLEs. Lastly, an engineer from Advanced Cyclotron Systems Inc. was able to share information on a new and innovative way to produce medical isotopes.

**Interviews with Health Care Professionals**

Nuclear medicine specialists have knowledge of medicine and patient care, expertise concerning the safe handling and use of medical isotopes as well as radiation protection and safety training. They are “an integral part of a larger nuclear medicine community that includes technologists, physicists and radiopharmacists. As a result, nuclear medicine specialists are uniquely able to balance the health of patients, the safe handling of medical isotopes and overall patient management” (Ad Hoc Health Experts Group, 2008: 6).

Professionals (doctors and researchers) within the nuclear medicine community talked about the role of medical isotopes in modern medicine and reflected on alternative production methods for generating medical isotopes, alternatives to their use for diagnosing and treating diseases along with the impacts on patient care due to shortages.

**Interviews with Academics**

The interviews with academics focused on the various technologies for production of medical isotopes currently available and technically feasible as well as information into how medical, science and technology polices are implemented in Canada as well as other countries.
Interviews within the Nuclear Industry

Industry experts discussed the technologies involved in the production of medical isotopes and alternative ways to produce them.

Interviews within Government

Interview participants with experience of working within the Canadian government help establish why certain policies have been implemented with respect to isotope production, science and technology policy as well as how a new policy could be introduced which would lessen the current shortage.

3.3.2 Issues and Procedures

Elite interviews were conducted either face-to-face at the participant’s workplace or via telephone with 8 experts between January and March 2010. Each prospective interview participant was contacted by telephone or email to take part in this study for either an in-person or a telephone interview depending upon the proximity of the participant’s location from the researcher. Although, “we generally glean more information from face-to-face exchanges, where the interviewer can assess the personality of the subject as well as the nuances, gestures, omissions, and dynamics taking place” (Odendahl and Shaw, 2001: 308-309), given that some of the participants work and reside in provinces and countries other than the researcher’s, conducting interviews over the phone enabled those participants to take part in this study.

An interview was scheduled based on the participant’s convenience after written or verbal consent was obtained. All of the interviews were conducted by the author of this study and lasted from approximately 30 minutes to an hour and half. The face-to-face and telephone

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9 The researcher tried to contact AECL for an official/attributional comment, but was unsuccessful after repeated attempts.
interviews were a conversational exchange, digitally recorded\textsuperscript{10} and later transcribed into a Word document.\textsuperscript{11}

An interview schedule guided the conversation; it was sent to one participant in advance as he requested to preview specific questions prior to the interview. This was for a later interview which was scheduled to be 30 minutes and as such by having the participant aware of the questions gave the participant time to reflect on his responses to provide more comprehensive, well thought out information encapsulating multiple points of interest to the researcher. The shorter time span for the last two interviews was not a considerable problem given that “[t]he later interviews of an in-depth interviewing project are usually more focused on specific probes and verification of what has been learned in earlier interviews” (Johnson, 2001: 112). The previous longer (typically one hour to an hour and half) interviews covered both general and specific inquiries as “early interviews will embody much more “grand tour” questioning…than later interviews, which tend to be more focused on checking out and verifying research observations, analyses, and presumptive findings” (Johnson, 2001: 114).

3.3.3 Ethical Issues

The researcher informed the participants of the objectives of the investigation to ensure they adequately understood the nature of the study; each participant knew the research aims and his or her role in the study.

The participants were informed that the information given during the course of the research would be confidential in that they would not be personally identifiable, unless (a) the interview was conducted over email in which case confidentiality of identity could not be

\textsuperscript{10} All participants agreed to be electronically recorded, however, due to a malfunction in recording equipment, one interview done via telephone was not adequately recorded and so the notes taken were used in data collection. However, the participant signed off on the researcher’s notes to verify their accuracy. Another interview was not recorded, but notes were taken to verify the researcher’s findings.

\textsuperscript{11} Since the transcripts total over a hundred pages, a sample transcript is provided in Appendix G.
guaranteed since email is not a confidential medium and/or (b) they expressively wished to have their name used. Their respective field(s) of expertise is made known in order to establish their credibility as experts. All of the face-to-face and telephone participants agreed to have their name and title used as well as agreed to follow up questions over email if required.

Participation in the interviews was voluntary. There were no risks involved in participating in this study, beyond those risks encountered in everyday life. All participants were given the right to withdraw retrospectively any consent given, and to require that their own data, including recordings, be destroyed up until thesis submission to the library. Furthermore, participants were given the right to review, comment on, and/or withdraw information prior to the project’s submission; any direct quotes were made available for review if the participant so desired. Six of the eight participants requested to view quotations prior to publication; no retractions were made from interview data and analysis. Lastly, a written or verbal description of the nature of the investigation and key findings were provided to all participants, at the end of the study, in the form of an Executive Summary before publication to complete participant’s understanding of the study.

### 3.3.4 Thematic Analysis

An “interpretation” of the interviews was conducted in the analysis. A researcher employing qualitative methods “cannot study individual cases devoid of their context in a way that a quantitative researcher often does” (Robson, 2002: 179). This is because the individuals who took part in the interviews are providing their opinions which are shaped by their backgrounds and their place of employment will influence their responses. This framing of the interview data is applicable to the researcher conducting the interviews as well as the participants. This is to say that, “[t]he interviewer, like the respondent, participates in the interview from historically grounded biographical as well as disciplinary perspectives. Biographical perspectives may frame entire analyses or affect the selection of illustrative quotes” (Warren, 2001: 97). The
researcher acknowledges that the production of information is socially constructed within the interview as it is in any conversation. Discussions with the thesis supervisor have helped to situate the knowledge within the academic and policy context.

The analysis provides an interpretation of data obtained from the interviews. These are presented as “themes.” Transcripts of each interview were made by the researcher and analyzed to “identify connections and patterns, to make systematic comparisons, and to develop interpretations” (Pope, van Royen and Baker, 2002: 150), all of which are supported by quotations from the transcripts. Thematic analysis “relies on systematic and rigorous searching of text for categories and themes. These categories and themes are collected together, compared, and re-analysed to develop hypotheses or theoretical explanations” (Pope, van Royen and Baker, 2002: 149). When conducting this coding analysis the researcher gives consideration to the actual words used, their context and the internal consistency (Pope, van Royen and Baker, 2002).

Each theme is organized as follows. An argument pertaining to a theme is given, evidence is provided along with the implications and a conclusion is drawn relating the particular theme to the policy problem and/or research question(s). Thematic analysis is a subjective process in that the researcher is integrally involved in the process of data interpretation (Warren, 2001). “[E]ach research project involves the observer or interviewer as an active sense maker and interpreter of what is seen or heard in the research context” (Johnson, 2001: 105). Likewise, “[e]ach inevitably depends on the researcher’s own standpoint and place in the community, as well as his or her own self-understandings, reflections, sincerity, authenticity, honesty and integrity” (Johnson, 2001: 105).

Various production methods for generating medical isotopes, shortages and how to elevate the need for medical isotopes were the primary data that was sought. The conclusions identify substitute isotopes and alternative ways to produce medical isotopes and as a result present ways to secure supply of a staple of modern medicine and other ways to diagnose and
treat diseases with the use of isotopes. The possible implications for individuals and communities are reduced isotope shortages and therefore reliable supply for diagnoses and treatments improving patient’s health as well as greater global nuclear safety.

3.4 Secondary Data Collection

3.4.1 Statistical Data Collection

Data from the OECD’s Nuclear Energy Agency (2005) was gathered, analyzed and used in the background to show how many nuclear reactors and linear accelerators there are worldwide, which type of isotope each produces and whether the isotope(s) can be used in nuclear medicine. There are 54 reactors and 273 accelerators in the report, of which only a handful produce the highly sought after isotopes of Mo-99 and Tc-99m. Statistical data provided for each country enables the researcher to establish how production is currently carried out and is used in the policy options section to examine how easily production could be converted to accelerators. The data is publicly available and accessible via the internet.

3.4.2 Rationale for Case Study Selection

Since, “[i]n-depth interviews rarely constitute the sole source of data in research” (Johnson, 2001: 104), the case study adds another dimension of analysis. From the literature review and elite interviews the researcher learned that conversion to LEU is not only possible, but necessary for future uranium-based production. Interview participants posed the question of why Canada could not convert its production, either in the past or in the future. The answers could not be found in a review of the literature. Information was needed on LEU conversion to substantiate findings from interviews and to fill in gaps due to missing information from the interviews. The case study aims to attain that information. Data triangulation is used to look at the overall consistency of findings.
Case studies also provide information and analysis of policy options and instruments implemented in other nations that can help gauge their effectiveness and applicability to Canada. “[C]ase studies…are generalizble to theoretical propositions and not to populations or universe. In this sense, the case study…does not represent a “sample,”…[the] goal [is] to expand and generalize theories (analytic generalization)” (Yin, 2003: 10). Weaknesses of case study are the limit of variables or themes that can be analyzed for particular cases given a lack of information available.

The researcher had originally intended to examine the 5 countries which account for a combined total of 95 percent of production along with Argentina and Australia as the specific cases of investigation. Various aspects of medical isotope production were identified as factors. These were to be examined with data collected for each factor for each country, and then an overall comparison was going to be made between the countries. The differences in LEU and HEU production being a result of particular variables within a country. However, that was not possible due to lack of documentation. The analysis was done instead by comparing Canada to a particular country with respect to a specific factor, and then another comparison was made between Canada and another country for a different factor. Various aspects of production in Australia, Argentina, the U.S., Belgium and South Africa were made in relation to Canada’s production of medical isotopes. Similarities, in general, between the cases (countries) range from parliamentary structure to geographical. This allowed the researcher to look at different factors influencing production. The use of these cases is particularly helpful because it allows the researcher to make a comparison between some of the major producers and those who have moved towards production methods not using HEU. In the end, this was useful because lessons learned can be put into policy options.

Due to non-proliferation agreements and security concerns, moving away from the use of HEU in either reactor fuel or targets should be a consideration with respect to medium and long-
term policy options. A comparison was made in hopes of identifying best practices that may be applicable to Canada. The case study focuses on examining specific policy criteria in national and international security as well as providing valuable information on LEU production for generating medical isotopes.

All of the information gathered for the case study was publically available. For example, Australia’s medical isotope production was selected for investigation using information primarily from the Australian Nuclear Science and Technology Organization (ANSTO). Independent variables (i.e., themes) were selected from the literature and expert interview findings.

**Countries – Justification for Case Inclusion**

Canada, Australia, Netherlands, France, Belgium, South Africa and Argentina were the original 7 cases studied. Five of these countries’ combined production accounts for 95 percent of the global supply of medical isotopes. The production in two additional countries – Australia and Argentina – although combined only account for approximately 1 to 3 percent of global supply, are compared to the 5 other cases. The justification for including these 7 countries was due to the fact that they account for nearly all Mo-99 production and Argentina and Australia were added because they are the only countries employing LEU throughout their entire production processes. Australia was selected as a case since it has the world’s only commercial production of medical isotopes using low enriched uranium; while Argentina’s production is very small, it was the first to use LEU throughout the entire production process. The case study was modified to 6 cases – Canada, Belgium, South Africa, the U.S., Australia and Argentina. Argentina and Australia were included because they are the only countries employing LEU in their production processes, while South Africa and the United States are examining LEU conversion of their reactors and Belgium is planning to convert its fuel to LEU in the future. Another reason for the inclusion of these cases was that documents were readily available for each of them.
Table 2  Summary of Case Study Justification

<table>
<thead>
<tr>
<th>Countries</th>
<th>Reactor</th>
<th>Percentage of Global Supply</th>
<th>Target Enrichment Type</th>
<th>Age</th>
<th>Inclusion in Final Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>NRU</td>
<td>31%</td>
<td>HEU</td>
<td>53 years (1957)</td>
<td>Yes</td>
</tr>
<tr>
<td>Australia</td>
<td>OPAL</td>
<td>1%</td>
<td>LEU</td>
<td>3 years (2007)</td>
<td>Yes</td>
</tr>
<tr>
<td>Netherlands</td>
<td>HFR</td>
<td>33%</td>
<td>HEU</td>
<td>49 years (1961)</td>
<td>No</td>
</tr>
<tr>
<td>France</td>
<td>OSIRIS</td>
<td>8%</td>
<td>HEU</td>
<td>44 years (1966)</td>
<td>No</td>
</tr>
<tr>
<td>Belgium</td>
<td>BR2</td>
<td>10%</td>
<td>HEU</td>
<td>49 years (1961)</td>
<td>Yes</td>
</tr>
<tr>
<td>South Africa</td>
<td>SAFARI-1</td>
<td>13%</td>
<td>HEU</td>
<td>45 years (1965)</td>
<td>Yes</td>
</tr>
<tr>
<td>Argentina</td>
<td>CNEA</td>
<td>1%</td>
<td>LEU</td>
<td>8 years (2002)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States</td>
<td>MURR</td>
<td>0%</td>
<td>HEU</td>
<td>---</td>
<td>Yes</td>
</tr>
</tbody>
</table>

3.4.3 Proposed Data Analysis

Comparisons between Canada and other countries was made in terms of the various factors identified to contribute to a country’s decision to convert to LEU. Factors included cost, research into the feasibility of conversion, age and whether the country had signed a non-proliferation agreement. Age is an important factor for LEU conversion since new medical isotope production from existing sites such as in the U.S. will require LEU. From this data, the researcher drew conclusions about the barriers to Canada not pursuing LEU conversion.

The case study is also beneficial in supporting the policy options and recommendation(s). Switching to LEU is a concern for global non-proliferation concerns and this security is one of the criteria used to evaluate policy options. The evaluation criterion of security is measured based on whether or not a production process uses HEU.
4: Elite Interview Findings

To avoid repetition and to focus on the interpretation of the interviews, the findings are presented according to the following themes: (1) extent and nature of problem; (2) effectiveness of dealing with shortages by substituting isotopes; (3) outcomes from shortages, (4) ensuring reliability by diversifying supply; (5) effects of Canada ceasing isotope production; (6) short-term solutions; (7) long-term solutions including the MAPLEs, conversion to LEU and accelerators; (8) dispute between AECL, NRCan and the nuclear safety regulator; and (9) Canadian policy.

4.1 Crisis? What Crisis? Expert Perspectives on the Extent and Nature of the Problem

The importance of assessing the level of severity of the medical isotope shortages (i.e., whether they constitute a problem or crisis) for medical interventions leads to options available and proposed. For example, if a potential crisis is averted due to physicians using different isotopes, then a solution could be to produce and utilize more of those alternative isotopes. However, if attempts to mitigate the situation have not lead to effective results, then new approaches should be considered.

The evidence gained from the interviews suggests that recent medical isotope shortages, from 2007 to 2009, had varying effects on Canadian patient care. They were most problematic in 2007 due to the unexpected nature of the shortages. As a result guidelines were put into place to deal with subsequent shortages, mitigating the impact of later shortages. Also, contracts with suppliers resulted in greater impacts on Central provinces in 2009. Rural areas were hit hardest throughout the country. Alternative isotopes aided in the shortages, but were not without problems of their own. These key findings are discussed below.
The situation was worse in 2007 than with the longer periods of the 2008 and 2009 shortages because it was unanticipated:

Never gone through that before. Sudden, totally unexpected, out-of-the-blue, loss of radioactive material. In a setting where we had never really been through that before and no one had thought out any mechanisms for dealing with it (medical specialist).\(^\text{12}\)

One medical specialist said that 2007 “was like being hit by a baseball bat over the head, unprepared and unable to defend yourself at all.”

In 2008 and 2009, the medical isotope shortages, had less effect on patient care because having dealt with the situation in 2007 there were guidelines in place to deal with possible future shortages, and due to the contracts with various distributors the impacts varied greatly across Canada. The guidelines and policies were developed over a couple of years for the more efficient use of medical isotopes and will likely continue on even when medical isotope supply stabilizes. The guidelines – new policies and procedures developed in 2007 recommended the more efficient short and medium-term use of medical isotopes. These recommendations were to (1) switch over to thallium-201; (2) to lower the dose per procedure; (3) to increase the scanning time; and (4) to consider using Iodine-131 more frequently as compared to technetium for Iodine assessment.

One doctor noted that “by moving to thallium you reduce the need for technetium-based isotopes by 50% so that was a big savings that got us thought the crisis in 2007 and 2008 again.” All of the medical professionals consulted, although in different regions of the country, confirmed that the policies put into effect with respect to the 2007 shortages aided in the continuation of patient care in the 2009 shortages.

The shortages from 2009 to early 2010, had varying impacts across Canada. Western provinces had contracts with a European reactor, while Central and Atlantic provinces were relying on the Chalk River reactor for isotope supply. Thus, when the Canadian reactor was

\(^{12}\) All of the medical professionals interviewed for the study specialize in the use of medical isotopes and nuclear medicine.
unexpectedly shutdown, central and eastern regions were affected more severely. Primarily, Western provinces were able to cope, while Ontario, Quebec and the Atlantic provinces were hit hardest. British Columbia and Alberta faired better due to the contracts set up with different producers:

In Alberta and BC there was a larger market share with Covidien – a company that obtained its medical isotopes from the Petten reactor in the Netherlands – and as such has been able to keep its shipments of technetium and molybdenum going into those areas. So, in Alberta you say, “What crisis?” Whereas, the provinces that had their contracts with the Canadian reactor at Chalk River were decimated by the reduction or the stoppage of medical isotope production because now we had to scramble to find sources of medical isotopes which BC and Alberta didn’t have to (medical specialist).

As Quebec, Ontario and the Atlantic provinces relied predominately on the Chalk River reactor, its closure meant “the ability to have medical isotopes in those provinces pretty much dried up over night” (medical specialist).

There was also a variation in the negative impact of shortages within provinces, where the larger urban centres were less affected whereas community outlying hospitals were most compromised. The lack of supply meant encouraging more efficient use of medical isotopes and so larger, urban areas where they are more likely to be used were supplied more frequently than rural centres which have fewer patients. And,

[s]o not only was there patchwork across Canada of impact, there was also a patchwork within each province (medical specialist).

Any policy option will have to consider whether it will be able to address the issue of proper medical care reaching rural areas.

