Sudden Radioisotope Shortage Threatens Patient Care

In what members of the nuclear medicine community referred to as a "devastating" and "catastrophic" series of events, the Canadian supplier of more than 50% of the world's marketed radioisotopes shut down its reactor in late November. The result was an immediate shortage of ^{99m}Tc generators that forced a scramble for alternative suppliers and drastic reductions in the numbers of nuclear imaging studies performed in North and South America and the Far East. At Newsline press time in mid-December, no resolution had been reached, and the effects of the shortages were being felt in almost every nuclear medicine department and practice.

On November 18, Atomic Energy of Canada Ltd. (AECL) shut down its Chalk River, Ontario, National Research Universal (NRU) reactor for what was initially described as 5 days of routine maintenance. Twelve days later, when shortages were already being felt, MDS Nordion, which manages wholesale marketing and distribution of radioisotopes from the reactor, alerted customers to a more serious interruption in the supply of ^{99}Mo used in the manufacture of ^{99m}Tc generators and ^{131}I. MDS reported "a scheduled reactor maintenance shutdown has been extended to complete an upgrade to the electrical system, addressing a technical regulatory issue." Although concerned with identifying stopgap supplies and/or identifying alternative procedures, most users were encouraged by the news that "an approval of the upgrade plan is anticipated shortly with a targeted return to full production in mid-December."

But only a few days later, a longer and indefinite delay in production was announced. On December 4, AECL explained in a press release that "a decision was made to remain in shutdown and make the modifications required for the installation of 2 new motor starters for the reactor cooling pumps, and to connect the motors to an additional back-up power supply." However, AECL provided no firm date for when production could be expected to resume. In comments to the media, AECL official Brian McGee speculated on a 75% probability that the reactor would be in operation by the end of December and a 95% chance that it would return to service by the end of the first week in January. MDS Nordion, cognizant of the effect the announcement would have on customers worldwide, provided a more informative and sobering assessment on the following day: the shutdown would definitely extend "into January 2008."

As the media in both Canada and the United States soon reported, the NRU shutdown was in fact the result of noncompliance with safety orders that were part of the AECL license from the Canadian Nuclear Safety Commission (CNSC). According to the CNSC, the license was renewed in 2006 only after the AECL stipulated that a requisite emergency power system had been connected to the 50-year-old reactor's cooling pumps. A routine inspection during the November 18 shutdown revealed that the system was not and had never been operative. "It was a surprise to us because our expectation was that it was in place and in service," Barclay Howden, a CNSC director general, told *The Canadian Press*. "From a nuclear safety point of view, this is a very serious situation." During an emergency government hearing on December 6, AECL representatives responded that they had believed the power-system upgrade to be a recommendation and not a compulsory requirement. Because parts to complete the upgrade were not immediately available, the timeline for resumption of radioisotope production remained unclear. After the parts are acquired and installed, the reactor cannot go back on line until it is reinspected by the CNSC and, even then, the regular supply of radioisotopes will not resume for at least 1 week.

Immediate Fallout

By December 7, the radioisotope shortage was in the headlines and the focus of attention from government agencies in both the United States and Canada. "This is a catastrophe for patients," said Sandy McEwan, MD, SNM. "A lot of centers in the U.S. are already down to 20% or 30% of capacity"—a percentage likely to be further reduced over the coming weeks. The search for alternative supplies was on, and, despite offers of assistance from suppliers in Belgium and South Africa, the prospects for immediate relief were dim. "We are working hard to be able to provide some quantities to Nordion from the end of next week," said Bernard David, head of production at Belgium's Institut National des Radioelements (Brussels). David cautioned that the European reactor would be able to supply only a small percentage of the routine AECL production.

Most hospitals without alternative supplies began to cancel patients scheduled for elective nuclear medicine procedures that rely on ^{99m}Tc. Immediate estimates were that for each month of disrupted supply, 50,000–90,000 patients in Canada and as many as 200,000 patients in the United States would be affected. Many hospitals set up hotlines for patients who had questions about their studies. Nuclear medicine departments worked to alert clinicians to appropriate alternative studies. SNM established an online "Molybdenum-99 Shortage Resource Center" to keep the nuclear medicine community informed of updates on supplies and alternative sources. "Patients' lives are now at risk," warned the SNM in a public statement. "The practice of nuclear medicine across North America is in serious

danger. An increasing number of hospitals and imaging centers across the United States and Canada are prioritizing their patient lists and may be unable to appropriately treat many patients with cancer, thyroid, heart, and kidney disease."

Lack of Back-Up

The immediate reaction of many patients and providers was surprise and dismay at the realization that the most common nuclear medicine procedures are largely dependent on a single provider. Many nuclear medicine practitioners, however, were aware of the dangers of this dependency. McEwan told *The New York Times* on December 7 that SNM has long pushed for the United States to build its own reactor to produce medical materials. "This is a bad news story in every sense of the word," said McEwan. "It means patients are going to suffer. People are going to look at this and say, 'Why are we so reliant on a single supplier?'"

One answer is that for more than a decade new reactors that would have relieved the single-reactor dilemma have been waiting to be activated at the Chalk River facility. The Maple 1 and Maple 2 reactors were intended to provide the capability to supply the world's needs for ^{99}Mo *and* to offer continuous back-up and redundancy. The new reactors were originally slated to go on line in 1999 and 2000. After cost overruns and safety concerns caused delays and resulted in friction between AECL and MDS Nordion, the reactors, still unfinished, became the property of the AECL in 2006. Although a spokesperson for AECL told the *Toronto Globe and Mail* that Maple 1 will be operational by the end of 2008, industry observers called this projection optimistic at best.

"If there is 1 positive aspect to this unfortunate and still unfolding situation," McEwan told Newsline, "It is that it presents the nuclear medicine community with a compelling example of the need for government and regulatory agency attention to enhanced support for redundancy and back-up in radioisotope production to ensure that we are able to continue to provide high-quality and much-needed care to our patients."

At Newsline press time, CNSC safety inspectors were on site at Chalk River observing the upgrade process with a goal of initiating start-up approval as quickly as possible. The agency was also fast-tracking strategies for the import of isotopes and for amended licenses to help alleviate the shortage. Developing news on this story will be updated regularly on the SNM Web site at www.snm.org.

As Newsline went to press:

On the evening of December 11, the House of Commons fast-tracked bill C-38, an act to permit the resumption and continuation of the operation of the National Research Universal (NRU) reactor at Chalk River, *via the Committee of the Whole process. C-38 allows the safe operation of the NRU reactor for 120 days despite certain license conditions set by the Canadian Nuclear Safety Commission.*

The legislation will be considered by the Senate on December 12. If passed, it will then be presented to the Governor General for royal assent.