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New isotope manufacturing methods head for regulatory approval

When it comes to finding new ways of generating radioisotopes for medical imaging, the job's not over until the paperwork is done. Having met most of the technical challenges of using particle accelerators to produce these radioactive materials, three research teams across the country are now preparing to meet the bureaucratic challenge of getting Health Canada to approve the regulatory process for bringing products to market.

The three groups are sharing $25 million that Natural Resources Canada (NRC) announced at the end of February for the Isotope Technology Acceleration Program. This is the next phase of the Non-reactor-based Isotope Supply Contribution Program, which began in 2011 following the breakdown of the nuclear reactor in Chalk River, Ontario. That reactor had been producing about half the world's supply of isotopes for the single photon emission computed tomography (SPECT) imaging conducted on millions of people every year.

The reactor breakdown and ensuing shortage of isotopes led to a search for alternative sources, particularly as the aging nuclear facility is set to be retired from isotope production by 2016. In Canada, the search has focused on cyclotrons and linear accelerators, both of which are feasible sources for the regular production of technetium, the workhorse agent employed with SPECT. Now the challenge lies in defining quality-control standards that will grant these isotopes the same regulatory status that reactor-generated isotopes have had for decades.

"This next phase is to show that we can do it in a commercially viable operation," says Steve McQuarrie, Director of Cyclotron Operations at the Cross Cancer Institute in Edmonton. The site, which has one longstanding cyclotron and a new, more powerful one being installed this spring, has been investigating this new means of isotope production for several years. Last year this research culminated in the country's first clinical trials with cyclotron-generated isotopes in patients.

Those trials reflected the ultimate goal of yielding a product that is essentially identical to the isotopes that currently come from nuclear reactors. Only a handful of the world's nuclear reactors carry out this work and some of them are rapidly approaching retirement age, just like Canada's. Controversy has also dogged the weapons-grade uranium they use for medical purposes, as well as the accompanying radioactive waste. These problems simply do not apply to particle accelerators. However, these complex machines are being employed in new ways, which is why the Isotope Technology Acceleration Program will analyse their ongoing performance.

"We talk about this being the development and deployment phase," explains Tim Meyer of TRIUMF, the Vancouver, British Columbia–based cyclotron facility. "We have to be able to say to Health Canada that we have a recipe for this product, and these are the known variations and contaminants, and these are the known variations in the purity."

The three groups receiving NRC funding cut a wide swath through all of the country's expertise and resources in this field. TRIUMF is working with the BC Cancer

Agency in Vancouver, BC, the Lawson Health Research Institute in London, Ontario, and the Centre for Probe Development and Commercialization in Hamilton, Ontario.

University of Alberta researchers will be working on existing and new cyclotrons serving the Cross Cancer Institute, in collaboration with the Centre Hospitalier Universitaire de Sherbrooke — Hôpital Fleurimont in Sherbrook, Quebec, which already has two similar cyclotrons. Both of these teams are working with the manufacturer of these devices, Advanced Cyclotron Systems in Richmond, BC. The third group, Manitoba-based Prairie Isotope Production Enterprise — with participants from Winnipeg's Health Sciences Centre, the Regional Health Authority, accelerator manufacturer Mevex, an independent radiation research lab and local universities — is working with modest-sized linear accelerators rather than room-sized cyclotrons, though both yield technetium for SPECT imaging in the same way.

Between cyclotrons and linear accelerators, then, isotope-based imaging should be able to continue without interruption once the Chalk River reactor turns out its last batch of medical radioisotopes. At that point Canada should become the first place in the world to shore up its supply of an increasingly important medical resource without the need for a nuclear reactor. And, despite a considerable outlay of energy and expense to wean the country off reactor-generated isotopes, the actual imaging procedure should look just the same to the patients and doctors, who likely have more important things to worry about than where those isotopes came from.

And for his part, Steve McQuarrie insists that he is just fine with that lack of attention.

"If we're successful, nobody will notice the difference," he says. "There will be no difference." — Tim Lougheed, Ottawa, Ont.

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