Despite these problems, hospitals continued to cope relatively well in maintaining patient care. Some interview participants suggest that the impact of future shortages may be minimal in urban areas such as Vancouver with other events such as the Winter Olympics likely to cause more problems for patients receiving adequate medical attention as technologists as well as
patients struggle to reach hospitals. At a medical level, problems caused by shortages have been dealt with effectively as hospitals always employ triage in terms of patient management. This resulted in the rescheduling of procedures (at most delayed by one or two days), but no cancellations (medical specialist). Other ways of coping with shortages were revealed in the interviews. Concerning cardiac diagnosis and treatment, time constraint imposed by the use of thallium (when the patient exercises first) Vancouver General Hospital (VGH) switched to a one day protocol from the more usual two days. At VGH, the amount of activity (isotope) was reduced. By reducing the amount of activity for a given cardiac study by imaging for a longer period, more patients can be treated with the same overall amount of isotopes. This means that patients receive reduced radiation, but needed to be scanned for a longer period of time which means that on the same amount of time with the same technologist and the same camera, fewer studies are possible. This leads to an extended workday demanding more medical staff time, on the part of both technologists and doctors, and hence is more costly as well. Alternatively, greater efficiency in patient scheduling needs to be implemented (medical specialist).

An industry expert pointed out that “the nuclear medicine community screamed wolf too loudly” in 2007. This demonstrates the need to effectively deal with shortages by implementing new policies. The impact from the 2007 shortages is not as grave as it could have been:

They were able to manage. It’s not a good situation, but some of the proponents are yelling too loudly, sounding hysterical, and it’s a grave situation, but not a hysterical situation (industry expert).

By making a situation sound worse than it really is results in the loss of credibility. Maintaining credibility is important because the nuclear medical community should be consulted when there are isotope shortages (as discussed earlier in the Background section of this study). In 2007, experts were consulted by the Minister of Health, eventually leading to the opening of the NRU against the advice of the nuclear regulator. Speculation of the severity of the shortages’ effects was given as dire and worse than the situation actually was.
Expert interviewees agreed that the situation would worsen for all regions across Canada in late February and March 2010 with the planned 6 month shutdown of the Petten reactor in the Netherlands on February 19th. This means that the two largest reactors for medical isotope production – Chalk River and Petten – will close simultaneously for many months. It is likely that Canada will experience a crisis in terms of the shortage of available medical isotopes throughout the country as centres will not be able to keep up due to other suppliers, such as South Africa, having already expanded their production significantly and not being able to contribute more. Various medical specialists noted:

So, for those provinces that did not feel the brunt of the medical isotope shortage initially, they will begin to feel it as of February 19th (medical specialist).

The fragility of the system is now evident by what’s going to happen March and April of this year (medical specialist).

We have a problem now, but it will turn into a crisis at the end of February 2010 raising concerns about patient access (medical specialist).

All of the participants reported that the current situation which began in 2009 caused a problem for the diagnosis and treatment of patients, although the extent of this problem varied throughout the country. Hospitals were able to cope with longer shortages in 2009 and early 2010 by substituting other medical isotopes for the traditional technetium and because the recommendations/policies that were put in place with the 2007 shortages. The effectiveness of these are examined next.

4.2 Making Do: Substitute Medical Isotopes and Lack of PET Technology

A range of substitute medical isotopes were identified in the interviews. The three most widely used substitutes for technetium-99m are iodine-131, thallium-201 and fluorine-18. A problem with the solutions currently being employed is that only certain isotopes can be used in
lieu of technetium and they are not as effective. Iodine, for instance, cannot be used to look at the heart or bone at all as it is a completely different type of imaging agent.

Iodine-131 is used predominately for the assessment and treatment of thyroid cancer, attached to other molecules to treat certain other specific niche cancers. But for the general purpose of cardiac assessment or the general assessment of lung cancer, breast cancer, colon or renal cancer, Iodine-131 will not have any use (medical specialist).

Tc-99m is generally not replaceable, although some have replaced it with thallium for cardiac studies (medical specialist). Vancouver General Hospital has not been relying on thallium for their heart studies. A medical specialist explained:

We’ve chosen not to [use thallium-201 and fluorine-18] because we feel it’s not quite as useful and we’re not particularly set up to do it that way…We’ve done other things to try and get by.

In Ontario, the main substitute isotope is thallium-201. For example, in Ontario they…do about 12,000 heart scans a month and about 9,000 bone scans a month. In Ontario we were able to reduce the need for Tc-99m-based agents by about 50% if we converted the majority of our heart studies over to Thallium-201 (medical specialist).

Thallium-201 was the main heart imaging agent from the 1970s to the 1990s. It is a very good agent, but it has some problems, particularly with radiation exposure:

There is a higher radiation exposure to a patient using Thallium, still within accepted levels, but higher than if we using Tc-99m agent (medical specialist).

In addition, it is not as user friendly meaning that you cannot scan as many patients per day as with Tc-99m, so waiting lists tend to become longer (medical specialist).

Fluorine, on the other hand, while a better imaging agent than technetium, cannot be widely used in Canada due to a lack of PET scanning equipment – fluorine only works with PET cameras:

Unfortunately in Canada there is such a limited installation base for flourine that the impact on overall patient care will be minimal at best because Canada has
taken a stance that limits PET development than in Europe or the U.S. for that
matter. And so Europe and the United States are in a better position to use
fluorine-18 than Canada is (medical specialist).

A doctor noted that Fluorine-18 “…is good for certain tumours, so it would have a targeted
impact on certain patients, but not all patients.” Quebec has the majority of PET cameras so they
have been better equipped to deal with the shortages. While in provinces, such as BC, some
centres have had good access to PET imaging and availability of fluoride which can replace some
of the bone scanning done with technetium (medical specialist). Replacing Tc-99m with F-18
can provide a bone scan with a PET scanner. To deal with the lack of PET cameras in BC, excess
flow from the greater Vancouver area goes to Washington state as they have 10 PET scanners
there (medical specialist).

Fluorine gives a better study, however, no one in BC is using it: “There’s only one PET
scanner in BC so it was not possible” (medical specialist). PET scanning is better even though it
does not yet have the wide range of radio-pharmaceuticals available (medical specialist), however
it cannot be used for all diseases:

So, with PET you have been able to move some of your patients over to obtain a
better understanding of their disease in a time of medical isotope shortage. Now
that doesn’t mean nuclear medicine should be replaced by PET scanning in its
entirety without being an inappropriate use for PET because there are many
aspects of medical care that routine nuclear medicine procedures play a vital role
which are not cancer related (medical specialist).

The utilization of PET technology contributes to how well hospitals are able to cope with
shortages:

[Quebec’s] been able to cope a little better because of the larger PET installation
base as compared to Ontario which has a large PET installation base, but the
most underutilized PET programs in the world (medical specialist).

Ontario has a significant problem with PET technology. As an example, Manitoba uses PET
scans more often than does Ontario. Manitoba has one PET scanner, while Ontario has 10. An
interviewee pointed to the role of politics and its effect on patient care for Ontario’s lack of PET
equipment. With respect to the underutilization of PET technology, one medical specialist commented:

Ontario, being the prime example of political interference in an establishment of allowing access, allowing patient, to innovative technologies.

He was referring to how medical equipment decisions are made at the provincial level and are driven by costs. An industry expert raised the issue that PET has much better resolution, but is more expensive and in Canada there may be 1000 gamma cameras across the country, whereas there are only 20 to 30 PET cameras.

A reason for the lack of PET equipment utilization is that the entire field of medical isotope production is built around Tc-99m. The modern generator relies on the fission of U-235 (industry expert). Also, Canada has been a late adopter of technology compared with the rest of the world (medical/governmental specialist). Many doctors agreed that it should be examined more, but that it is a provincial decision.

### 4.3 Outcomes From the Shortages

While it is widely believed that the impact of the recent medical isotope shortages from 2007 to 2009, thus far, has not resulted in any patient deaths in Canada according to the medical specialists interviewed, there have been negative outcomes from the shortages: (1) there has likely been an effect on morbidity rates; (2) patient care has been adversely impacted; (3) a possible negative effect on employment for technologists; and (4) Canada has lost respectability in the business of medical isotope production. A positive outcome from the shortages is that other countries have begun production for their domestic needs.

One outcome from the shortages is a likely effect on morbidity rates. In general, they are likely to have increased with the lack of medical isotopes to conduct procedures to obtain a proper patient diagnosis and to arrive at a diagnosis sooner. Also, another negative impact from
the lack of preferred medical isotopes is the effects from using alternatives for the diagnosis
themselves.

There are patients that are not getting the diagnosis they should be getting; they are using other techniques to be diagnosed. These can require more radiation, more CT and they may not be as informative – might not be able to pinpoint the problem (industry expert).

A patient might come back later and find out that what was missed before is now progressing.

In my perspective, it’s probably the morbidity meaning the impact on, not people keeling over and dying, but the lack of proper information (industry expert).

There is no doubt that there are some diagnoses that are unequivocally made earlier with nuclear medicine tests (government/medical specialist).

People might be getting more sick and could have been treated more effectively and sooner. This stems from people not getting the most active, most cost-effective, clinically effective tests as early as they might (medical specialist).

Nuclear medicine gives specific, unique types of information only achievable through medical isotope assessment which is why nuclear medicine continues to exhibit a growth rate (medical specialist). And you are usually achieving the information with CT at a higher radiation level and a higher potential death rate because the X-ray contrast agent that has to be given has a death rate associated with it (medical specialist). Whereas, in nuclear medicine you are able to obtain or assess disease at a lower radiation exposure safely – no one dies from a nuclear medicine procedure – and obtain information at a earlier stage as compared with those findings of a CT or MR (medical specialist).

You get a false sense of security, in the sense, “Oh, I can go have a CT,” but it still may not give you the information that a routine, bread and butter, nuclear medicine scan will give you (medical specialist).

While people have always gotten CTs and MR scans, the reason there are three types of tests is that the CT and MR are not able to answer all of the questions (medical specialist).
Another outcome of the shortages is a reduction in the quality of patient care. Patient care is compromised when lack of medical imaging reduces the reliability of conducting emergency procedures. One participant explained that there have been individuals who could not have a CT scan, but had a blood clot in the lung or who were bleeding from the intestines. These are the two types of situations that are really urgent in a nuclear medicine environment because of the high death rates associated with patients with those conditions. Of his own experiences, the interviewee said:

In my own hospital here, there were days when patients could not get the appropriate test available because there was no isotopes available. Yes, patient’s lives were placed at risk as a result of the shortage, again more pronounced at the community hospital setting, but still here (medical specialist).

One medical specialist remarked, “the physicians of patients had to make decisions on best treatment management without having all of the information available that would have been considered the standard of care.”

A third outcome from the shortages might be an effect on employment. Since the shortages in 2007 and given the future of domestic medical isotope production is uncertain, this may have an effect on people choosing nuclear technician work as a career option (medical specialist). The situation is better from the medical perspective since many doctors are trained in dual certification usually in internal medicine or nuclear medicine (medical specialist). There is concern that jobs will not plentiful as they would be as if Chalk River were up and running. In addition to the technologists required in hospitals, scientists are required to work with the technologies themselves at places such as TRIUMF. There is no information available with regards to basic scientists entering or not entering nuclear physics, however, human resource considerations will not affect policy options significantly given that all of the technologies will require some scientists.
A fourth outcome from recent shortages is that Canada no longer has respectability in the medical isotope business. From a global perspective:

I think we’ve destroyed our credibility in the world. Canadian prominence in the radioisotope world is over…We can’t get two branches of government to collaborate in an important sort of thing like medical isotope supply in 2007. And we can’t get two reactors that we said would be easy enough to make and to produce and put all the money in and we can’t get them to work (medical specialist).

The implication is that with the latest shortages, the U.S. has decided to begin its own domestic production of medical isotopes, breaking off any reliance on Canada for future production. This will affect decision making with respect to how much production, if any, is needed in the future in Canada.

This points to a fifth impact from the shortages – the response of other countries to pursue domestic production of medical isotopes, thereby ending reliance on Canada. Alongside the U.S.’ move to set up their own independent medical isotope production capabilities, South Korea is doing the same as are some European countries such as Poland (medical specialist). Australia now has independence of supply. So, without further government action, Canada will move from world leader to one of the few major countries that will be dependent on other countries for its own medical isotope supply. “Canada has gone from a leading supplier to a net importer” (medical specialist). It will take 3 to 5 years before the U.S. can start domestic production with the University of Missouri reactor and the Babcox & Wilcox reactor (independent industry expert; medical specialist). This shows the importance of getting Chalk River up and running and extending its license up to 2016, possibly even beyond that if possible, since it will take the other countries many years to get their independent medical isotope supplies going. This is important for Canadian patients because “you want to ensure that the other countries have access to supply capabilities to ensure that Canadian patients do not fall through the cracks before you close Chalk River” (medical specialist). If the federal government closes
the NRU reactor too soon and other countries are not yet capable of net exporting of medical isotope supply then Canadian patients will suffer. This means that all of the policy options developed and to be considered must include extending the license of the NRU reactor for a few years at minimum.

Any choices that Canada makes will have to take into consideration what other countries, most importantly what the U.S., will be doing over the next 3 to 7 years. There will be no need for Canadian taxpayers to fund reactors to meet world demand, if other countries will be relying on their own domestic production in the future. Any option will have to carefully evaluate what other countries are doing to obtain medical isotopes and whether they will be willing to rely on Canada in the future. It is very likely that the U.S. will have at least one reactor capable of meeting the needs of 30 percent of its market within 6 years, if not sooner.

4.4 Ensuring Reliable Supply: Geographical Placement of Scientific Infrastructure, Diversification and Multiple Production Sites

This theme concerns the issues of having a reliable long-term supply of medical isotopes after the Chalk River reactor is permanently shutdown. Various factors can ensure reliability such as building multiple production sites and the type of technology used in production. Interviewees felt that geography is a concern since production facilities should overlap in their coverage resulting in a greater guarantee that an area will be covered if production at a nearby facility is shutdown. Multiple domestic sites ensure that production can continue in Canada when one facility is shutdown eliminating the need to appeal to other countries for entire domestic supply. Production facilities, domestic or global, need to coordinate with one another and so an international agreement may be a viable option.
Diversifying Supply – Multiple Production Sites

Multiple production sites are an important aspect of guaranteeing long-term supply (industry expert). Since, if one production facility becomes unavailable, another will be able to increase production and compensate, in part, for some of the shortages. Having multiple sites, for instance, spread across Canada, enables BC to receive some, albeit, fewer isotopes if a site went offline; whereas if there was only one national source shutdown shortages would be experienced throughout Canada with back up supplies having to come from other nations.

Most participants interviewed suggested that a mix of options would be best. Availability of supply of medical isotopes is the most important issue along with diversification of supply (medical specialist).

Geography

On a global scale, geographic areas have already naturally come about in the distribution of medical isotopes when some areas experienced a loss due to a reactor shutdown. Each area would need to ensure that proper infrastructure was in place. Geographic areas could be divided for production and distribution into Canada, U.S. and Mexico; South America; Africa; Euro-Asia and Polynesia:

If you looked at it from that point you would be able to divide the world up into 5 or 6 regions and move forward with a coordinated process of isotope production and distribution (medical specialist).

Limitations of Medical Isotope Production Technologies and Resources

Interviewees agreed that linear accelerators and cyclotrons would be a viable option, however cyclotrons are better for large urban centres, whereas linacs can provide national supply more easily. Supply becomes an issue when you get 30 to 40 kilometres away from urban centres. One medical specialist suggested that once you move out of urban centres you would need to use molybdenum-based generator capability.
The other aspects to be considered are whether resources – pharmacists, physicists, engineers to run each of these accelerators – are available. The scientific infrastructure has to be in place to maintain the linear accelerators and cyclotrons on a regular basis. Considerations have to be taken for the many outlying areas across Canada that still rely on generators and molybdenum (medical specialist):

…the best approach would be to consolidate our medical isotope supply production capabilities in Chalk River as we have done now with a multi-purpose research reactor which Chalk River is. We already have the infrastructure for processing and delivery through the Kanata processing unit (medical specialist).

**International Consortium and a Regulatory Body**

By concentrating medical isotope production in a few facilities, one reactor shutdown effects the global supply of isotopes (industry expert; medical specialist). Since the costs to start new production are high and the benefits low, an international consortium for future medical isotope production could potentially alleviate these problems. Establishing a more coordinated international process for medical isotope production and delivery requires better global scheduling of regular maintenance and having plans in place to increase production of medical isotopes around the world when one of the major reactors shuts down for a long period of time.

In terms of regulation, such an international consortium could operate under the supervision of the IEA or the UN. A government official said it probably could be done and could be interesting. He warned that regulation of such a consortium should be an international endeavour, not governed by just one country. In terms of precedence, the Petten reactor decided to operate while requiring repairs for a number of months with increased safety screening and monitoring by asking the IEA for a group of experts to review that decision (industry expert).

Also, the reliability of other countries would have to be examined. As pointed out by an interviewee (see theme 3 above), Canada no longer has respectability in the business. Other countries may not be willing to work with Canada.
4.5 Short-term Solutions

Many within the nuclear medicine profession view the current shortages very differently. One doctor commented that “there is no solution to a long-term shortage,” while another asserted there is no short-term solution to the shortages. There is no short-term solution besides Chalk River coming back online to resume supply. Coping with the shortages was not viewed by some interviewees as a short-term solution given that scheduling challenges and people having to work weekends and work longer hours “can go on for a short period, but at some point the system will break” (industry/nuclear medicine expert). There is no long-term solution in that the government has not put any proposals into action. A short-term solution is the more effective use of medical isotopes, which could be done by modernizing the gamma cameras across Canada either through hardware or software upgrades to utilize the medical isotopes more efficiently. This could be started today without any research with the appropriate funding to upgrade the equipment.

Possible solutions for the long-term are examined next.

4.6 Stick with the Old or try Something New? A Consideration of Medical Isotope Production Technologies for Long-Term Solutions

Securing medical isotopes over the long-term involves careful consideration of whether to use innovative technologies or to continue reliance on reactors, such as the MAPLEs. This section examines made-in-Canada production solutions for medical isotope shortages.

In terms of long-term solutions, there have been recommendations by two expert panels concerning the development of a multi-purpose reactor for research and for Canadian patients. A new reactor is not a solution which can be implemented in the short-term. A primary concern with new Canadian reactor-based production of medical isotopes is whether the MAPLEs should be used, or if another reactor should be built.
A reluctance to try new technologies presented itself. This was to be expected from those with vested interests in reactors, especially the MAPLEs, but it presented itself with nonpartisan experts alike. One interviewee commented that:

Rather than reinventing the wheel, redeveloping distribution processes with the uncertainty of having human resources issues, I would think that the best and most capable approach would be a multi-purpose research reactor and that is what the rest of the world has done. They’ve looked at the options and said the best option is multi-purpose reactor (medical specialist).

