A ROCK AND A HARD PLACE: THE ISOTOPE CONUNDRUM

Geoff Norquay

In the summer of 2009, the world is experiencing an acute shortage of medical isotopes used to diagnose illness and treat various kinds of cancer. Atomic Energy of Canada Limited's aging National Research Universal reactor is offline for repairs, and there is no backup reactor in the world capable of replacing the supply of medical isotopes. Contributing Writer Geoff Norquay traces the history of the medical isotope business in Canada, and explores how a plan to ensure future global supplies of isotopes and secure Canada's leadership in a vital area of science and technology went terribly wrong.

Été 2009. Le monde fait face à une grave pénurie des isotopes servant à des fins diagnostiques et au traitement de plusieurs cancers. Or le vieux réacteur NRU d'Énergie atomique du Canada attend d'être réparé et aucun autre réacteur au monde n'est en mesure de produire des isotopes de rechange. Notre collaborateur Geoff Norquay retrace l'historique du secteur canadien des isotopes médicaux et se demande pourquoi le plan visant à assurer l'approvisionnement mondial en isotopes et à consolider le leadership du Canada dans le domaine crucial des sciences et des technologies a si mal tourné.

In 1940, the brilliant Canadian scientist George Laurence began an audacious experiment. Following on the discovery of nuclear fission in 1939, Laurence build a prototype nuclear reactor in a room at the National Research Council headquarters at 100 Sussex Drive in Ottawa. First, he borrowed half a ton of uranium oxide from Gilbert LaBine, the prospector who was the father of the Canadian uranium mining industry. Then, to slow down the neutrons released by the fission process so that they could be captured by neighbouring atoms, he piled paper bags of the uranium oxide in a regular pattern, surrounding them with sacks of powdered coke. Finally, in the middle of this pile, he inserted a neutron source to initiate the chain reaction.

The experiment was only a partial success. While he induced fission, it's generally assumed that it was only the impurities in the materials he used that prevented George Laurence from being the first human being to create a sustained nuclear reaction. Within a year, Enrico Fermi succeeded in this quest at the University of Chicago, laying the groundwork for the Manhattan Project, which produced the atom bombs that ended the Second World War.

Laurence's pioneering work encouraged Canada to partner with a group of senior British and European scientists to create the National Research Council's Montreal Laboratory Division, and Laurence became its senior Canadian representative in 1942. The Montreal Laboratory quickly outgrew its surroundings and the Chalk River Nuclear Laboratories were opened in 1944. By the following year, the ZEEP (Zero Energy Experimental Pile) reactor had been constructed at Chalk River, and when it went critical for the first time on September 5, 1945, it became the first nuclear reactor to operate outside the United States.

In 1947, the 20-megawatt National Research Experimental (NRX) reactor was commissioned at Chalk River, and for several years it was the largest of its kind in the world. In the space of a very few years, Canada had built the second-largest nuclear infrastructure in the world, and was at the forefront of global physics research. Atomic Energy Canada Limited (AECL) was subsequently created by the federal government in 1952 to pursue Canada's interests in nuclear technology, and it assumed responsibility for the Chalk River facility.

The NRX was a multi-purpose reactor. Its capabilities included the production of weapons-grade plutonium for the US nuclear program, the testing of materials and nuclear fuels for future reactors and the production of neutrons used in condensed matter physics. It also made possible — for the first time — the development and widespread application of nuclear medicine, starting first with the production of cobalt-60 for teletherapy machines to treat cancer.

Because the expected lifespan of the NRX reactor was unknown, design work to create its successor began in 1949, and the result was the National Research Universal (NRU) reactor, which began operations in 1957. Like its predecessor, the NRU reactor was built with several purposes in mind: engineering research and support for future reactors, neutron physics research and the production of industrial and medical isotopes. The NRU reactor proved to be an incredible workhorse, its research leading to the creation of the CANDU power generation technology and ground-breaking neutron beam research. After the production of molybdenum-99 was launched for international markets in 1975, the NRU reactor's isotope production ultimately grew to account for between one-third and half the world's medical isotopes.

Eighty-five thousand times every day in hospitals around the world, nuclear medicine practitioners perform a modern miracle. A patient with a suspected heart attack is injected with a medical isotope, which provides a cardiac image that enables the physician to evaluate precisely the location, the nature and the seriousness of the problem. In another country, a medical isotope is being used to shrink and eradicate a thyroid tumour. Meanwhile, in a third country, a medical isotope is being used for a bone scan to search for signs of infection.