Half of the participants interviewed for this study favoured commissioning the MAPLEs while the other half were opposed. Interestingly enough, the divide was not along professions, but for matters of personal opinion as half of the industry experts and half of the medical specialists were either opposed to or supported the MAPLE projects. One medical specialist conveyed that to him the production origins of medical isotopes was not a concern, as long as his patients had a reliable and regular supply. At the hospital or patient level, production is only a concern in that the method used to generates isotopes works.

MAPLEs as a Long-Term Solution

Arguments made for commissioning the MAPLE reactors included their proven worth as a technology, they are already built and paid for, and they constitute the most efficient way to make medical isotopes by fissioning highly enriched uranium. Most of the interview participants pointed out that there are two reports for the federal government already out. One was a medical report (Ad Hoc Health Experts Group report) dealing with the crisis and their recommendation was the development of Canadian capability for medical isotope production. And the second, was the recently released Expert Panel report for NRCan which made similar statements. Interviewees acknowledged that the federal government now has two reports saying the same thing yet has not made a decision public. The later report recommends building a new reactor,
not commissioning the MAPLEs. There are significant problems with the MAPLE reactors which need to be resolved, hence the Expert Panel’s report recommends building a new reactor.

In terms of operating the MAPLEs, interviewees discussed the issues which need addressing – safety with respect to the positive PCR, re-designing them to work with LEU and determining their capacity to supply isotopes with an independent review. The arguments for their safety changes depending on a stakeholder’s personal interests in the project. This is important to acknowledge since various stakeholders advise government on policy.

**MAPLEs and Balancing Risks**

All of the interviewees recognize that there is a problem with the positive PCR. Some suggested that the MAPLE reactors could be run at half power significantly reducing the risk for a runaway reaction (not correcting the positive PCR), while others argued the problem with the positive PCR issue should be fixed prior to their operation. The issue is framed in terms of balancing one risk with another. As one industry expert pointed out – “you are balancing a very small risk around the reactor operations and causing a potentially larger risk with the lack of available medical isotopes for diagnosis and treatment.” Another way of framing the issue is in terms of the potential risk from running the MAPLEs with a positive PCR – the balancing of risk between operating a nuclear reactor without being able to fully predict how it will run when it could be re-designed to operate with a negative PCR.

The MAPLEs could run at half power, which would be safer than commissioning them without making any modifications. At half power you still have the ability to provide the same quantities of isotopes as NRU provides. A safety case could be made for operating them with a slightly positive power coefficient of reactivity at half power and that it would be acceptable to the CNSC the Canadian nuclear safety commission (industry expert). Michael Binder, the president of the CNSC, is on record at the NRCan hearing as saying he is not opposed to running
the reactor with a positive PCR. CANDU power reactors operate that way. He would just need to see a safety case for that method of operating the reactors which was never submitted by AECL (industry expert). AECL provided 3 safety cases, when only one was required, prior to the discovery of the positive PCR and never developed and submitted a revised safety case to operate at half power with a positive PCR.

The underlying issue, however, is not whether they are safe to run as they are now, it is rather, that they do not run as predicted. Operating a nuclear reactor, even at half power to make essential medical isotopes, when no one knows what will happen, seems to be a risky policy decision, especially since the problem of PCR could be addressed:

I do understand that there are people who say you can’t operate them with positive reactivity coefficient, but the question I would ask is given what we understand about reactors why would you do that when you could probably fix it pretty easily? (independent industry expert).

Given that reactor technology is well understood, running the MAPLEs should only be considered if they are re-designed, i.e., if the positive PCR issue can be corrected. This can be overcome in multiple ways, either by making modifications to the fuel\(^\text{13}\) in the reactor or replacing the core which is the most expensive option (industry expert). These could take between 18 months to five years to implement and cost anywhere from tens of thousands to hundreds of millions depending on which solution is put in place (industry expert).

Which options to take for the MAPLEs could be assessed by an independent expert panel – it would be able to analyze the risk and come up with a suggestion about whether it is acceptable to operate them at half power for future production.

MDS Nordion has been pushing the government on numerous occasions to put together an expert panel to review all this data and to come up with the best solution, then balancing the risks (industry expert).

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\(^\text{13}\) The Korean HANARO reactor which is a MAPLE design had some problems with the reactivity coefficient after it was started up. The fuel was bowing – not maintaining its geometry – and that was causing the positive PCR. The fuel was stiffened and the reactivity coefficient was fixed (independent industry expert).
The Government of Canada has already spent years and millions of dollars trying to find out why the reactors are not operating as predicted – AECL has already had scientists come in from all over the world, e.g., from Brookhaven National Laboratory and elsewhere. The proposed expert review differs in that it will not be examining ways to solve the issue – they would not review AECL’s calculations to see if the modelling was done correctly as was done before. Rather, this would be a group of experts, potentially the IEA, to “look at the asset and see where it’s at to determine what would be required to have it operating static isotopes” (industry expert). AECL, never reviewed whether you could operate at 50 percent and make enough isotopes to make it worthwhile because at that time we were not in a shortage situation. Those types of options were not evaluated (industry expert).

Others did not recommend operating a reactor with a positive PCR:

I wouldn’t advocate running a reactor with a positive reactivity coefficient, even though at that power level you could probably get away with it (independent industry expert).

It’s a very well understood technology. I think they could design and build a core that they could have a high certainty of a negative reactivity coefficient that would work just fine in that reactor (independent industry expert).

**LEU Conversion of the MAPLEs**

Interviewees stated that running the MAPLEs at half power does not solve the problem of shortages in the short-term, it is only a long-term solution. Given that the U.S. will limit and eventually ban transporting HEU over international borders (will be phasing out HEU exports in 7 to 10 years), and that after 9/11 getting radioactive materials across international borders became much tougher (independent industry expert), if the MAPLE reactors are to be used as a long-term solution, they ought to be re-designed to run with LEU, which could also eliminate any positive PCR issues. One industry interviewee who visited the Chalk River facility as an independent consultant discussed that the use of LEU would lower the positive PCR:
One of the experiments they did which was kind of fun, and testing to try to understand the positive low reactivity coefficient, they did run the reactor with LEU target in place of HEU targets, and the LEU targets they used were just the same as the fuel in the MAPLEs, and they cut the reactivity coefficient down by about half, but it didn’t eliminate it (independent industry expert).

Re-designing the core could eliminate the problem entirely. A second reason for a re-design is that the target design in the MAPLEs is completely different than that of the targets in the NRU reactor requiring a completely different processing system. One interviewee called it “a strange design choice.” This means that whatever experience AECL had with processing HEU targets in the NRU wouldn’t carry forward (independent industry expert). There are two elements of reactors that use uranium – the fuel (which in this case is already LEU) and the target (designed to use HEU). Conversion to LEU requires re-designing the targets to be converted to use low enriched uranium by making modifications to the processing facility. Another expert said that the small low core means that if you have to start over you can, and the fact that it’s an open pool design, not pressurized, not in a field vessel, makes all this easier.

One industry expert pointed out that this needs to be done “in order to deal with the additional waste that’s produced when you’re using five times as much material as high enriched uranium” requires. With LEU conversion, for a given amount of Mo-99 you are pushing five times as much uranium through the system. So you are going to end up with more waste. This is a popular belief throughout the industry. For example, one participant discussed Chalk River’s aversion to converting to LEU based on the issue of generating more waste:

When our committee visited Chalk River, that was a big emphasis. We were out looking at big concrete canisters where wastes were stored. We were being told just how conversion is an awful thing because it would make a lot more waste (independent industry expert).

Producing more waste is not a valid argument against conversion despite popular belief amongst the industry. One participant said, “I sort of think the waste issue is, as an argument against conversion, is sort of a red herring” (independent industry expert). The industry is not
viewing the problem correctly because the storage of waste is dominated by “decay heat and criticality” and if conversion to LEU took place there would be the same amount of decay heat and criticality is easier to manage than with HEU (industry expert). In other words, “the mass of the waste is five times bigger, but the volume is no bigger when the waste is configured to control criticality” (independent industry expert). Chalk River had not been looking at it that way (independent industry expert). The one place in the medical isotope production system where weapons quality HEU accumulates is in the waste.

It is certainly possible to convert and producers are aware that it can be done, but there is no incentive for conversion as long as the U.S. does not cut off HEU exports (independent industry expert). The timeframe for conversion is 7 years (industry expert). Medical isotope distributors thought it was cheaper to lobby to have the U.S. law banning HEU export changed with the Burr Bond amendment than to convert (independent industry expert). The companies convinced nuclear medicine doctors that if they did not support the lobbying by distributors of medical isotopes, their patients would suffer from losses of isotopes. Upon realizing that producers like Chalk River, were not doing any real work to convert, one doctor who had helped get the amendment passed reflected, telling an interviewee:

‘Boy, did we drink the Kool-Aid.’ They weren’t doing any real work to look at conversion. They were taking the view that it would be cheaper to get the law changed than to convert, and [they] wanted the cheapest path (independent industry expert).

One interviewee faced “a very strong sense of hostility” to low enriched uranium production at Chalk River. Chalk River said the problem was “waste, through put, extraction yields…” The general response and mindset from Chalk River came across to an interviewee as:

‘…we know how to do it and we’re not hurting anybody and we’ve got guards and we’re secure. Our use of this HEU doesn’t pose any sort of threat that anyone should care about’ (independent industry expert).
‘Don’t need no stinkin’ LEU’ was sort of the message we heard at a few places (independent industry expert).

This hostility to conversion was evident from producers when asked about what they were doing to determine if conversion to LEU was feasible. One interview participant continually received the response, ‘Well, a lot of things, but we’re not sure we want to tell you about them because some of them are proprietary technologies we don’t want out in public’ (independent industry expert). What producers are actually doing is “pretty limited” (independent industry expert). This was evident from discovering that at some sites they said they were examining conversion, but had not even performed cold tests – building an LEU target and dissolving it.

The answer was, ‘no, we haven’t done that.’…If you were going to do any physical work looking at conversion the first thing you would do is a cold test. Because you know you don’t make any waste. It’s pretty easy, you can do it in a lab. You don’t need a hot cell (industry expert).

Arguably, AECL is being responsible if it will take 7 years to convert to LEU and NRU only goes to 2016. While lobbying for exemption makes sense short-term, converting the MAPLEs is a long-term solution to the medical isotope shortages. The South Africans have confirmed that the economics of conversion are worthwhile because they announced that they are in fact converting both fuel and targets to low enriched (industry expert). The director of the IRE reactor was opposed as well, but since his retirement, they have announced they are going to convert too.

**Expert Panel Findings**

The Expert Panel report to NRCan recommends building a new reactor, instead of repairing and commissioning the MAPLEs. It discusses the possibility of fixing the dedicated isotope facility - which is the MAPLE reactors plus the new processing hot cells that are in the MAPLEs. Most of the interviewees from industry disagreed with the Expert Panel report. One cited his frustration:
They take a very skeptical tone of whether that can be done. They categorize it as a higher technological risk than starting from scratch with a brand-new research reactor. And I just think that’s the wrong answer (independent industry expert).

Criticism stems from the report’s conclusion that a reactor which only produces isotopes is a failed business model, but MDS Nordion thought it was a fine business model in 1996 when they announced the MAPLE project and is still pushing the government to commission them.

And certainly Nordion thought that it came to an isotope production model that was a fine business model. So the question is what’s changed? (industry expert).

Another criticism given by multiple interviewees was that the Expert Panel report cites economic analyses done of the MAPLEs concluding that any reactor that does no other irradiation services is a failed business model and cannot be made to work. However, they do not provide that analysis; they simply say that was in a report done for them, “and you can’t review it, it’s not transparent” (independent industry expert). Many interviewees displayed distrust in the recommendations due to the lack of transparency in the report. Another interviewee (not from TRIUMF) commented that:

If you look at the TRIUMF report, they’re really clear about how they calculated the numbers, what assumptions are used how they came up with their costs. That same data is not available, to me at least, in the Expert Review Panel report (industry expert).

The economic considerations that this study uses for linear accelerators are taken from the TRIUMF report. No cost findings from the Expert Panel report were employed in this study.

In response to Prime Minister Harper’s announcement that Canada would get out of the isotope business, an industry expert said, “that policy statement reflects itself in the Expert Panel report.”

I still think that an even evaluation was not done. That Expert Panel report views a new from-the-ground-up reactor and rebuilding the MAPLEs reactor as medium technological risk. I don’t understand it. Construction uncertainties? Funding uncertainties? (industry expert).
Abandon the MAPLEs

There was a lack of trust in the government’s decision to cancel the MAPLEs. They announced that it would be alright because they were going to put a lot of money into extension of the NRU, extend its license into 2016 and spend hundreds of millions of dollars on NRU upgrades and maintenance without addressing how they planned to make repairs without significant amounts of downtime. One industry expert questioned the government’s decision and wanted to ask:

Is this work you can do while it’s operating? It seems unlikely. And what are you going to do to backfill isotope supply when NRU’s down? (industry expert).

Arguments against commissioning the MAPLEs were predominately based on cost and length of time to repair/re-design.

The MAPLEs are not a short-term fix. If it was decided that they could be reconfigured that is probably at least four more years work before they could be operational. And I don’t know how much money. I agree with the NRCan recommendation that if the pirate private sector wants to take it on a look at it absolutely. But this is a project that has taken what $500, $600 million of public money? And I have been told that two external reviews looked at it already (medical/government expert).

The issue of whether the MAPLE reactors ought to be a viable policy option for Canada rests primarily with whether they can run as designed and work with LEU.

Accelerator Technology

MDS Nordion has been pushing the Canadian government to commission the MAPLE reactor, but is also investing in alternate technologies because they believe that there is a place for them in the supply chain (industry expert). They are examining both linacs and cyclotrons.

An important reason for getting involved in the production of medical isotopes is the return. A government expert said that we should “look at it like a business – if we could produce a reliable supply, would there be a sufficient return to government?” He supports linacs from a
purely business model. The reliability of the reactors is a given. Those “could work, but would require hundreds of millions of dollars? Is that a good investment?” he asked. Another interviewee asserted that cyclotrons are a very interesting technology that could be a cheap medium-term fix and one that could be run by the private sector from the get-go (medical specialist).

In addition to monetary benefits, there are also benefits for patient care with using accelerator technology, particularly cyclotrons. A physician pointed out that “if we move from technetium to PET-based imaging entirely, which I think is possible over the years, you have a direct path” in terms of producing PET isotopes with a cyclotron. Cyclotrons produce, not only technetium directly, but other PET-based isotopes as well.

4.7 Politically Radioactive – AECL and the CNSC

The NRU reactor shutdown in 2007 and subsequent shortages were not due to safety concerns, rather they stemmed from the NRU’s licensing agreement and CNSC’s legal interpretation of its legislation (medical specialists; industry experts), misinformation provided to the government (medical specialist) and the unwillingness of AECL and the nuclear regulator to cooperate (government expert). The CNSC’s decision to keep the reactor shutdown resulted in global shortages of medical isotopes.

The CNSC ordered the reactor to remain closed when it was shutdown for maintenance. The reason cited was safety concerns over noncompliance with their licence agreement. The matter was viewed as one more of legality rather than safety. An interviewee explained, “It was purely a legalistic interpretation of what they had approved to do and not approved to do and what they had done and not done” (medical specialist). This interpretation was shared by many experts interviewed since the NRU had been allowed to run without the required repairs, but then was suddenly and “out-of-the-blue” not allowed to be re-started when it was shutdown for
maintenance. As such the closure in 2007 can be seen as an “administrative decision and not a risk decision” (medical specialist).

The media reports along with the federal government forcing the NRU reactor to re-open in December 2007 was said to be due to the health of people being severely affected and people dying. The government’s decision to override the CNSC’s safety recommendation gave the impression that the reactor closing down a month earlier for 4 weeks, albeit unexpectedly, was a significant problem for the health of patients. The medical experts interviewed agreed that the CNSC’s decision to keep the NRU closed resulted adversely in terms of patient care, but no one could determine at the time if it would result in patient deaths. A medical specialist spoke of the effect on his hospital remarking that “our patients were impacted in a real way,” adding “patients were being denied care. That was a major issue. Some were affected more than others.”

The doctors interviewed argued that the closure itself caused safety concerns in terms of patients not being able to get appropriate medical care. The CNSC said the closure was done to ensure people’s safety from the reactor. The closure resulted in greater lack of safety than if the NRU would have been allowed to operate. One medical specialist shared his thoughts on the issue:

In 2007, there was no crisis, no risk to human life as a result of keeping Chalk River going at that time. There was a risk to human life by closing Chalk River down and so I believe that the wrong decision was made by the Canadian Nuclear Safety Commission in 2007 by closing Chalk River when they could have done it in a different way...And it was the wrong decision to be made because it put patient’s lives at risk around the world needlessly.

Medical specialists had to take care of their patients best they could with the shortages. From the perspective of the medical community, a medical specialist asserted that, it was “seemingly so ridiculous to us on this side.”

There were detrimental consequences from the closure and as such the matter ought to have been resolved by the parties involved. Had the two bodies of government been able to
effectively communicate with one another, global shortages would not have arisen (medical specialist). An interviewee explained:

…there was a total lack of communication between these two branches – one not appropriately to the other and vice versa (medical specialist).

I don’t think anyone knows what went on behind closed doors. There was a degree of animosity between those two branches of government that resulted in suddenly everyone digging in their heels and refusing to change (medical specialist).

The situation was characterized by a former deputy Minister as a “silly fight” that should have been resolved. On a similar note, other interviewees characterized the issue as “an internal fight within different parts of government” and “a confrontation” with “[p]ushing and shoving behind the scenes.” A governmental interviewee argued that the government was not taking steps to help industry. A Deputy Minister could have solved the problem (government expert).

Most medical experts interviewed maintain that the federal government forcing the reactor to open was due to political reasons, there was no health or safety issue involved in their decision. It was in response to the CNSC’s stance that repairs to the reactor needed to be done prior to its re-opening. While some in the nuclear medicine community in 2007 said that people were dying, so the government ordered the reactor to start back up. However, those advising the government said that patient’s lives were at risk. One doctor noted that “it’s an issue that is continually vexing, to say the least. The issues that happened in 2007 were as much a political issue as a real issue. There was no reason for that to have happened in the end.” A medical specialist commented, “It is irritating when it’s a political issue” and added:

It just made Canada look so silly. Bureaucrats arguing with one another while patients were being denied care.

Many interviewees agreed that it would have been better if the CNSC, AECL and the federal government had come to an agreement. It gave the impression that the regulator does not
have independence, that there was government inference in an independent regulatory body, when the situation was more an internal fight:

I don’t think many of us saw it as a regulatory component of government being overridden by government, it was a bunch of personalities that had to be overridden by government (medical specialist).

Regulation for medical isotope is important. Anything that involves high power electricity and radiation needs some kind of regulation.

All the cameras and nuclear medicine devices are regulated by government and you really want to ensure that the public is protected (industry expert).

As one interviewee noted, the key is to balance public good with safety, without going overboard with safety. An independent regulatory body, especially for something like nuclear safety, should not be interfered with, however, this assumes that the person running it knows how to run it effectively and has a clear mandate from government. A government expert commented, “Everyone has the same objective – make sure the enterprise is as safe as possible.” One participant added that the situation has been characterized as “politically radioactive”:

All I can get when I talk to Canadian friends is that that issue is so radioactive you can’t discuss it here (independent industry expert).

4.8 Canadian Policy

In response to how decisions concerning national science policies are made, a government expert noted that scientific innovation is viewed by the government as a way to enter into the corporate world. One virtue of ground breaking research is higher performance in the private sector. And so R&D budgets are usually viewed as an “engine of future prosperity.”

Canada performs relatively poorly at supporting basic research (government expert). This is an important point for future medical isotope production – new technologies should be given R&D support; they can aid the private sector once successful. For example, cyclotron Tc-99m
production could be sold to other countries with Canada having been a leader in its innovation. The same applies to photo-fission.

In terms of moving forward with technological advances such as LEU-based reactor production, one medical expert said he did not understand how South Africa is able to move forward and Canada is not:

I see that the Australians can fix their issues with their reactors, but for some reason we as Canadians cannot

During the most recent shortages, South Africa was able to increase production from their reactor for Iodine-131. One medical specialist commented:

And right now we are relying on South Africa for radioactive iodine treatments… So we owe a great debt to South Africa which is an interesting statement because South Africa was able to do something that Canada cannot do.

This lack of Canada to convert its reactors is examined in the case study findings.
5: Case Study Findings

This case study compares the reactor production of medical isotopes within the policy context of 6 countries, namely Canada, Australia, Argentina, Belgium, South Africa and the United States.

Always considered to be theoretically possible, Australia’s production is the first of its kind and relatively new so its effectiveness and reliability were examined. Given that Australia and Canada are similar in a number of ways, the process of policy implementation might be much the same as well. This will be examined in terms of governmental procedures as well as cultural acceptance. Also, both countries rely heavily on their resource industries, in fact they house most of the global supply of LEU – in Canada, Saskatoon is the source of one-quarter of the world’s uranium (White, 2009). However, the findings showed that highly enriched uranium can solve the short-term problem of isotope shortages. This is a problem since medium and long-term solutions should take global security into consideration. This latter point relates to the literature review demonstrating that isotope production is a public policy concern in terms of national and global security.

Australia has the only commercial production of isotopes using low enriched uranium (LEU). Argentina first used LEU to produce medical isotopes, but due to the size of the production can supply their small domestic needs. The only commercial production of isotopes using low enriched uranium (LEU) takes place at ANSTO in Australia.

Issues for the reactors such as in which country it is located, the percentage of global supply it contributes to, target uranium enrichment type and age were all investigated with respect to the policy context within each country. The mechanism or underlying reason for the decision
was identified. This was done to provide information on why LEU conversion occurs in one nation, but not in another. The reasons behind the various factors help identify Canada’s aversion to conversion. Examination of the policy contexts in a particular country along with the respective production similarities and differences will yield some policy options for Canada or at the very least suggest considerations that ought to be undertaken when evaluating policy options.

This chapter is organized as follows. The case study questions investigated are presented, then the factors influencing production and conversion along with the key findings for various countries, and lastly, a concluding summation of the findings as they relate specifically to Canada.

5.1 Case Study Research Questions

The sub-questions investigated in the case study are (1) How does the organisational and policy context influence the production conversion of medical isotopes? (2) What factors underpin the efficient and stable LEU conversion of production? These are examined with respect to answering the question, why have some countries converted to LEU-based production when Canada has not? The purpose of the case study is to find factors influencing Canada’s aversion to LEU-conversion.

The first of these questions will compare the structure and internal organizations with respect to a country with AECL, CNSC, the Minister of Natural Resources and the federal government in Canada. The second question is directed at the type and number of powerful stakeholders who are making decisions. For example, there may be only one powerful stakeholder in a particular country leading to quick and efficient decision making, however, without consultation this could lead to potential problems not foreseen at the time of policy implementation.
5.2 Key Factors

The key factors selected as points of comparison for the case study are discussed here. Their definitions, how they are evaluated are provided along with the reason for their inclusion in the case study.

Percentage of Global Supply

The percentage of medical isotopes that one country produces with respect to global supply is provided to show the impact to global supply when one reactor shuts down for conversion. This factor can be viewed as showing one of the relative disadvantages for LEU-conversion.

Age of Reactor

The ages of each reactor are measured from the year of criticality, not from their initial conception or testing, since criticality is when self-sustained production begins. Argentina’s medical isotope production employing LEU is innovative and has been running for years, so it was investigated for reliability. Australia’s production of medical isotopes using the OPAL reactor is likewise innovative, but it is relatively new, so its reliability was investigated.

Policy Context

Policy context entails a number of considerations. These are points of comparison such as how a particular policy was implemented, the number of agencies that took part in the decision making process, whether they worked together efficiently or if there was tension between them and whether outside consultation was taken.
5.2.1 Why have some countries converted to LEU-based production when Canada has not?

Data from the interviews informed the researcher about the technical aspects of nuclear reactor conversion to work with LEU in both fuel and targets. This was discussed primarily in terms of the MAPLEs and the American MURR reactor in Missouri. Some interview participants raised the concern and frustration that while some countries are able to easily convert to LEU production for medical isotopes, Canada cannot. Although, experts on engineering, conversion to LEU, and medical isotope production, they could not clearly articulate why Canada has not and does not seem willing to convert given that Canada supports international non-proliferation agreements. This part of the case study answers the question, why are some countries able to convert to LEU-based production when Canada has not?

The cases for comparison are Australia, Argentina, the U.S., Belgium, South Africa and Canada. The first three are compared to Canada in terms of incentives for conversion.

All large scale reactor producers of Mo-99 use LEU fuel except the South Africa’s SAFARI-1 Reactor and Belgium’s BR2 reactor, but the former is in the process of converting, while the latter will convert when a suitable LEU fuel becomes available (U.S. National Research Council, 2009).

Conversion to LEU-based targets for production of Mo-99 requires that the producer choose how to convert based on its own assessment of cost, time, and technical practicability, where R&D will be essential for making the most appropriate selection (U.S. National Research Council, 2009). Research and development can be carried out using cold testing and radioactive tracer testing at relatively low costs in production lab facilities (U.S. National Research Council, 2009). Based on the findings from interviews, AECL said it was looking into conversion, but had not done any cold testing, which is one of the first steps in converting to LEU after analysis.
There are no technical barriers to converting Mo-99 production from HEU targets to LEU targets. Production itself is technically feasible and is being done by two producers.

So, it seems that a willingness to convert, the costs for converting and to reduce production capacity is required for conversion. Conversion to LEU-based production was not found to result in substantial savings in security costs, including transportation security costs (U.S. National Research Council, 2009). Another substantial cost to convert is in attaining FDA approval for the LEU-based Mo-99. This would take from 4 to 18 months and cost anywhere from tens to hundreds of thousands of dollars.

Australia announced in 1997, that it would fund and replace its first nuclear reactor, HIFAR. It was decided to use LEU for reasons “of nuclear security and safeguards, this is a distinct advantage over earlier nuclear reactors” (ANSTO, 2005: 1). Argentina has been using LEU-based production since 2002. The U.S. is moving towards LEU-based production once the Department of Energy can supply LEU to reactors. The DOE has been pricing HEU higher than LEU, which provides a disincentive for conversion.

The South Africa Nuclear Energy Corporation commissioned a study entitled, “A Neutronic Feasibility Study For LEU Conversion of the SAFARI-1 Reactor” with Argonne National Laboratory in 2000, which was presented at the 2000 International Meeting on Reduced Enrichment for Research and Test Reactors. They made comparisons of the reactor performance with using 90 percent enriched HEU fuel and two types of 19.75 percent (low) enriched fuel. Their results show that there is 5 to 10 percent lower thermal flux with LEU fuel than with HEU fuel. Recall that reactor flux determines isotope production capabilities. This means that conversion to LEU will not result in far fewer medical isotopes produced as commonly believed and indicated in the elite interviews.

Canada, on the other hand, has not examined LEU conversion or published any study to find out if it would be feasible. While the Expert Panel commissioned by Natural Resources
Canada stated that LEU should be required in the future, it did not examine the feasibility of converting the MAPLEs stating that it would not be economically feasible given their short life span. They concluded that although transitioning to LEU fuel has been significant progress, large-scale is still being optimized, isotope production is reduced to one-fifth of its efficiency for the same amount of uranium, and converting from HEU to LEU is costly in terms of modifying hot cells, designing new targets, poor yields and increased waste costs (Expert Panel Report, 2009). Furthermore, AECL proposed the MAPLE reactors be designed with HEU targets. This was decades after Canada had agreed to support international non-proliferation treaties.

5.3 Summary of Findings

The summation answers the questions, why has Canada not converted its medical isotope production to LEU-based production? And will Canada convert to LEU-based production in the future?

R&D might have already been done by the Government of Canada in the form of a preliminary analysis, whose findings were not made public. Physical testing for LEU-conversion has not taken place in Canada. Australia’s ability to commercially use LEU demonstrates that isotope production can move away from using HEU. Examining how Australia was able to have a LEU production of medical isotopes, allows the researcher to present such production as a viable policy option to ensure Canada’s role in reducing global shortages.

Cost is the main obstacle to conversion. The MAPLEs could be converted (requiring a target re-design). Under the contract between MDS Nordion and AECL, MDS Nordion would be responsible for paying the costs of conversion. From the interview findings, the researcher discovered that MDS Nordion views re-designing the MAPLEs as a last resort and would prefer operating them at half power as they currently are. The case study added to this assessment of costs. The U.S. Department of Energy sells LEU at a higher price than HEU. Given that Canada
receives its HEU from the United States and that the U.S. is moving towards banning all exports of HEU over international borders, if Canada continues to rely on the U.S. for uranium, it should set up an agreement before the ban takes effect, allocating pricing of LEU at the cost of HEU. This may not be possible as the U.S. could refuse to sell Canada any uranium. This points to another reason for why Canada should continue domestic production of medical isotopes and open new facilities.

Other countries view conversion more positively than Canada does. For instance, Australia views security concerns as a main reason for conversion. In addition, production levels will not be greatly reduced by conversion. Since one MAPLE reactor can provide global demand, if production was lower, it would still meet Canadian demand. The conclusions from the South African’s scientific analysis confirmed interview findings were correct.

The findings from this case study corroborate the elite interview findings that Canada has not been willing to convert to LEU due to economic disincentives associated with re-designing the MAPLE reactors. This data triangulation verifies the previous chapter’s findings.

The case study has brought up important considerations in terms of policy analysis. Reactor-produced Mo-99 using LEU is one of the policy options provided. Although employing the same technology – reactors – LEU is safer than the current process of using highly enriched uranium since it poses no security and terrorist risks. LEU-based technologies can be viewed as having a possible competitive edge if countries were to adopt policies favouring imports of LEU-based Mo-99 production.

Canada’s reluctance to convert to LEU-based production could be avoided by pursuing non-reactor-based production of medical isotopes. Such policy options are presented next.
6: Policy Options/Alternatives

There are a number of options which the Government of Canada could take, including options such as maintaining the status quo, leaving the isotope business all together, commissioning the MAPLEs, abandoning them, building a new reactor, building linear accelerators, purchasing cyclotrons, having a combination of technologies or being a part of an international consortium for medical isotope production.

All of the options assume decommissioning the NRU reactor at Chalk River. It is over 50 years old and corrosion is leading to a greater numbers of leaks occurring more frequently. The time to locate and repair the leaks results in the reactor shutting down for several months. Added to this is the time to refuel the reactor so it can start again, which is at minimum an additional 2 weeks. The time that the reactor is shutdown approximately corresponds to how long shortages last. The reactor does increase production before shutting down, but this only helps with closures lasting about a week, after which the effects of shortages are spread worldwide. Given that “any new replacement options will require significant lead time and financing to implement” (Ad Hoc Health Experts Group, 2004: 5) the NRU’s license should be extended to 2016 at minimum.

None of the alternatives employ HEU. Canada should move away HEU in keeping with its position on the peaceful use of nuclear energy and support of international non-proliferation treaties and because of the risks of reliance on long-term access to US supply.

The status quo position consists primarily of inaction on part of the federal government. As stated earlier, Prime Minister Harper announced Canada is leaving the isotope production business, but in response to the latest Chalk River shutdown and subsequent shortages, his
government is reviewing proposals for alternative production. The Expert Panel sent their report to the Minister of Natural Resources on November 30, 2009 for the purpose of advising the federal government, but there been no action on part of the government in terms of long-term commitment (it funded an expert panel to review proposals and allocated money in the recent Budget towards further research), thus the status quo position to date can be viewed as waiting for other (i.e., foreign) sources to come online. The first of the policy options below represents the status quo position given the information that is currently available or has been released by the government. It differs with respect to funding allocated for R&D into alternatives in the last Budget which is taken into account with the evaluation of options.

The following are options that the Government of Canada can choose to do with respect to the current isotope situation and anticipated future isotope shortages.

1. Rely on the NRU reactor until 2016, risking serious leaks and more closures, and then shut it down permanently without building any replacements.

2. Licence NRU to 2016, while re-designing the MAPLEs to work with LEU.


5. Fund and build 8 cyclotrons across Canada and close NRU in 2016.

6.1 General Attributes of Production, Distribution and Use of Medical Isotopes

Based on the expert interviews conducted and case study findings, generally beneficial attributes have been identified with respect to the production, distribution and use of medical isotopes. These are: (1) domestic production of isotopes; (2) redundancy in the isotope production system; (3) a nuclear safety regulatory body which is independent; (4) moving away from HEU in all aspects of production, i.e., reactor fuel and targets; (5) international coordination.
with respect to shutdowns for maintenance and (6) optimising the use of available medical resources. The first three have been discussed at length in this study. With a certain level of redundancy built into the system, an unscheduled shutdown will not result in significant shortages. The best way to ensure reliability is with domestic production. In regards to the third attribute above, the CNSC’s decision to keep the NRU reactor offline was based on their interpretation of their current mandate, but this needs to include consideration of the effects from shutdowns on the health of Canadians when assessing reactor safety concerns. The CNSC prior to 2001, used to confer with medical professionals. It needs to take account of this perspective again. The U.S. is moving towards banning all transport of HEU across international borders, so Canada should either prepare to have LEU-based production domestically or develop technologies which do not require uranium of any kind. In doing so, when faced with a shortage or problem, Canada will be able to utilize targets from the States (for uranium-based production).

There has been very good coordination between the other 4 major reactor producers and even the smaller ones, such as Australia helping out, but in the past Chalk River was the least open about their scheduling of routine maintenance.

Having better equipment and utilizing it more effectively will result in a greater efficiency and better capability to deal with future medical isotope shortages should they arise and reduce costs.

6.2 Policy Option # 1 – Status Quo

Currently, the NRU is still offline due to ongoing repairs. AECL announced in late March 2010 that the repairs would not be completed until July. The Petten reactor – the second largest medical isotope producer – scheduled for maintenance has been offline starting in mid February 2010 expecting to be closed for 6 months if all goes as planned. With the NRU shutdown, there have been resultant shortages in medical isotope availability. With the second
reactor closure, there will be significant shortages that will adversely effect healthcare not only in Canada, but worldwide as well. Hospitals are not prepared to deal with that great of a loss of Tc-99m.

Countries such as the U.S. and more recently Poland, have announced that they are moving towards domestic production of medical isotopes. If Canada decides to leave the isotope production business, it will be forced to rely on other producers. Securing supply, with an acceptable level of reliability, will become more difficult with dependence on foreign suppliers. Issues concerning the lack of supply will still be present since Europe and South Africa rely predominately on aging reactors such as the HFR in Petten, Netherlands and are subjected to shutdowns for leakages and maintenance. There are uncertainties present with regards to future sources of production in the U.S. Another concern surrounding not having domestic production is that although producers are not required to set aside a guaranteed allocation of domestic supply, countries usually supply their own citizens before shipping isotopes to other nations. As such, future shortages from international sources will result in shortages for Canada as well. A government can take extraordinary measures to deal with a situation that threatens its citizens. Recall that the Canadian government overruled a nuclear safety regulator to re-open supply when faced with the possibility of severe domestic shortages.

### 6.3 Policy Option # 2 – One MAPLE Reactor with LEU

Commissioning the MAPLE reactors with LEU is a sound technical policy alternative. One approach would be to have a group of experts who will review whether the MAPLEs can be re-designed to use LEU targets. If this goal is attainable, i.e., the MAPLEs run as predicted in the testing period, then they could be commissioned. Provided that they can be re-designed will result in the security of medical isotope supply, not just for Canadians, but globally as well. Given that just one of these reactors is able to supply the world’s needs, both would meet the redundancy attribute. If they are able to function as predicted in their design they could ensure
medium-term supply by the option of using HEU targets and operating at half power, while the new core is redesigned to work with LEU. This would be similar to how the Argentineans converted their reactor to LEU.

If the proposed group of experts concludes that the MAPLEs cannot be retrofitted or if have that option will be too costly or take longer than building a new reactor, then other alternatives should be considered. This means that this option might require spending money to only find out that the MAPLE 1 and MAPLE 2 reactors should be abandoned.

There is a variation within this option that should be addressed. For instance, one reactor could be re-designed and commissioned so the costs for maintenance over its 50-year life will be halved. However, when the reactor is shutdown for maintenance there will be resultant shortages. There is a trade-off between cost and reliability of supply. Given the policy problem, care should be taken to ensure that reliability of supply is met when crafting policy options. Nevertheless, other nations are pursuing domestic production. Given that the U.S. is Canada’s largest market for medical isotopes and they are moving to supply their own isotopes, paying for two reactors when one is enough to supply world demand is unrealistic.

6.4 Policy Option # 3 – Canadian Neutron Source Reactor

This option requires building a new reactor in Saskatchewan by the Canadian Neutron Source. Although the NRU reactor has leaks resulting in global shortages of medical isotopes, these leaks having been occurring at the end of the reactor’s life. It has been operating safely (for the most part) for over 50 years. The elite interview findings confirmed that the option of building a new reactor will cost considerably more than the alternatives.
6.5 Policy Option # 4 – Fund Photo-Fission R&D and Build a Linac

The third alternative is to conduct the necessary R&D and then build a linear accelerator using LEU and the photo-fission process. Having at least one linear accelerator will enable Canada to maintain its medical isotope supply, however a second would provide redundancy. Canada has been on the forefront of accelerator technological innovation for the past 50 years. The construction of an accelerator using the photo-fission process will allow Canada to continue to be a leader in accelerator technology, but photo-fission has never been used on a commercial scale to produce medical isotopes and is untested with respect to function and longevity.