These diagnoses and treatments benefit some 30 million people around the world every year. Until recently, it's likely that very few Canadians knew anything about Canada's critical contribution to the development of nuclear medicine, or the role this country plays today in providing a significant proportion of the world's medical isotopes. That began to change in November 2007, when a dispute between the Canadian Nuclear Safety Commission and AECL interrupted the flow of isotopes to the world from the NRU reactor at Chalk River.

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In September 2009, that same NRU reactor, 52 years old and well beyond its expected lifespan, is offline for several months while AECL attempts to assess and fix a leak of heavy water from the reactor vessel due to corrosion. There is no backup to the NRU reactor in Canada, and no other nuclear facility in the world can match its normal operating capacity and output. How all this came to be is a fascinating story, one of groundbreaking achievement on the frontiers of science, great expectations and dashed hopes, failed technology and huge expenditures of public and private sector funds.

Because medical isotopes have a half-life measured in days and hours, creating, processing and distributing them around the world is a complex, time-sensitive process with challenging logistics, all aimed at just-in-time delivery. In the Canadian context:

- Uranium-aluminum alloy targets are placed into the NRU reactor and bombarded with neutrons for five to seven days.
- The result is the creation of molybdenum-99, an isotope that decays at a rate of 1 percent per hour. After removal from the reactor, the targets are transported to MDS Nordion's Ottawa-area facility to extract pure moly-99.
- MDS Nordion then transports the moly-99 by chartered aircraft to a Massachusetts radiopharmaceutical manufacturer, where it is incorporated into lead-shielded technetium generators. The generators are then distributed to radiopharmacies and some hospitals.
- As the molybdenum decays inside the generator, it produces technetium-99m (Tc-99m), which is extracted for use in nuclear medicine. Tc-99m has a half-life of six hours.
- At the radiopharmacy or hospital radiology department, depending on the purpose of the dose, the extracted Tc-99m is then "tagged" to a chemical compound, and is ready to be administered to a patient.
- On average, the elapsed time between the removal of the targets from the reactor and the actual use of medical isotopes in a hospital in Canada, the United States or another country is 41 hours. Obviously, given the rate of decay of isotopes, they cannot be accumulated, saved or stockpiled.
- Tc-99m is the workhorse among medical isotopes. Approximately half the diagnostic nuclear medicine procedures conducted around the world require Tc-99m; in Canada, the proportion is roughly 90 percent. In addition to moly-99, the NRU reactor also produces a number of additional medical isotopes, including iodine-131, iodine-125, xenon-133, cobalt-60, carbon-14 and iridium-192.

After moly-99 created by the NRU reactor was launched into international markets in 1975, the NRU grew to become the principal global source for medical isotopes. But as time passed, and the NRX reactor was taken out of service and decommissioned in 1992, it became obvious that plans were needed to replace the NRU, which had then been in operation for 35 years.

Around the world, the medical isotope business is a public-private enterprise. Governments build the reactors and private sector companies handle the purification, processing and distribution of the isotopes. Enter

Nordion, which had begun life years earlier as AECL's Radiochemical Company. In 1988, the federal government announced it would privatize this entity, and the Radiochemical Company was incorporated as Nordion International Inc. and transferred to the Canada Development Investment Corporation. In 1991, now the pre-eminent isotope producer in the world, Nordion was sold to the MDS Health Group Ltd.

In the early 1990s, AECL announced a plan to ensure a reliable supply of isotopes after the NRU reactor reached the end of its lifetime. AECL would build a new dedicated isotope reactor, the MAPLE-X10 (Multipurpose Applied Physics Lattice Experiment-10 MW), to replace the aging NRU reactor. AECL also agreed to a 23-year arrangement for the exclusive supply of medical isotopes to MDS Nordion.

Relations between the two sides quickly began to sour, as AECL realized it had underestimated the costs of both operating the NRU reactor and building the MAPLE. The federal government suspended construction and in turn, MDS Nordion sued AECL, claiming that the Crown corporation was required to complete the project and honour its isotope supply agreement. The issues were ultimately resolved through arbitration, and the result was a new agreement in 1996, in which MDS Nordion hired AECL to design and construct the two MAPLE reactors and a processing facility at Chalk River for $140 million. The MAPLEs would be dedicated to isotope production; MAPLE 1 would be the principal isotope producer, while MAPLE 2 would be the designated backup to supply isotopes when the first unit was down for maintenance. MDS Nordion would own both the reactors and the processing facility.