6.6 Policy Option # 5 – A Network of Cyclotrons

The fourth alternative is to install a number of cyclotrons across Canada using molybdenum or lead targets. Although, cyclotrons can use multiple types of targets to produce technetium-99m, cyclotrons using the process employed at Advanced Cyclotron Systems Inc. based on NRC technology will be considered in this study, since this has been demonstrated to work. A network of 8 cyclotrons will ensure that national demand is met. Since they make direct production of Tc-99m, they are capable of supplying both urban centres and rural communities – the 6-hour half life of Tc-99m makes it possible to reach all patients, as has been demonstrated with current cyclotron production.

This option has already proved to guarantee supply to several major centres in Canada during the current NRU reactor shutdown. Cyclotrons have very recently (since after the start of this study) been supplying several hospitals throughout the country to help with the shortages.
7: Policy Analysis – Evaluation of Options

Evaluation criteria provide a way to assess the different aspects of policy options in decision analysis. “In order to evaluate [options], we need standards; criteria against which we measure the projected outcomes…. [C]riteria apply to judging the outcomes of alternative interventions, not the alternatives themselves” (Collins, 2005: 195). The status quo and 4 alternatives are evaluated against the following criteria (1) health outcomes, (2) equity/inclusiveness, (3) reliability, (4) effectiveness/built-in redundancy, (5) government costs, (6) patient and environmental safety, (7) global security, (8) technological feasibility, (9) political feasibility/commitment, (10) stakeholder acceptability, and (11) administrative ease. All of these are first weighted equally, and then to test the sensitivity of the analysis, governmental cost, global security and reliability are weighted more heavily because these criteria are vital to production and reducing future shortages.

In terms of weighting, if an option cannot guarantee a reliable supply of isotopes, but is, for example, an environmentally friendly option, then it should not be implemented. Not producing any medical isotopes from this moment forward is the most environmentally friendly alternative, but it does not meet the policy goals. This illustrates that some criterion are more important than others and is the basis for the unequal weighting of the criteria. A total score for each option is provided with and without the weighting, showing that the rankings with double weighting are not biasing the results in favouring a policy option that would not otherwise be chosen, instead they show the importance of the variables deemed to have greater influence on a policy option.

The criteria’s order of presentation does not carry any significance. Definitions and measurements of each criterion are listed below in Table 3. The criteria are used to evaluate each
proposed policy option with respect to the policy problem and research questions. A summary of
the results is provided in an Evaluation Matrix in Table 4 at the end of this chapter. Each option
is ranked according to Low, Medium, High and Very High. These are translated to numbers as
shown in Table 4 for easier comparison. Ranging from Low, indicating the worst, to Very High,
indicating the best, each option was ranked as follows.

7.1 Criteria Measurements and Policy Evaluation

Table 3 represents 11 criteria grouped into two categories. The ‘consistency’ criteria
evaluate the consistency of an alternative with the overall policy and research objectives, while
the ‘procedural’ criteria assess the expected performance of a given policy option on other
considerations.
### Table 3  Criteria for Policy Analysis Evaluation

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Definition</th>
<th>Weight</th>
<th>Method of Assessment</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consistency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Outcomes</td>
<td>Does a policy option aid or hinder a patient’s health? Viewed from the patient’s perspective</td>
<td>1</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Equity/ Inclusiveness</td>
<td>Does it include patients from both rural and urban areas?</td>
<td>1</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Reliability</td>
<td>How reliable is the alternative for insuring medical isotope supply?</td>
<td>2</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Effectiveness/ Built-in Redundancy</td>
<td>Can the option stop/prevent future isotope shortages? Is there a built-in redundancy in the production system?</td>
<td>1</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Government Costs</td>
<td>What are the associated expenditures to be paid by government for the option? Dollar amount.</td>
<td>2</td>
<td>- Literature Review, Back of envelope Calculations</td>
<td>Low = 4; Medium = 3 High = 2; Very High = 1</td>
</tr>
<tr>
<td>Patient and Environmental Safety</td>
<td>Relative amount of nuclear waste (if any) from each option.</td>
<td>1</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Global Security</td>
<td>Use of HEU, LEU or neither.</td>
<td>2</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td><strong>Procedural</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technological Feasibility</td>
<td>Does the technology exist? Is it readily available to implement, i.e., has been demonstrated to work on a commercial scale?</td>
<td>1</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Political Feasibility/ Commitment</td>
<td>Is the option likely to gain acceptance from the current government? Will it demonstrate political commitment on part of the government?</td>
<td>1</td>
<td>- Elite Interviews, Case Study</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Stakeholder Acceptability</td>
<td>Is the option likely to gain acceptability from the various stakeholders? Based on whether isotope manufacturing continues or is halted.</td>
<td>1</td>
<td>- Elite Interviews, Literature Review</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
<tr>
<td>Administrative Ease</td>
<td>How complex is the process of implementing, administering, monitoring and enforcing the option?</td>
<td>1</td>
<td>- Elite Interviews, Literature Review, Case study</td>
<td>Low = 1; Medium = 2 High = 3; Very High = 4</td>
</tr>
</tbody>
</table>

#### 7.1.1 Health Outcomes

Enabling patients to have better health outcomes is a central goal of this study. This criterion is important because it examines the differential effects of each policy and measures
how a patient’s health will be impacted and in what ways. This criterion is assessed through elite interviews and with supporting literature.

Patients worldwide will suffer from lack of proper diagnosis and treatment without medical isotopes. Shortages are detrimental to patient’s health. Health outcomes are determined by whether a particular option will aid or hinder a patient’s life. This is an important criterion since “[t]he impact on individual patient care must be considered and factored into any decisions that might result in disruptions of the supply of medical isotopes” (Ad Hoc Health Experts Group, 2008: 11).

Against this criterion, Option (1) ranks Low, (2) and (3) rank Medium/High, while (4) and (5) both rank High/Very High. Options (2) and (3) will supply the market when running, however, when shutdown for maintenance, they will result in a complete loss of all domestic production of medical isotopes. Options (4) and (5) both employ multiple sources of production and will be able to supply some isotopes to the market, but (4) will not be able to meet complete demand when one accelerator is unavailable due to servicing.

### 7.1.2 Equity/Inclusiveness

Equity is a primary consideration, given the vulnerable nature of patients needing medical diagnosis and treatment. In order for a proposed option to be considered equitable it must enable patients in all parts of Canada to have similar levels of access to medical isotopes, i.e., it must be inclusive.

In terms of inclusiveness, Option (1) ranks High, (2), (3) and (4) rank Very High and (5) receives a ranking of High/Very High. A ranking of Very High is given for those options which result in production of Mo-99. Since its half-life is 66 hours (6 days) it can be shipped to rural communities. Whereas, with direct production of Tc-99m, the production source must be close
to a hospital since its half-life is only 6 hours. Only cyclotrons make Tc-99m directly and they are located on site at the hospital.

7.1.3 Effectiveness/Built-in Redundancy/Reliability

Effectiveness can best be understood as an evaluative mechanism to determine whether the policy is achieving its intended goal. In terms of measurement, effectiveness can be considered achieved when the goal of the policy problem is reached, the determination of which will be assessed primarily through stakeholder interviews, previous case studies and other documentary support.

Accelerators would produce amounts of Mo-99 at several magnitudes less than a reactor, which is why a network is proposed in Options (4) and (5). So this leads to the evaluation of options being based on whether they will be able to answer the research questions – ensure reliability of supply. This is achieved through a built-in redundancy in the production system. Option (1) is Low, (2) and (3) rank Low/Medium and (4) and (5) are both ranked as High. None of the policy options can meet the criterion’s ranking of Very High, even the network of production model. This is because when one of the linacs or cyclotrons is offline due to maintenance, there will be a shortage in the amount of production than normally available. Although, the other machines in the network will be able to produce isotopes while one is shutdown, it will be better than if a reactor, the only domestic production source, is shutdown for maintenance.

7.1.4 Government Costs

Cost is a critical criterion in any public policy analysis. This criterion will help determine the cost of each option for the federal government. In this study, the economic criterion examines the short-term and long-term financial costs of each policy option, while also assessing feasibility in terms of budget constraints. The short-term is measured by infrastructure and one-time
investment costs. The long-term costs are the administration costs associated with running the policy option. Costs for the transportation of isotopes is not included, although they would represent a saving to the provincial government in Option (5). Costs for health care expenses will be reduced for patients if there are properly and quickly diagnosed and treated. Without medical isotopes to diagnosis an illness, a patient may get much worse resulting in the need for greater medical care later and at a greater cost. Costs in the policy analysis are provided in terms of the amounts for various technological options, cost savings for a reduction in health care are not provided because they are speculative and figures are not available. Governmental financial assistance to the industry and particular firms is included. This was specifically addressed in the 2010 Budget, in the sections entitled, “Diversifying the Supply of Medical Isotopes” (82) and “TRIUMF” (78-79).

The costs are significantly less for building accelerators than reactors, while pulling out of the isotope business has no direct costs. There are significant costs with decommissioning existing facilities, but since the NRU will likely be licensed only to 2016, decommissioning costs are associated with each option. Advanced Cyclotron Systems Inc. (ACSI) can establish a National Cyclotron Network for a one-time investment of $52.5 million with no annual governmental costs. The costs are much greater for just one linear accelerator. The construction costs including labour for a linear accelerator using photo-fission is currently estimated to be $125 million and to manufacture targets for irradiation, storage of radioactive waste from target processing and hot-cell facilities to recover and refine Mo-99 another $50 million. TRIUMF submitted a 5-year (2010-15) funding proposal to the National Research Council in 2009 in order to secure funds for the construction of an electron linear accelerator. Over the next 5 years, National Research Council is providing $96 million, while Budget 2010 allocated an additional $126 million over 5 years.
The estimated costs of building a reactor in Saskatchewan are between $500-750 million with the province offering 25 percent of the construction provided the federal government paid for the remaining 75 percent as well as 60 percent of the annual operating costs which are estimated between $45-70 million. The total construction costs to federal government are in the range from $375-562.5 million, while the province pays $125-187.5 million. An additional $27-42 million will be paid annually at the federal level, and $18-28 million at the provincial.

While there are no figures for converting the MAPLEs to LEU, but given that some of the infrastructure is already built and the rest, such as the hot cells, will have to be re-designed, it is reasonable to assume that the cost will be of the same order of magnitude as a new reactor, and far more than both accelerator options according to the experts interviewed.

For costs, Option (1) ranks Low, (5) ranks Low/Medium, (2) and (3) rank Very High and (4) ranks Medium. Option (1) costs nothing. Option (5) is given a Low/Medium since it is the cheapest alternative to the status quo. Option (4) will cost twice as much as option (5), but is far less than both (2) and (3). Although, Option (4) is the second least expensive, given that is has not been demonstrated to work commercially, it is a high risk option. Options (2) and (3) are the most expensive by a wide margin and require additional financial support each year going forward.

7.1.5 Patient Safety/Radiation Exposure

Patient safety is assessed in terms of the levels of radiation exposure associated with an option. It is measured by whether a patient is exposed to greater radiation than he or she would otherwise be exposed to relative to an alternative option. “In decision-making, [one must] ensure a balance between the health and safety of the public and the health outcomes of individual patients” (Ad Hoc Health Experts Group, 2008: 11).
In terms of health, Option (1) ranks Low since future shutdowns are likely and this will result in further shortages in which patients are given alternative tests, some of which expose the patient to greater doses of radiation than with the standard isotope of Tc-99m. Options (2) and (3) rank Medium, while (4) and (5) both rank High. No ranking of Very High is assigned since when each production system is unavailable there will be a shortage of medical isotopes. The extent of these shortages varies with the proposed production system – whether there is only one source for the production or there are multiple units in a network.

7.1.6 Environmental Protection

In June 2007, Canada’s Nuclear Waste Management Organization recommended a long-term strategy to deal with nuclear waste. The environmental impacts of an option are considered in terms of whether it generates nuclear waste.

Accelerators have a safer nuclear containment than reactors. Option (1) ranks Medium, while (5) ranks Very High, (2) and (3) are both ranked Medium and (4) ranks High. Although, both reactor options and the linac option uses LEU, Option (1) is ranked Medium because the nuclear waste is only generated for another 6 years.

7.1.7 Global Security/Risk of Terrorism

The determination of global security is based on whether or not the production process uses HEU. No production of Mo-99, via either linear accelerators or nuclear reactors should employ HEU because less than five percent of the HEU in the target is consumed and, in most cases, is not recycled. “The HEU in the waste is therefore still weapon-usable and has accumulated in the Mo-99 producing countries in amounts that would be sufficient to make many Hiroshima[-like] weapons” (von Hippel and Kahn, 2006: 152). Roughly 85 kg of HEU is used for making Mo-99 per year in Canada, Europe, and South Africa (von Hippel and Kahn, 2006). The reason why so much is required is because Mo-99 is produced in only about 6 percent of all
fissions of U-235. Even granted that medical isotopes use small amounts of HEU compared to basic research and that it might be costly to convert to LEU, the risks from a terrorist getting hold of HEU affect not just the country from which it was stolen, but threaten global security as well.

Not surprisingly, Option (1) ranks Very High, while (2), (3) and (4) all rank Low/Medium, and (5) ranks Low. Option (5) does not require uranium of any kind and poses no security/terrorist threat risks in that respect. Option (1) operates on highly enriched, weapons grade uranium, while (2), (3) and (4) use LEU.

7.1.8 Technological Feasibility

Reactor technology has been in use for over 50 years. The reasons for the shortages are not due to a failure on part of the technology currently being used. Rather, it quite the opposite – since the technology works for producing isotopes, it has not changed. The 5 reactors which account for 95 percent of all medical isotope production are all over 43 years old; the NRU and HFR, the two reactors accounting for 65 percent of all medical isotope production are 53 and 49 years old respectively. The reactors are old and as such have corrosion. This, in turn, leads to leaks. In terms of adopting new technologies “[p]olicy makers must balance the potential risks of premature adoption with the loss of benefits if introduction is delayed” (Wiktorowicz and Deber, 1997: 117).

The Expert Review Panel for NRCan deemed re-designing the MAPLEs as a high technological risk, more so than the building a new reactor from the ground up. Their evidence for this is based on economic considerations and is not provided in their analysis. A few of the interview participants raised this critique. Moreover, from an interview with an industry expert, it was discovered that Argentina had converted its reactor to a LEU production process by re-designing their reactor. The fact that South Africa is converting to LEU demonstrates that it is feasible.
The TRIUMF Task Force on Alternatives for Medical-Isotope Production examined accelerator-driven photo-fission technology and concluded it was the way to generate medical isotopes from an accelerator without employing HEU. However, it is has yet to be shown to be commercially viable. Whereas, cyclotron technology is currently being used for isotope production in 5 centres, in BC, Quebec and Ontario. Although, a fairly recent commercial development, it has proven to work well.

For feasibility, Option (1), (3) and (5) rank Very High, while (2) ranks High, and (4) ranks Medium. A rank of Low would have been assigned to an option had it been at a theoretical stage only in terms of development.

7.1.9 Political Feasibility/Commitment

Political feasibility is the likelihood that a political party will commit to a particular option because either it fits with their party’s policies or they want to win over public opinion. The level of commitment is ranked with respect to each option. This criterion is assessed with the following information. The Harper government announced in 2007 that Canada would be leaving the medical isotope business, however it had set aside $6 million for the Expert Panel to review proposals for alternatives/solutions to the shortages. Moreover, Budget 2010 on March 6th, allocated funding for examining alternative production demonstrating a commitment on part of the government. The government had to step in after a public outcry when the NRU reactor was shutdown in 2007. Prime Minister Harper’s announcement to leave the isotope production business is not accepted by most health care providers. The government did not take any action in 2008 when there was another shortage. It was only upon the announcement that the NRU would be shutdown for many months in 2009, that the government established an Expert Review Panel.
Not producing isotopes in Canada is probably not feasible, either medically or politically. Option (1) ranks Low, (2) ranks Medium, (3) ranks Low/Medium, (4) is Medium and (5) is High. Option (1), no action on part of the government is not politically feasible given that the shortages have resulted in bad press for the current government. This is confirmed by the federal government setting aside funds for examining alternative production in the recent Budget, this implies it might consider options employing alternative production methods which are (4) and (5). Option (5) is the only one of these proven to work commercially so it ranks higher than Option (4). Option (2) does not seem probable given that the distributor for Chalk River’s NRU reactor production, MDS Nordion has sued AECL for nearly $2 billion.

7.1.10 Stakeholder Acceptability

Stakeholder acceptability measures the practical aspects of implementing an option by considering the level of acceptability that the policy option would achieve among stakeholders; these include nuclear medicine physicians and technologists, patients residing in urban as well as rural areas, political figures (within the federal government as well as the crown corporation, AECL) and industry – namely isotope processors such as MDS Nordion. The general public is not separately evaluated, since it is only those in the general public who become sick and need medical isotopes that this study concerns. Granted that as citizens they have all paid for the repair of the NRU reactor and have been subsidizing the reactor all along, suggesting medical isotopes is a public good. As such, the general public benefits indirectly by the service being there to be utilized if necessary. The fact that not everyone will use the medical isotopes is not a strong argument against having domestic production. Furthermore, since 90 percent of all nuclear medicine procedures require Tc-99m and given that 1.5 million such procedures are performed annually in Canada many Canadians will benefit from the use of medical isotopes in diagnosis and/or treatment. Stakeholder acceptability also considers the consistency with related policies within the existing structure. This is an important aspect as it addresses the extent to which each
policy will receive political support from key decision-makers in the federal public sector. Moreover, through interviews with the key stakeholders, especially doctors who possess an intimate knowledge of dealing with patients who need medical isotopes, it will be possible to determine the support of each of the aforementioned stakeholders for the five policy options.

Physician engagement in decision making is necessary since nuclear medicine specialists provide a broad knowledge base concerning medicine, patient care, safe handling and use of medical isotopes and overall patient management (Ad Hoc Health Experts Group, 2008: 6).

Medical professionals, patients, and workers employed in the production or distribution of isotopes all want isotope manufacturing to continue. This results in Option (1) being ranked Low since it may have to be shutdown at unpredictable times and will be permanently shutdown in 2016. Options (2) and (3) rank Medium, while both (4) and (5) rank High. Reactor Options (2) and (3), when shutdown for routine maintenance will not be able to supply isotopes at all. Options (4) and (5), on the other hand, will be able to continue a smaller supply since they are in a network and can be shutdown for maintenance one at a time. None of the options can be ranked as Very High given that a shutdown, even of one unit in a network, will still result in some shortages. It is for this very reason that a redundancy requirement is necessary and evaluated separately.

7.1.11 Administrative Ease

Administrative ease is evaluated based on how easy or difficult the process of administering, monitoring and enforcing the options would be. In order to be considered administratively feasible, an option must demonstrate a level of ease with integrating within existing administrative structures such as the CNSC. A low feasibility measurement would entail a process of having new tools that are complex and timely to carry out. This criterion is measured through the feedback provided from elite interviews and literature findings.
Given the how the Canadian government overruled the safety commission, nuclear reactor Option (1) ranks Low/Medium, while Options (2) and (3) both rank Low since they will require AECL to administer the reactors and CNSC to monitor the reactors. Option (1) is given a Medium/Low ranking since it will be temporary, i.e., administrative duties will only need to be carried out until 2016 and then these will shift as overseeing the reactor de-commissioning process. Option (4) has a ranking of Medium and (5) ranks as Very High. Option (5) is given a Very High ranking since, after an initial one-time investment, it will be run entirely by hospitals with Advanced Cyclotron Systems Inc. contracted by hospitals to oversee the maintenance. Hospitals are already licensed by the CNSC to handle isotopes. Unlike Option (4), which has a Medium ranking since it will need to be monitored and regulated federally given that this option uses uranium.

7.2 Policy Options Evaluation Summary

Getting out of medical isotope production entirely will have a negative effect on Canada’s ability to have a reliable supply of medical isotopes. None of the experts surveyed supported the proposition of quitting the isotope business as a viable option. The overall score for Option (1) is 32.5. By providing a comparison with the alternatives this option demonstrates that action on part of the federal government is essential. “The fact that there is a health problem that needs intervention indicates that the existing policy is not effective and the alternatives should be explored through analysis in order to address the problem” (Collins, 2005: 196).

Option (2) faired poorly with a score of 26.5, closely resembling Option (3) which received a score of 27. Neither of these two options – re-designing the MAPLEs or building a new reactor – is likely to be implemented by the Government of Canada given that after they received the recommendations of an Expert Panel to build a new reactor, they allocated funds towards alternative, cheaper technologies.
Option (4) scored a total of 35.5, while Option (5) received a total score of 43 points. This is reasonable given that photo-fission technology is new and has not been commercially developed. Five cyclotrons are currently supplying large centres throughout the country and have demonstrated a capability to provide an alternative which is alleviating the effects from the current shortages.

An Evaluation Matrix Results summary is provided in Table 4 below. Rank of Low, Medium, High and Very High indicate 1, 2, 3 and 4 respectively (except for the cost criterion, which is reverse). The higher the total score, the better the policy option fares under the various criteria.

### Table 4 Evaluation Matrix Results

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weight</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
<th>Option 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Outcomes</td>
<td>1</td>
<td>Low = 1</td>
<td>Med/High = 2.5</td>
<td>Med/High = 2.5</td>
<td>High/Very</td>
<td>High/Very</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High = 3.5</td>
<td>High = 3.5</td>
</tr>
<tr>
<td>Equity/Inclusiveness</td>
<td>1</td>
<td>High = 3</td>
<td>Very High = 4</td>
<td>Very High = 4</td>
<td>Very High</td>
<td>High/Very</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High = 4</td>
<td>High = 3.5</td>
</tr>
<tr>
<td>Effectiveness/Built-in Redundancy/Reliability</td>
<td>2</td>
<td>Low = 1</td>
<td>Low/Med = 1.5</td>
<td>Low/Med = 1.5</td>
<td>High = 3</td>
<td>High = 3</td>
</tr>
<tr>
<td>Government Costs</td>
<td>2</td>
<td>Low = 4</td>
<td>Very High = 1</td>
<td>Very High = 1</td>
<td>Medium = 2</td>
<td>Low/Med = 3.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Safety/ Radiation Exposure</td>
<td>1</td>
<td>Low = 1</td>
<td>Medium = 2</td>
<td>Medium = 2</td>
<td>High = 3</td>
<td>High = 3</td>
</tr>
<tr>
<td>Environmental Protection</td>
<td>1</td>
<td>Medium = 2</td>
<td>Medium = 2</td>
<td>Medium = 2</td>
<td>High = 3</td>
<td>Very High = 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global Security/Risk of Global Terrorism</td>
<td>2</td>
<td>Very High = 4</td>
<td>Low/Med = 1.5</td>
<td>Low/Med = 1.5</td>
<td>Low/Med = 1.5</td>
<td>Low = 1</td>
</tr>
<tr>
<td>Technological Feasibility</td>
<td>1</td>
<td>Very High = 4</td>
<td>High = 3</td>
<td>Very High = 4</td>
<td>Medium = 2</td>
<td>Very High = 4</td>
</tr>
<tr>
<td>Political Feasibility/ Commitment</td>
<td>1</td>
<td>Low = 1</td>
<td>Medium = 2</td>
<td>Low/Med = 1.5</td>
<td>Medium = 2</td>
<td>High = 3</td>
</tr>
<tr>
<td>Stakeholder Acceptability</td>
<td>1</td>
<td>Low = 1</td>
<td>Medium = 2</td>
<td>Medium = 2</td>
<td>High = 3</td>
<td>High = 3</td>
</tr>
<tr>
<td>Administrative Ease</td>
<td>1</td>
<td>Low/Med = 1.5</td>
<td>Low = 1</td>
<td>Low = 1</td>
<td>Medium = 2</td>
<td>Very High = 4</td>
</tr>
<tr>
<td>Total Score without Weighting</td>
<td></td>
<td>23.5</td>
<td>22.5</td>
<td>23</td>
<td>29</td>
<td>35.5</td>
</tr>
<tr>
<td>Total Score with Weighting</td>
<td></td>
<td>32.5</td>
<td>26.5</td>
<td>27</td>
<td>35.5</td>
<td>43</td>
</tr>
</tbody>
</table>

Specific policy recommendations and their implications based on the above evaluation are provided next.
8: Policy Recommendations

8.1 Recommendation # 1 – Accelerating Production

This study’s recommendation is to implement Option (5) with Advanced Cyclotron Systems Inc. (ACSI) since this is the most viable, safe (in terms of both patient safety and global protection from terrorism), environmentally friendly, effective/reliable and administratively easy alternatives accepted by stakeholders. It is also one best options in terms of achieving health outcomes, technological feasibility and cost saving. By building multiple cyclotrons the criteria of equity would also be ensured. The project will take at most 3 years to complete and will cost about $52.5 million. This option also fulfills Industry Canada’s Science and Technology mandate: to foster a growing, competitive, knowledge-based Canadian economy by improving Canada’s innovation performance, developing industry and technology capability, fostering scientific research and promoting investment.

Recommendations resulting from policy analysis can be a combination of different options because the pro’s and con’s of each were evaluated. As one health policy analyst points out,

Weighing different alternatives does not necessarily mean that the policy options are mutually exclusive. Sometimes choosing one alternative implies forgoing another, and sometimes it means simply adding one more policy action that might solve or mitigate the health problem, perhaps in conjunction with other alternatives (Collins, 2005: 195).

This cyclotron network should be supplemented with research into building a linear accelerator using photo-fission to create Mo-99. A network of cyclotrons and one linear accelerator would eliminate all reliance on foreign suppliers with a built-in redundancy for domestic production ensuring national supply that can source all urban centres and rural
communities, with the cyclotrons being able to ensure supply when a linac is offline for routine maintenance. Furthermore, since the MURR reactor will only be able to supply 30 to 50 percent of American demand, Canada could continue to supply part of the U.S. market. The construction and labour costs for such a linear accelerator are $125 million, coupled with $50 million to manufacture targets for irradiation, storage of radioactive waste from target processing and hot-cell facilities to recover and refine Mo-99. The total cost for a linac project is $175 million. Over the next 5 years, TRIUMF is receiving $222 million from the federal government in part to pursue research and a commercial demonstration of photo-fission technology over the next few years.

Ideally, Canada will fund and build at least one linac, preferably more, while the United States completes and brings the MURR reactor online. Just one accelerator along with the American reactor will account for all of Canada’s needs and 30 to 50 percent of the U.S. isotope demand. By constructing additional accelerators in Canada, the entire North American market could be supplied. This paper provides a policy recommendation for Canada which aids the U.S. with the objective of increasing both isotope production and reliability of supply, which will ultimately strengthen the field of nuclear medicine and relations between the two countries. Furthermore, “the photo-fission accelerator technology for Mo-99 production is unique…and, if developed…would support Canada’s continued economic dominance in this world market” (TRIUMF, 2008); Canada could sell its designs to other countries. Lastly, with the implementation of this recommendation, Canada can continue to be on the forefront of nuclear science with an investment in linear accelerators.

8.2 Recommendation # 2 – Expanded Role of Inter-Provincial Health Technology Committee

In addition to a network of accelerators, it is recommended that the Health Technology Assessment Task Group (HTA Task Group) aid the provinces and territories in delivering health
technology by encouraging researchers to examine the optimal use of medical isotopes. Since this committee already exists, this recommendation will be relatively easy to implement into the current policy framework. The HTA Task Group would encourage the submission of proposals for projects to be funded by the Canadian Institute of Health Research (CIHR). The HTA Task Group would not provide funds directly. CIHR does not provide funding directly to research topics, such as medical isotopes, but rather funds individuals. So, by advocating for further research, funds will be allocated towards better technologies that can use medical isotopes more efficiently.

This is a cost-saving recommendation. The research projects will likely find ways to use isotopes more effectively by examining new technologies. This would reduce overall health care costs to the provincial and territorial governments. There is a strong link between research and production of medical isotopes. Currently, there is a need for further research into the usage and effectiveness of medical isotopes to diagnose and treat diseases such as cancer.

Another reason to encourage proposals for medical isotope research is to investigate why there are differences between provinces for patient care using medical isotopes such as with PET technology. For example, Ontario does not utilize PET scans as frequently as Manitoba. The underlying reason for this issue warrants investigation. The research could examine regional differences with respect to health technology delivery and effectiveness. The HTA Task Group’s implementation of this recommendation should result in a reduction of health care costs to provinces and territories. Identifying the barriers to better technology-aided assessments of patient illnesses and treatments will continue to improve the results from nuclear medicine technology.

Another outcome of this recommendation strengthening the Canadian nuclear medicine community is it might enable PET technology to be used more effectively.
8.3 Recommendation # 3 – Modify CNSC’s Mandate

The Canadian Nuclear Safety Commission’s mandate should be modified to explicitly state that effects to Canadian patient care will be taken into consideration when making decisions regarding the operation, maintenance and shutdowns of reactors and other nuclear facilities. By doing so, future conflicts can be avoided.

Currently, the CNSC’s mandate is not specific with respect to taking into account the regulation of the production, possession or use of nuclear substances when the health of Canadians, for medical reasons, depend upon such nuclear substances.
9: Conclusion and Further Considerations

The recommendations made in this study are similar to those made by two independent expert panels, however, they differ in respect to the main recommendation for production based on information that became available after the panels reported. The Expert Panel Report for NRCan recommends that a new nuclear research reactor be funded for isotope production because that would be the most cost-effective option. This study suggests that a network of cyclotrons supplemented with a linac is the cheapest option, by a large margin, while also assuring reliability, environmental protection, global safety against terrorist threats, protection of patient’s health outcomes and equity. The previous studies were published before cyclotrons were proven to work commercially. Since the demonstrated use of cyclotrons, the federal government has provided funds for alternative technologies to reactors. A made-in-Canada solution that assures a secure domestic supply of raw material was the preferred option of the Ad Hoc Health Experts Group, and the Expert Panel also recommended Canada seek domestic production capabilities.

The federal government seems to be moving away from a government-run domestic production of medical isotopes. AECL is currently for sale. Prime Minister Harper announced that Canada would cease medical isotope production, but the federal government also funded proposals to consider alternative methods and ways to secure supply. In addition, it allocated funds in the millions of dollars specifically for medical isotope R&D of production technologies, imaging technologies and for optimizing the use of isotopes in the health system. These “objectives” support my findings. Both of the previous studies agreed that Canada should continue its predominance in medical isotopes as does this study. The production of medical isotopes is a growing business opportunity (Ad Hoc Health Experts Group: 2004).
In the short-term, Western Canada will move from an ‘inconvenience phase’ to a shortage of medical isotopes, while Central and Atlantic Canada moves from a shortage to a ‘crisis’ in late February 2010. The Petten reactor in the Netherlands will be offline for 6 months starting February 19th, while the NRU reactor will not be running until at least July 2010. These two reactors account for two-thirds of the global supply of Mo-99.

With all options, the first step is to repair the NRU reactor at Chalk River and to extend its license until 2016 to secure short-term supply. The Health Technology Assessment Task Group should encourage research examining the efficient use of medical isotopes. In addition, the Canadian Nuclear Safety Commission’s mandate should be revised to specifically consider the implications of its decisions to the health of Canadians.

Long-term solutions to the NRU reactor shutdown shortages will not be available on average for 4 to 6 years. New applications of technologies such as linear accelerators using photo-fission, or reactors being converted/upgraded for commercial production of Mo-99 will not be ready until about 2014 to 2017. This study urges the Government of Canada to fund a National Network of Cyclotrons. Large-scale operations could begin within eighteen months by leveraging existing cyclotron technology and distribution centres, while all domestic market needs could be met in two to three years.

Future research into the affect of medical isotopes shortages on morbidity rates is needed to support the findings from this study. Further confirmation of problems resulting from isotope shortages will support the need to ensure a reliable and consistent supply.
Appendices
Appendix A: Isotopes Used in Nuclear Medicine

Table 5 Reactor Radioisotopes

<table>
<thead>
<tr>
<th>Radioisotope</th>
<th>Half-life</th>
<th>Use in Nuclear Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth-213</td>
<td>46 min</td>
<td>Used for targeted alpha therapy (TAT), especially cancers.</td>
</tr>
<tr>
<td>Chromium-51</td>
<td>28 days</td>
<td>Used to label red blood cells and quantify gastro-intestinal protein loss.</td>
</tr>
<tr>
<td>Cobalt-60</td>
<td>5.27 years</td>
<td>Formerly used for external beam radiotherapy, now used more for sterilising.</td>
</tr>
<tr>
<td>Dysprosium-165</td>
<td>2 hours</td>
<td>Used as an aggregated hydroxide for synovectomy treatment of arthritis.</td>
</tr>
<tr>
<td>Erbium-169</td>
<td>9.4 days</td>
<td>Used for relieving arthritis pain in synovial joints.</td>
</tr>
<tr>
<td>Holmium-166</td>
<td>26 hours</td>
<td>Being developed for diagnosis and treatment of liver tumours.</td>
</tr>
<tr>
<td>Iodine-125</td>
<td>60 days</td>
<td>Used in cancer brachytherapy (prostate and brain), also diagnostically to evaluate the filtration rate of kidneys and to diagnose deep vein thrombosis in the leg. It is also widely used in radioimmuno-assays to show the presence of hormones in tiny quantities.</td>
</tr>
<tr>
<td>Iodine-131*</td>
<td>8 days</td>
<td>Widely used in treating thyroid cancer and in imaging the thyroid; also in diagnosis of abnormal liver function, renal (kidney) blood flow and urinary tract obstruction. A strong gamma emitter, but used for beta therapy.</td>
</tr>
<tr>
<td>Iridium-192</td>
<td>74 days</td>
<td>Supplied in wire form for use as an internal radiotherapy source for cancer treatment (used then removed).</td>
</tr>
<tr>
<td>Iron-59</td>
<td>46 days</td>
<td>Used in studies of iron metabolism in the spleen.</td>
</tr>
<tr>
<td>Lutetium-177</td>
<td>6.7 days</td>
<td>Lu-177 emits just enough gamma for imaging while the beta radiation does the therapy on small (endocrine) tumours. Its half-life is long enough to allow sophisticated preparation for use. It is usually produced by neutron activation of natural or enriched lutetium-176 targets.</td>
</tr>
<tr>
<td>Molybdenum-99*</td>
<td>66 hours</td>
<td>Used as the ‘parent’ in a generator to produce technetium-99m.</td>
</tr>
<tr>
<td>Palladium-103</td>
<td>17 days</td>
<td>Used to make brachytherapy permanent implant seeds for early stage prostate cancer.</td>
</tr>
<tr>
<td>Phosphorus-32</td>
<td>14 days</td>
<td>Used in the treatment of polycythemia vera (excess red blood cells).</td>
</tr>
<tr>
<td>Isotope</td>
<td>Half-life</td>
<td>Use</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Potassium-42</td>
<td>12 hours</td>
<td>Used for the determination of exchangeable potassium in coronary blood flow.</td>
</tr>
<tr>
<td>Rhenium-186</td>
<td>3.8 days</td>
<td>Used for pain relief in bone cancer. Beta emitter with weak gamma for imaging.</td>
</tr>
<tr>
<td>Rhenium-188</td>
<td>17 hours</td>
<td>Used to beta irradiate coronary arteries from an angioplasty balloon.</td>
</tr>
<tr>
<td>Samarium-153</td>
<td>47 hours</td>
<td>Sm-153 is very effective in relieving the pain of secondary cancers lodged in the bone, sold as Quadramet. Also very effective for prostate and breast cancer. Beta emitter.</td>
</tr>
<tr>
<td>Selenium-75</td>
<td>120 days</td>
<td>Used in the form of seleno-methionine to study the production of digestive enzymes.</td>
</tr>
<tr>
<td>Sodium-24</td>
<td>15 hours</td>
<td>For studies of electrolytes within the body.</td>
</tr>
<tr>
<td>Strontium-89*</td>
<td>50 days</td>
<td>Very effective in reducing the pain of prostate and bone cancer. Beta emitter.</td>
</tr>
<tr>
<td>Technetium-99m</td>
<td>6 hours</td>
<td>Used to image the skeleton and heart muscle in particular, but also for brain, thyroid, lungs (perfusion and ventilation), liver, spleen, kidney (structure and filtration rate), gall bladder, bone marrow, salivary and lacrimal glands, heart blood pool, infection and numerous specialized medical studies. Produced from Mo-99 in a generator.</td>
</tr>
<tr>
<td>Xenon-133*</td>
<td>5 days</td>
<td>Used for pulmonary (lung) ventilation studies.</td>
</tr>
<tr>
<td>Ytterbium-169</td>
<td>32 days</td>
<td>Used for cerebrospinal fluid studies in the brain.</td>
</tr>
<tr>
<td>Ytterbium-177</td>
<td>1.9 hours</td>
<td>Progenitor of Lu-177.</td>
</tr>
<tr>
<td>Yttrium-90*</td>
<td>64 hours</td>
<td>Used for cancer brachytherapy and as silicate colloid for relieving the pain of arthritis in larger synovial joints. Pure beta emitter and of growing significance in therapy.</td>
</tr>
</tbody>
</table>