By 2000, the first of the MAPLEs was ready to enter commissioning tests, but during the process, the shut-off rods, a critical part of the reactor's safety and operational systems, failed to drop fully into the reactor, due to debris that had contaminated the system during construction. The regulator, the Canadian Nuclear Safety Commission (CNSC), investigated, and at the 2001 relicensing hearing for the reactors, it expressed concerns about AECL's management of the project, its quality assurance program and the remedial steps taken to fix the problem. Two years later, AECL had the shut-off rod problem pretty well under control, but other design and technical problems arose, including difficulties with various control systems and pressure valves. The commissioning process continued.

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In 2003, a new problem was discovered, and it was significant. When a nuclear reactor is designed, nuclear scientists must submit calculations that predict exactly how the reactor will behave under all operational circumstances, especially when it is turned on and powers up. These predictions must be strictly confirmed through observation by the regulator during commissioning tests in order for the reactor to be licensed. In the nuclear reactor business, if design prediction and observed performance don't match up, that's a major issue.

A nuclear reactor is powered up in stages. The control rods that prevent nuclear fission from taking place are incrementally withdrawn from the core. In the pause between the stages, the rods are pushed back into the core to a lesser distance, and the reactor is supposed to become slightly less reactive. This is known as a "negative power coefficient of reactivity," or PCR. Unfortunately, the MAPLE's behaviour did not match the predictions; when it went through the power-up sequencing, it displayed a *positive* power coefficient of reactivity. The discrepancy was not huge but it brought the system to a halt, not only because of the negative-positive issue, but also because the reactor simply wasn't supposed to do that. John Waddington, who has spent his career in the nuclear safety business including 11 years as director general of the CNSC, described the situation to the House of Commons Natural Resources Committee in 2008:

"The difference was quite slight; it's just a few millimetres difference in rod height. The important point, though, was that as far as the CNSC and indeed AECL were concerned, the reactor was not behaving as it was predicted to behave. It was also slightly positive instead of slightly negative. But the important point here is that the behaviour didn't match the predictions."

By 2005 the entire effort was years behind schedule and hundreds of millions of dollars over budget. Having already sunk $350 million into the project to no avail, MDS Nordion sued AECL once again. In a complex out-of-court settlement reached in 2006, the structure of the project changed once more:

- AECL assumed ownership of the reactors and the processing facility, and committed to have the reactivity problem solved and the MAPLEs completed, commissioned and in service by October 31, 2008, and October 31, 2009, respectively.

- Project completion costs and ongoing operating costs would be borne by AECL, and the corporation also paid MDS Nordion $25 million for the transfer of title and acquired $47 million worth of dedicated isotope facility-related inventories from MDS.

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- AECL also signed a 40-year supply agreement with MDS Nordion, which in turn agreed to provide a share of net revenues to AECL and to share in the costs of safe storage and long-term waste management.

With the ownership and financing of the project apparently back on track, AECL went back to solving its nuclear physics problem. The CNSC needed an explanation and AECL continued its intensive efforts to find the answers. With the help of outside experts, AECL had identified roughly 200 possible explanations and over the next several years conducted many tests to track down the problem. They were able to identify some possible causes but not all, and the search for a definitive explanation continued.

By the spring of 2008, the entire project was years overdue, it had cost an estimated $600 million, and AECL had still not solved its positive reactivity challenge. On May 16, 2008, AECL pulled the plug on the MAPLEs and discontinued work on the project, citing “the costs of further development, as well as the time frame and risks involved with continuing the project.” (Whether AECL was pushed by the government or jumped of its own accord is unclear.) Two months later, MDS Nordion launched a $1.6-billion lawsuit over its 40-year supply agreement with AECL.

Until the NRU reactor developed its leak in 2009, the medical isotopes continued to flow to the world. But today, with the NRU offline for several months while the leak is located and repaired, isotope suppliers and nuclear physicians in several countries are scrambling to obtain alternative supplies of isotopes and develop alternative treatment approaches. The federal government is under heavy criticism for not having had a plan in place to deal with the shortage, and Canada’s once exemplary nuclear medicine and research reputation is in shambles.

There are no easy solutions. None of the other research reactors around the world have the capacity of the offline NRU, most are just as aged and decrepit, and all need to be shut down periodically for maintenance and repair. And it’s clear that other countries, anticipating that the MAPLEs would ultimately become operational, made no alternative plans to build their own reactors. The United States now appears to be moving toward the construction of its own reactor, or upgrading an existing facility at the University of Missouri to produce isotopes, but either solution is likely years away.

The search for public policy lessons to be learned from Canada’s isotope saga is tortuous and inconclusive.

As a public policy sector, nuclear is like no other.

First, it is incredibly complex. The issues and concepts involved in amending immigration laws or changing the mandate and operations of a long-gun registry may be complicated, but they are easily accessible and understandable to cabinet ministers. In nuclear, governments are essentially at the mercy of their scientists; second-guessing by cabinet is not on. So when the previous and current governments were told that a fix was coming on the positive reactivity issue, they had few alternatives but to trust the advice and pay the bills.