* fission product

From World Nuclear Association, 2010
<table>
<thead>
<tr>
<th>Radioisotope</th>
<th>Half-life</th>
<th>Use in Nuclear Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobalt-57</td>
<td>272 days</td>
<td>Used as a marker to estimate organ size and for in-vitro diagnostic kits.</td>
</tr>
<tr>
<td>Copper-64</td>
<td>13 hours</td>
<td>Used to study genetic diseases affecting copper metabolism, such as Wilson’s and Menk’s diseases, and for PET imaging of tumours, and therapy.</td>
</tr>
<tr>
<td>Copper-67</td>
<td>2.6 days</td>
<td>Beta emitter, used in therapy.</td>
</tr>
<tr>
<td>Fluorine-18</td>
<td></td>
<td>Tracer. Used as FLT (fluorothymidine), F-miso (fluoromisonidazole), 18F-choline. Positron emitter used in PET for studying brain physiology and pathology, in particular for localising epileptic focus, and in dementia, neuropharmacology and psychiatry studies. It has a significant role in cardiology. F-18 in FDG (fluorodeoxyglucose) is very important in detection of cancers and the monitoring of treatment progress.</td>
</tr>
<tr>
<td>Gallium-67</td>
<td>78 hours</td>
<td>Used for tumour imaging and localization of inflammatory lesions (infections).</td>
</tr>
<tr>
<td>Gallium-68</td>
<td>68 min</td>
<td>Positron emitter used in PET and PET-CT units. Derived from germanium-68 in a generator.</td>
</tr>
<tr>
<td>Germanium-68</td>
<td>271 days</td>
<td>Used as the ‘parent’ in a generator to produce Ga-68.</td>
</tr>
<tr>
<td>Indium-111</td>
<td>2.8 days</td>
<td>Used for specialist diagnostic studies, e.g., brain studies, infection and colon transit studies.</td>
</tr>
<tr>
<td>Iodine-123</td>
<td>13 hours</td>
<td>Increasingly used for diagnosis of thyroid function. It is a gamma emitter without the beta radiation of I-131.</td>
</tr>
<tr>
<td>Iodine-124</td>
<td></td>
<td>Tracer.</td>
</tr>
<tr>
<td>Krypton-81m from Rubidium-81</td>
<td>13 seconds 4.6 hours</td>
<td>Kr-81m gas yields functional images of pulmonary ventilation, e.g., in asthmatic patients and for the early diagnosis of lung diseases and function.</td>
</tr>
<tr>
<td>Rubidium-82</td>
<td>1.26 min</td>
<td>Convenient PET agent in myocardial perfusion imaging.</td>
</tr>
<tr>
<td>Strontium-82</td>
<td>25 days</td>
<td>Used as the ‘parent’ in a generator to produce Rb-82.</td>
</tr>
<tr>
<td>Thallium-201</td>
<td>73 hours</td>
<td>Used for diagnosis of coronary artery disease, other heart conditions such as heart muscle death and for location of low-grade lymphomas.</td>
</tr>
</tbody>
</table>

*From World Nuclear Association, 2010*
Appendix B: Production and Distribution of Medical Isotopes

Figure 6  Production and Distribution of Medical Isotopes

Appendix C: Canadian Medical Isotope Supply Chain

Figure 7   Canadian Medical Isotope Supply Chain

Appendix D: Summary of Medical Isotope Production Methods

(1) The nuclear fission process
U-235 → Mo-99 + other fission products
A neutron strikes a U-235 atom and fissions to produce Mo-99.

(2) The cyclotron process
Pb → Tc-99m + ...
A beam of protons generated by a cyclotron hits a target, such as lead, to produce Tc-99m.

(3) The neutron-capture process
Mo-98 + e’ → Mo-99
An intense neutron beam generated by a nuclear reactor adds one neutron to a Mo-98 target to produce Mo-99.

(4) The photo-neutron process
Mo-100 - e’ → Mo-99
An intense photon beam generated by an electron accelerator removes a neutron from a Mo-100 target to produce Mo-99.

(5) The photo-fission process
U-238 → Mo-99 + ...
A very intense photon beam generated by an electron accelerator causes a uranium target to fission to produce Mo-99.

Above diagrams for (1), (3), (4) and (5) courtesy of The Task Force on Alternatives for Medical-Isotope Production. Diagram (2) was adapted from above diagrams.
Appendix E: Semi-Structured Interview Schedule

The following questions were used to guide the expert interviews.

Topics for Open-ended Discussion

1.1. Purpose of Medical Isotopes

• What type of diagnostics are isotopes used for?
• Which diseases can isotopes treat?
• How are isotopes used? E.g., injected directed into the body.

1.2. Production

• How are medical isotopes produced?
• Where are they produced?
• Are the production methods of alternative treatments/forms of diagnosis able to compete with today’s most widely used isotopes? Yes/No.
• Where could reactors/accelerators be located? Why there?
• Do alternatives to Mo-99 and Tc-99m have the production capacity to supply the global nuclear medicine market? Yes/No.

1.3. Alternatives

• Are there alternatives to Mo-99 and Tc-99m in the diagnosis and treatment of diseases? Yes/No.
• If so, what are these alternatives?
• Have these alternatives been tested or are they just theoretically possible? Yes/No.
• Shortages compromise the global health of patients. How will alternatives be able to address this problem?

1.4. Shortages

• Why do shortages occur globally?
• Why do shortages occur in Canada?
• What can be done globally to reduce/stop the shortages?
• What can be done to reduce/stop the shortages in Canada?
• How can production be increased?

1.5. Policy

• Who makes the decision regarding isotope production?
• How are decisions concerning national science policy made?
• What are the major factors that influence Canadian medical isotope production?
• How are think tanks involved in the decision process?
• What are some policy alternatives and their implications?
Appendix F: Interview Participant Biographies

Biographies of expert interview participants and, if applicable, their employer’s role with medical isotopes listed alphabetically.

**Jay Burbee**

Mr. Burbee is Cylcotron Engineer at Advanced Cyclotron Systems Inc. (ACSI). ACSI is a world leader in the design and manufacturing of cyclotron equipment, including PET and SPECT radioisotope production cyclotrons. It manufactures and supplies complete systems for radioisotope and radiocompound production – cyclotrons to nuclear medicine markets worldwide, including the U.S., Canada, Europe and Asia. Users include hospitals, universities, research facilities and commercial distributors of medical isotopes. Customers include GE Healthcare, MDS Nordion, Cardinal Health, Brookhaven National Laboratory, Covidien, Gemelli Hospital, and Bangkok General Hospital.

**Jill Chitra**

Ms. Chitra is the Senior Vice-President of Strategic Technologies and Regulatory Affairs at MDS Nordion. She is past Vice-President, Global Research & Development and Vice-President, Strategic Technologies. MDS Nordion is the Canadian distributor of medical isotopes produced at Chalk River and TRIUMF. She has a MBA and a Bachelor of Chemical Engineering from Queen's University, and is a member of the Association of Professional Engineers of Ontario.

**Dr. Alexander (Sandy) McEwan**

Dr. McEwan is Advisor to the Canadian government on Medical Isotopes (known informally as the ‘Isotope Czar’), Chair of the Department of Oncology at the University of Alberta, Adjunct Professor of the Department of Radiology and Diagnostic Imaging, Associate Director of Research and the Acting Director of the Department of Oncologic Imaging at the Cross Cancer Institute in Edmonton. He has been recognized for his research on radioisotope therapy, novel radiopharmaceuticals, clinical trials with imaging biomarkers, radiopharmaceutical dosimetry and very low dose radiation effects in radioisotope therapy. He has been instrumental in the development of the Positron Emission Tomography (PET) Programme at the Cross Cancer Institute. He has won several awards including the Western Regional Society of Nuclear Medicine Distinguished Scientist Award for Distinguished Contributions to Nuclear Medicine. He is a member of the Canadian Association of Nuclear Medicine, the Society of Nuclear Medicine, the European Association of Nuclear Medicine, and the World Radiopharmaceutical Therapy Council as well as past president of the Board of Directors for the Society of Nuclear Medicine.

**Dr. Christopher O’Brien**

Dr. O’Brien is a physician and the medical director of nuclear medicine at Brantford General Hospital in Brantford, Ontario. He is also the President of the Ontario Association of Nuclear Medicine. It represents the opinions of the nuclear medicine community to federal regulatory agencies and industry.

**Dr. John Powe**

Dr. Powe is a physician at Vancouver General Hospital and a clinical professor in the Department of Radiology at the University of British Columbia. He also contributes to the Centre of Excellence for Functional Cancer Imaging at the BC Cancer Research Agency. Their research program is developing radiopharmaceuticals for cancer diagnosis and characterization and is also finding improved methods to
predict and monitor tumor response to therapy. The latter uses functional imaging tools such as positron emission tomography (PET) along with computed tomography (CT).

**Dr. Tom Ruth**

Dr. Ruth has a PhD in Nuclear Spectroscopy. He is a senior research scientist and head of the life science program at TRIUMF, research scientist at BC Cancer Agency and at the BC Cancer Research Centre, research professor of medicine at Vancouver Hospital, adjunct professor of pharmaceutical sciences and medicine at the University of British Columbia (UBC), chemistry at Simon Fraser University, and physics at the University of Victoria and was the director of the UBC/TRIUMF PET program for 19 years. He is a leader in the production and application of radioisotopes for research in the physical and biological sciences receiving the Canadian Nuclear Medicine Society’s highest award of meritorious status. Recognized for his expertise in the field of radioisotope production, Dr. Ruth has participated on multiple international committees, including the U.S. National Academy of Sciences, the U.S. Department of Energy, the Society of Nuclear Medicine, the Institute of Medicine’s Committee on Medical Isotopes, the NRC’s Committee on the State of the Science in Nuclear Medicine, and the International Atomic Energy Agency (where he serves as an expert on radioisotope production).

**Dr. Harry Swain**

Dr. Swain has a PhD in economic geography. He served for 22 years in the federal government, ending as Deputy Minister of Indian and Northern Affairs and later Industry. He was the Director of the merchant bank Hambros in London and CEO of its Canadian subsidiary. He joined the public policy consultancy Sussex Circle as a partner and headed its Toronto office. He chaired the Research Advisory Panel for the Walkerton Inquiry and the subsequent Ontario Expert Panel on Water and Wastewater. He has received LL.D. for contributions to Canadian science policy. He is currently Senior Research Associate at Centre for Global Studies, President and Executive Director of Pacific Climate Impacts Consortium, and Director of the Canadian Institute for Climate Studies.

**Dr. Chris Whipple**

Dr. Whipple has a PhD in engineering science from the California Institute of Technology. He is a principal in the California office of ENVIRON International Corporation, an environmental consulting firm. He has consulted widely in risk assessment involving radioactive materials for private clients and government agencies. He is a member of the National Academy of Engineering and is serving as co-chair of the Academies’ Report Review Committee. He previously served as Chair on both the National Academy of Sciences Committee on Medical Isotope Production Without Highly Enriched Uranium study as well as the National Research Council’s (NRC’s) Board on Radioactive Waste Management. He has served on and chaired numerous NRC committees, is a long-time member of the National Council on Radiation Protection and Measurements and is a member of the Board on Environmental Studies and Toxicology.
Appendix G: Sample Interview Transcript

Phone Interview with Dr. Christopher O’Brien

Researcher: Moly and technetium are used for diagnosing and treating heart ailments and various cancers, and also for bone scans. So, with the shortages, if you are using different isotopes, say fluorine or iodine, are they as good? Do you get as good results from those?

Well, with iodine we don’t use that to look at the heart or bone at all, that’s a totally different type of imaging agent. With fluorine, you’re talking about positron emission tomography. Unfortunately in Canada there is such a limited installation base for fluorine that the impact on overall patient care will be minimal at best because Canada has taken a stance that has limited PET development in this country as compared to Europe or the United States for that matter. And so Europe and the United States are in a better position to use fluorine-18 than Canada is. No, fluorine-18 is not a panacea; it is good for certain tumours, not good for other tumours, etc. so it would have a targeted impact on aiding certain patients, but not all patients.

Researcher: What about iodine, is that being used as well then?

Iodine-131 is a radioactive agent that is used predominately for the assessment and treatment of thyroid cancer. It could also be attached to other molecules which can be used to treat certain other specific niche cancers. But for the general purpose of cardiac assessment and the general assessment of lung cancer, breast cancer, colon and renal cancer, Iodine-131 will not have any use.

Researcher: What other isotopes are primarily used in Ontario right now to deal with the shortages?

Well, thallium-201 is the main one. In Ontario, we do about 12,000 heart scans a month and about 9,000 bone scans a month. We were able to reduce the need for Tc-99m-based agents by about 50% if we converted the majority of our heart studies over to thallium-201. Thallium-201 was the main heart imaging agent from the 1970s right up to the 1990s. It is a very good agent; it has some issues with radiation exposure – there is a higher radiation exposure to the patient using thallium, still within accepted levels, but higher what you would get if we using the Tc-99m agent. In addition, it’s not as user friendly – you cannot do as many patients per day as with Tc-99m, so the waiting lists tend to become longer from that perspective.

Researcher: The shortages’ impact were different in BC and AB than out East – was that due to different equipment? Can you comment on that?

It’s the contracts that were set up. Out West – Alberta, British Columbia – there was a larger market share with a company called Covidien, and Covidien was a company that obtained its medical isotopes from a reactor in the Netherlands called Petten. And so Covidien has been able to keep its shipments of technetium and molybdenum going into those areas of the country that had contracts with them. So hence, Alberta, you say ‘what crisis?’ And British Columbia, not a very big issue because of that. Whereas, the provinces that had their contracts with the Canadian nuclear reactor at Chalk River, were decimated by the reduction or the stoppage of medical isotope production because now we had to scramble to find to sources of isotopes which BC and AB didn’t have to. Now with Petten going down in February for 6 months, all across Canada, there will now be significant shortages. So, for those provinces that did not feel the brunt of the medical isotope shortage initially, they will begin to feel it as of February, as of this month, February 19th.

Researcher: Gamma cameras, PET and SPECT are used with medical isotopes. Can you provide an overview of the three? And which ones are used primarily in Ontario?
Most of the equipment is the same across Canada. The difference being in Quebec, which has the largest PET installment base. When you’re looking at gamma cameras...what we’ve been recommending, at both the provincial and national level, is that new and innovative technology should be implemented faster than they are now. This is using a new type of gamma camera, which uses a solid-state crystal which can get the same images that we’re obtaining now, but using less technetium to obtain those images so this would be an attempt to reduce the need for medical isotopes. In addition, you can also do a similar type of process using software, computer programs, to help you reduce the necessity or the amount of medical isotopes that are needed to get the same study done. So, these technologies exist today and one of the things we have recommended, both provincially and federally, is that a medical equipment fund should be established to allow a modernization of gamma cameras across Canada so they become much more efficient in their use of medical isotopes.

Researcher: If Quebec has the majority of PET, are they facing the brunt of the shortages then?

Yes, they’ve had a significant brunt, same as Ontario and the Maritimes have, and Saskatchewan for that matter. So, they’ve been able to cope a little better because of the larger PET installation base as compared to Ontario which has a large PET installation base, but the most underutilized PET program in the world. And, as an example, Manitoba does more PET scans than Ontario does. Manitoba has one PET scanner, Ontario has ten. So, that’s putting it into perspective – the impact that politics has on patient access to health care. And Ontario, being the prime example of political interference in a establishment of allowing patient access to innovative technologies. So, with PET you have been able to move some of your patients over to obtain a better understanding of their disease in a time of medical isotope shortage. Now that doesn’t mean nuclear medicine should be replaced by PET scanning in its entirety without being an inappropriate use for PET because there are many aspects of medical care that routine nuclear medicine procedures play a vital role which are not cancer related.

Researcher: In 2007, and even currently, out West doctors have said it’s not really a crisis; they’re not characterizing the situation as a crisis, they’re saying it’s more of a problem. How is it in Ontario and Quebec and the Maritimes?

Well again, because Ontario, Quebec and the Maritimes have relied predominately on the Chalk River reactor, when it went down the ability to have medical isotopes in those province pretty much dried up over night. Whereas out West, because they tended to rely more on the European reactor, they were not as impacted, as much as Ontario and Quebec were. Now that being said, there was a variation in the impact in Ontario and Quebec, where the larger urban centres tended to have the least effect whereas community outlying hospitals had the greatest impact. And so not only was there patchwork across Canada of impact, there was also a patchwork within each province.

Researcher: And how was it dealt with in 2007 and now?

Well now we’re actually a bit better off than in 2007 because 2007 was like being hit by a baseball bat over the head, unprepared and unable to defend yourself at all. And over the past couple of years, we’ve established significant guidelines for the more efficient use of medical isotopes which will probably continue on even when medical isotope supply stabilizes. In addition, the companies have obtained different contracts with the other reactors around the world that can make medical isotopes. So, you now have a greater diversity in supply. Now, even with that, none of the reactors meet the Chalk River capability, so even though we’ve been able to find other medical isotopes we are still having to use thallium-201 because the combined production of all those other reactors do not meet the production capacity of Chalk River. So, we’ve able to reduce the impact, by still maintaining a lot of our heart studies by using thallium. And with companies moving out to find different sources, such as from Australia, South Africa and some of the other European reactors, we’ve been able to maintain at least a 50% supply to the world market for medical isotopes. Now, this is going to get much worse as of February 19th when Petten also goes down. So you’ll have the two largest reactors for medical isotope production – Chalk River and
Petten – close simultaneously for many months. And, so, we are very concerned about patient access starting at the end of February.

Researcher: Australia only supplies about 4% of the world’s isotopes.

Australia, even less, probably 1%.

Researcher: Were they actually able to supply Canada?

They are now beginning to supply Canada. Their reactor was a new reactor using what’s called lowly enriched uranium and it’s one of the first commercial uses of that reactor. They found that there were a lot of problems using the lowly enriched uranium fuel targets. They were anticipating a higher yield of molybdenum which decays into technetium, but unfortunately once they started production the yield of molybdenum was much less than they had anticipated based on what they were hoping to get. And again, this is a problem when you are using a new technology, such as lowly enriched uranium. You hope you’ll get the best, but reality does not necessarily meet that. Now they’re trying to increase production with their reactor and this is a slow process. Their product, however, has been approved by Health Canada as a safe product for Canadian use. And what’s happened now is that Australia is now at least self-sufficient so that South Africa was the reactor that was supplying Australia, [and] the medical isotopes that South Africa was sending to Australia can now be put onto the world market so other countries can use [them]. And as Australia increases its production capability and fine tunes its nuclear reactor, the excess that Australia does not need will then be able to go into the world market as well. And Lantheus has a contract with the Australian reactor to distribute that product within North America.

Researcher: When South Africa was supplying Canada, did that require approval from Health Canada?

The South African product was already approved.

Researcher: And how long does it generally take to seek approval? I know that they expedited it.

They expedited it and the actual amount of time I’m not sure. I know that Health Canada moved it so that we were able to get product within a month or two, which was a very rapid assessment. A similar thing happened with radioactive element Iodine-131 because Chalk River was making a significant portion of that. And then all of a sudden the world’s supply of that dried out up when Chalk River went down. And so South Africa was able to increase production from their reactor for Iodine-131. Right now we are relying on South Africa for radioactive iodine treatments around North America. So, we owe a great debt to South Africa, which is an interesting statement because South Africa was able to do something that Canada cannot do. An interesting prospective.

Researcher: Okay, but their reactor is over 40 years old as well, so they’ll run into problems in the future.

It will. Which is the importance of having Canada move to develop a reactor capability to produce medical isotopes. There were two reports out already to the federal government. One was a medical report dealing with the crisis and their recommendation was the development of Canadian capability for medical isotope production. And the second, was [the] recently released Expert Panel [Report] which basically stated the same thing. So the federal government now has two reports saying exactly the same thing and the federal government is not moving on this. Whereas you have the United States now that has moved to set up its own independent medical isotopes production capabilities. South Korea is moving for independence as well. The Europeans are moving for independence. Australia now has independence of supply. So, of the major countries around the world, Canada will be one of the few who will be dependent now on other countries for its own medical isotope supply and so Canada has gone from a leading supplier to a net importer.
**Researcher:** With the U.S., the University of Missouri reactor will not be fully online for 3 to 5 years at least.

Yeah, and even the Babcox & Wilcox reactor is still many years away. And that’s the importance of getting Chalk River up and running and probably even extending its license up to 2016 even if not beyond that if possible because it will take the other countries many years still to get their independent medical isotope supplies going. So, you want to ensure that the other countries have access to supply capabilities to ensure that Canadian patients do not fall through the cracks before you close Chalk River. If the federal government closes Chalk River too soon and the other countries are not yet capable of net exporting of medical isotope supply, then Canadian patients will suffer.

**Researcher:** PM Harper has said that he would like to move out of the Canadian isotope production business so hopefully it won’t be until licenses have been renewed…until 2016.

Yes, but if the other counties still do not have net export capability by 2016 I hope the federal government, at that point, will put Canadian patients first and try and extend the licence at Chalk River even further until we can close safely without compromising patient care. If we close too soon, where are our patients going to get treated?

**Researcher:** What would you like to see done in terms of a research reactor or using linear accelerators or using a cyclotron?

If you’re looking at cyclotrons and linear accelerators you also have to consider you’re going to need a lot of those scattered across Canada to be able to supply [demand] and you still have an issue in terms of supplying outlying areas because what they make is technetium right away predominately. The other proponent you have to look at is, do you have the resources – pharmacists, physicists, engineers – to run each of these accelerators and I’m not sure we do. It’s nice to talk about doing that, but do we have the scientific infrastructure in place to maintain the linear accelerators and cyclotrons on a regular basis? And the other component is we do have a lot of outlying areas of nuclear medicine service across Canada that still rely on generators and molybdenum and you have to answer the question – how will you supply those areas? And so far I have not seen an answer to that. So, I still think that the best supply or the best approach would be to consolidate our medical isotope supply production capabilities in Chalk River as we have done now with a multi-purpose research reactor which Chalk River is. We already have the infrastructure for processing and delivery through the Kanata processing unit outside of Ottawa. So, rather than reinventing the wheel, redeveloping distribution processes with the uncertainty of having human resources [issues], I would think that the best and most capable approach would be a multi-purpose research reactor and that is what the rest of the world has done. They’ve looked at the options and said the best option is a multi-purpose reactor.

**Researcher:** Wouldn’t you have the same problems though, if you have one reactor and it goes offline? You’ll have shortages again after a week.

What was lacking before was a coordinated process around the world to ensure that not of all of the reactors were down at the same time. Now with Chalk River…don’t forget Chalk River has gone down numerous times for maintenance and repair over the last 40 years and it’s only for a protracted downtime that you get into problems because what they do is increase production of molybdenum prior to closing down for a week’s service so that you actually have no disruption in medical isotope supply. You have a problem if that reactor is closed for 3 or 4 weeks, then you get into major issues. And we used to get into problems because the maintenance cycles for the reactors around the world were not coordinated so that you may have had 2 or 3 reactors down at the same time and that created an issue. We are in a better understanding that we cannot have all of reactors closed down at the same time. You can still do this if it’s a coordinated world process. Your point is well taken and the MAPLE reactors were built for redundancy in the since that either of the MAPLE reactors were capable of supplying the world. And you had backups right there. And there is still a lot of discussion as to whether the MAPLE reactors can be re-started or not.
and there is concern that the decision to close the MAPLEs was a political decision and not a scientific decision. We are still asking for an independent multi-national expert panel to evaluate the MAPLE reactors to determine once and for all if they are a viable option.

_Researcher:_ They did have physicists and nuclear scientists from all over the world take a look at the math and the design and no one could find any errors with it; so it’s not really an issue of the positive PCR so much as they cannot predict how they will run.

Well, the issue was the positive PCR was part of the design. If AECL did not comment on the PCR in their submission to the Canadian Nuclear Safety Commission, the MAPLEs would be running. The fact that they commented on it, now means that it’s on paper and they have to address the issue of why it’s not performing up to what they expected. They may not have commented on PCR in their submission, [but] once it’s on paper, you’re stuck with it.

_Researcher:_ They had three safety shutdown features. They didn’t need to have three of them.

Exactly, so this may just be an administrative issue. And that’s why we’re asking, we need an independent...The federal government, I think, is biased now because they made it clear that they want out. MDS Nordion is biased of course because they have a significant investment in the MAPLE reactors. So you need an independent, hands-off, body to really say, ‘Okay, we can move forward on this.’

_Researcher:_ Should the federal government use funds to build a new research reactor? Or do you think they should have an independent panel first to evaluate the MAPLEs and then use the money to build another research reactor?

We already have the MAPLEs built, so rather than re-invent the wheel, I think we should put to rest whether the MAPLEs can be used or not. I think [if] we are able move on that point and get a response within about a year, then the MAPLEs would be able to come back online relatively quickly perhaps in a span of 2 to 3 years, and still meet the 2016 shutdown for the Chalk River reactor. If the MAPLEs are found not to be able to run safely, then Canada should move very quickly in the establishment of a multi-purpose research reactor because we still have to address the issue where are post-graduate scientists going to get their training. There is still a lot of research that is done on the Chalk River reactor in addition to medical isotope production. And so, as Canadians we eventually have to come to the solution – do we ship our scientists to other countries for their training? Or do we establish training for them within Canada with the benefit of medical isotope production? So what should happen is the MAPLE issue should be put to rest, once and for all, through an independent, hands-off assessment in an expedited fashion [and] we get the answer quickly. If the MAPLEs cannot be run, then the implementation of the recommendations of the Expert Panel should be brought forward immediately. And then we should attempt to extend the Chalk River shutdown by 2016 for a few more years to allow a reactor to be developed, to allow other countries around the world to develop their capabilities as well. And then develop a coordinated world-wide process for medical isotope production and distribution.

_Researcher:_ Since the shortages in 2007, are there fewer people going into pharmacy and nuclear medicine?

Not from the medical perspective at this point because many of the doctors are trained in dual certification, either in internal medicine, nuclear medicine [or] radiology. But, we have seen some hesitation for our technologists to enter into nuclear medicine as a career because there is a concern that jobs will not be as plentiful as they would be as if Chalk River was up and running. So we have seen some signs that technologists are beginning to have second thoughts. With regards to basic scientists, I don’t have any information on that at this point.
Researcher: In terms of a solution, I have been speaking with scientists at TRIUMF and they are recommending a linear accelerator. I was thinking of a combination with a cyclotron, having a few of them scattered across the country, or having a few accelerators across the country and having a research reactor as well, that way you build a redundancy.

Yes, that would be a very viable option as well knowing that your linear accelerators and cyclotrons would only be able to supply urban centres and once you move out of the larger urban centres then you’d have to use generator molybdenum-based capability. That would be equivalent to, let’s say Abbotsford would need to be supplied by generators and perhaps Vancouver General would be able to be supplied by linear accelerators. So, even within your own province you wouldn’t be able to supply Trail, Terrace, Nelson, Nanaimo, [and] Victoria. Those areas would not be able to be supplied by linear accelerators; they would have to be supplied by generators which are molybdenum-based. So, those are the issues. The cyclotrons are good for your large urban centres, but once you get 30, 40 kilometres away from [them], it gets to be a very big issue.

Researcher: Are technetium generators not all in the States? Chalk River would take the moly, ship it to the U.S. and they had a few generators, say in St. Louis?

That’s the process and distribution capabilities that Canada has. So the molybdenum is made in Chalk River, it’s sent to Kanata, MDS Nordion’s processing labs, and from there it’s shipped to Lantheus, in Boston I believe, and then the generators are made and then shipped around North America from that point.

Researcher: Would you recommend not relying on the U.S., having it all domestic?

No, the capabilities of that are fine. It’s been a proven process. Now the generators we’re getting for Canada are coming from South Africa and Europe at this point. Now, it is more expensive of course. So, you do have to address the extra costs that are associated with importing medical isotopes from outside the North America market if you will. But, it is doable. Canada could survive if the United States is able to produce excess demand within their own country and has a solid agreement that their excess would be sold to Canada. But we’re not sure whether the Missouri or Babcox & Wilcox reactors will even be able to meet their own demand.

Researcher: They may not even combined because the MURR reactor will supply 30 to 50 percent of their demand and I think the other one is smaller than that.

Exactly and that’s the issue. Even with that, the U.S. will not be able to meet their own demand so they will still be relying on foreign sources of medical isotopes. And then, if Canada does not have capability, as we’ve shutdown Chalk River now, then what happens to our Canadian patients?

Researcher: In terms of using low enriched uranium - all of my policy options are looking at only using low enriched or not using HEU.

Yes, that’s the Australian reactor and they’ve been having a lot of problems where the yield was less than anticipated.

Researcher: Right. For your recommendation for using a multi-purpose research reactor would you recommend using high enriched or low enriched?

Well, right now the United States is going to stop shipping highly enriched uranium. Now the Europeans don’t have a problem with shipping highly enriched uranium, so I think it will depend on what the politicians want to do. The U.S. is very concerned about the development of terrorist use of highly enriched uranium. The Europeans are not as concerned, so we’ll have to see what happens and which way the politicians decide to go. If we do go for a lowly enriched process, we’ll have to be willing to pay more for
our isotopes because production yields will be smaller. As long as the governments are willing to pay the piper, to pay the costs of the increased dollar associated with using lowly enriched, then I don’t think we have a problem. But, if the governments are not willing to pay the costs for it, then if we can’t buy…then it’s the same as not having it. So again it comes down to a political decision.

*Researcher:* Well, that is interesting because there was a Bill in the U.S. several years ago to stop all exports of highly enriched uranium across the border – back and forth to Canada. It was MDS Nordion who lobbied the government and there was an amendment to the Bill that had a stipulation stating that it was fine as long as it was for nuclear medicine purposes. But now they’re moving away from that; it will probably be about 5 to 7 years though before they fully move away from highly enriched uranium.

Exactly, you can still make medical isotopes. The Australians are doing that now. The Argentineans are doing that now as well. But at a much lower yield than what you were getting with the highly enriched uranium product. So again there is going to be increased costs associated with that. As long as the governments are willing to meet the costs, I don’t have a problem with it, but my feeling is that governments will set up the stipulation of lowly enriched uranium, but not add the appropriate funding to ensure that Canadians still have access to the higher cost product.

*Researcher:* Do you know how much less Moly is generated from using low enriched?

No, I don’t have that information from Australia. But that’s why Australia has not been able to come onto the world market yet. They’re not capable of getting their product [recording cut out].

*Researcher:* And they also had a problem with their reactor too.

They did. A bad core design and they had to rebuild it. And if the Australians can rebuild their reactor why can’t we rebuild the MAPLEs?

*Researcher:* They have a great science and technology policy there, we don’t really have one in Canada; we have an unofficial one.

I did not know that. That’s an interesting point. Again, I look around the world and I see that South Africa is able to maintain theirs, are moving forward; I see that the Australians can fix their issues with their reactors, but for some reason we, as Canadians, cannot fix our own backyard reactors.

*Researcher:* What would you propose as a short-term solution?

Well the short-term solution is going to be more effective than efficient use of medical isotopes and therefore modernizing the gamma cameras across Canada, either through hardware or software upgrades, to utilize the medical isotopes more efficiently, and we can do that starting today without any research. We just have to get the appropriate funding to upgrade the equipment and we can move on. That would be the first thing. The second thing would be to address the MAPLE 1 and 2 issue as rapidly as possible, to put to bed the idea that they can be used or not. The third thing if the MAPLEs cannot be used to immediately implement the recommendations of the two expert panels concerning the development of a multi-purpose research reactor for Canadian research and for Canadian patients. And the fourth thing would be to establish a more coordinated international process for medical isotope production and delivery with better scheduling of regular maintenance and have plans in place to increase production of medical isotopes around the world when one of our reactors shuts down for a long period of time.

*Researcher:* What do you think of an international consortium?

An international consortium, I have no problem with that. It would be important to view the world as geographic areas that would require medical isotopes and having the infrastructure in each of those
geographic areas to supply that area, such as Canada, the United States and Mexico having a geographic area for medical isotope production and distribution; South America, Africa, Euro-Asia and Polynesia. If you looked at it from that point, you would be able to divide the world up into 5 or 6 regions and move forward with a coordinated process of isotope production and distribution and sale.

Researcher: Okay, and then you would not recommend that Canada get out of the isotope business entirely and rely on other countries?

I wouldn’t. No. I think we need for research capabilities to ensure Canadian access to medical isotopes. Canada has been a leader in this area for 50 years. And rather than abandoning our leadership role, we should move forward to ensure that we are still a major player in medical isotope production. This is going to be a growth industry.

Researcher: With respect to government inference in an independent regulatory body, in 2007 Linda Keen was fired from the Canadian Nuclear Safety Commission. As you commented earlier, many have said that it was a political issue, that it wasn’t in terms of safety. Do you have any comments on that?

Well, Linda Keen was in a situation where she only had 2 options – close it or keep it going – and she chose to close it. In 2007, there was no crisis, no risk to human life as a result of keeping Chalk River going at that time. There was a risk to human life by closing Chalk River down and so I believe that the wrong decision was made by the Canadian Nuclear Safety Commission in 2007 by closing Chalk River when they could have done it in a different way. The closure in 2007 was [a] administrative decision and not a risk decision. And it was the wrong decision to be made because it put patient’s lives at risk around the world needlessly.

Researcher: You had said that there were new policies or procedures in place for dealing with the shortages because you had experience from before?

Yes, in 2007 we did develop across Canada recommendations on how to utilize medical isotopes more effectively in the short-term and in the intermediate term. There is no solution for a long-term shortage.

Researcher: What were the recommendations?

Well, the recommendations were to switch over to thallium-201, to lower the dose per procedure and to increase the scanning time and to try to consider using Iodine-123 more frequently as compared to technetium for iodine assessment. Those were the main recommendations at that point. By moving to thallium you reduce the need for technetium-based medical isotopes by 50% so that was a big savings that got us thought the crisis in 2007 and 2008 again.

Researcher: In terms of patient care, it hasn’t...has it been really effected?

Well, it’s been a spotty impact, again more impacted on community hospital practices. The main issue was unreliability especially in 2007 and 2008 for the ability to do emergency procedures such as those individuals who could not have a CT scan, but were being concerned about having a blood clot in the lung, those individuals who were bleeding from the intestines, are the two types of situations that are really urgent in a nuclear medicine environment because of the high death rate associated with patients with those conditions. And in my own hospital here, there were days when patients could not get the appropriate test available because there was just no isotope available. So, yes, patients lives were placed at risk as a result of the shortage, again more pronounced at the community hospital setting, but still there.

Researcher: But there were no deaths as a result?
No, one because we’ve come a long way in the management of many diseases, etc., but the physicians of patients had to make decisions on best treatment management without having all of the information available that would have been considered the standard of care.

Researcher: Okay. So, instead of nuclear medicine tests being done, people were getting CTs and MRIs?

Well, they were getting those now anyways.

Researcher: Is that now with the crisis, with the shortages I mean, or prior or that as well?

No, prior to that. People have always gotten CTs and MRs. The reason you have 3 is that the CT and MR are not able to answer all of the questions. And there’s a reason why nuclear medicine has not gone away in light of CTs and MRs because nuclear medicine gives specific unique types of information that is only achievable through medical isotope assessment. And you are usually achieving the information with CT at a higher radiation burden and a higher potential death rate because the X-ray contrast agent that has to be given. There is a death rate associated with that. Whereas, in nuclear medicine you are able to obtain or assess disease at a lower radiation exposure, at a very safe – no one dies from a nuclear medicine procedure – and obtain information at a earlier stage as compared with those findings of a CT or MR. So you may get a false sense of security, in the sense, ‘Oh, I can go have a CT,’ but it still may not give you the information that a routine, bread and butter, nuclear medicine scan will give you.

Researcher: Okay. Or they might come back later and find out that what they missed before is progressing.

Yup. And that’s why nuclear medicine continues to show a growth rate even in light of all the CTs everywhere around the world, all the MRs, etc., because the information is unique and very important to patient management.

Researcher: There’s a 10% increase in nuclear medicine procedures each year in North America, is that just due to more machines being used or...?

It is due to…there’s newer types of machines. The SPECT camera has a greater capability than the routine gamma cameras. So as we’ve been able to move forward with better medical isotopes, moving forward with technology, our ability to do more and more increases and as such the physicians of patients realize [recording cut out] to have positron emission tomography has had a big impact as well, in the States anyway.
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\(^{15}\) Name withheld to protect participant identity. Due to request of AECL, participant phone interview was cancelled and prior exchanges were removed from this study.


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