The second issue is that nuclear is probably the most highly regulated industrial sector in the country, and for good reason. Accidents have happened in the nuclear age, and the consequences can be devastating. As a result, the CNSC has a robust safety mandate and operates as an independent regulatory agency. The current government learned how important that perception is when it overruled the president of the CNSC in December 2007 over her conflict with AECL over safety systems for the NRU reactor.

In the wake of the decision to abandon the MAPLEs, a lively debate has been raging over whether it was the right move. On one side are MDS Nordion and a number of nuclear experts who believe the MAPLEs’ problems can be solved relatively easily and that the technical challenges can be overcome at reasonable cost:

- A January report from a committee of the US National Academy of Sciences concluded, “The Committee assumes that the worst-case scenario for fixing the MAPLE reactors involves the replacement of the reactor cores. The cost of such replacements would likely be small (tens of millions of dollars) in comparison to the cost of building a new reactor (hundreds of millions of dollars).”
- Dr. Harold Smith, former manager of MAPLE nuclear commissioning, told the Natural Resources Committee in June: “Positive PCR requires a relative-

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Natural Resources Minister Lisa Raitt has been handed one of the most challenging and sensitive files in Ottawa: the isotope shortage. Geoff Norquay tells how Canada got to this place.

ly simple engineering fix to restrain the bowing of the elements and to reduce the PCR to approximately zero."

- John Waddington has suggested a redesign of the reactor fuel: "When you design fuel, you can design it with certain power characteristics right up front, depending on how you make the fuel and what you put in it. So AECL does have an option to redesign the fuel with a different set of characteristics that would enable it to have a very definite negative power coefficient of reactivity."
- As Jill Chitra, Vice-President, Strategic Technologies, MDS Nordion, told the Natural Resources Committee, the MAPLEs worked during the commissioning process, and isotopes were created: "During tests, targets were inserted into the reactor for a number of those tests. When targets are inserted into a reactor, neutrons impinge on the reactor and isotopes are created; moly-99 is created. Those targets were not processed because the processing facility was not yet finished commissioning."

On the other side is AECL, which appears distinctly unconvinced by these arguments:

- The company's CEO, Hugh MacDiarmid, also appeared before the Natural Resources Committee in June. On the unresolved technical issues, he told the committee: "When we looked at the possibilities, all of them were highly risky, expensive and lengthy. It was clear to us that it was not just the existence of a positive power coefficient of reactivity. It was that the actual behaviour of the reactor did not mirror the modelled behaviour of the reactor. For this reason, we were unable to state unequivocally that we knew what was causing the readings we got."

- MacDiarmid was equally definitive about the prospects of reconsidering the MAPLE decision: "To try to return the MAPLEs to service, it would be many years and many hundreds of millions of dollars before those reactors would be licensable and could be put into service. It's just not a realistic option at this time."
- How much might it all cost? Well, earlier in June, AECL's chief financial officer, Michael Robins, told a Senate committee that he estimated the cost of completing the project as "in excess of $1 billion": in other words, at least another $400 million on top of the $600 million already sunk into the project.

What's a government to do when confronted by such conflicting advice?

Earlier this spring, the Prime Minister announced the government's intention to "eventually" exit the isotope business altogether. That would appear to end the discussion.

Obviously, the delays, huge costs and unresolved technical issues involved to date in the MAPLE project were the key factors in AECL's decision to abandon it, and it's clear the government supported that decision. Despite frequent evidence to the contrary, modern governments increasingly apply risk analysis to major decisions, and it's likely that too much water has flowed under this bridge for the government to take another chance. Like the Liberals before them, the Conservatives have already been to this movie and they didn't like the ending.

Some believe that the CNSC's mandate is too much focused on safety, but there is little chance of the government making any moves on that front. Could the CNSC reverse itself on the positive reactivity issue? Possible, but then it would have to explain how its previous concerns about the discrepancy had been addressed, and explain how reactors that don't act as predicted could be considered safe in the future. Could the MAPLEs be licensed and allowed to operate only at half power? Another question with potentially risky answers.

Hopefully, in a few months, the NRU reactor will be fixed and will resume its production of medical isotopes. Even when that happens, the NRU will remain an ancient research reactor, and in need of substantial upgrades to be licensed for a still-limited future. In the meantime, Canada's government remains caught between a rock and a hard place, unable to rewrite the past and, because of that past, unwilling to take even greater risks to meet an uncertain future.

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