A Discussion of the Issue and Implications for the Health Care Industry

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Background
The use of radioactive materials to obtain X-ray images of tissues and organs (most often referred to as “Nuclear Medicine”) dates back to 1937 when the first clinical use of “artificial radioactivity” was carried out in the treatment of a patient with leukemia at the University of California at Berkeley. A landmark event for nuclear medicine occurred in 1946 when a thyroid cancer patient’s treatment with radioactive iodine caused complete disappearance of the spread of the patient’s cancer. Clinical use of nuclear medicine became more widespread in the early 1950s.¹

Understanding Nuclear Medicine
The use of injectable radioactive materials called “Radionuclides” differs from conventional X-ray in one fundamental way: emission vs. transmission.

• In a conventional X-ray, an electronic X-ray tube produces radiation outside the body, and the X-ray film records the amount of radiation “transmitted” through various parts of the body.
• In a radionuclide “emission” scan (nuclear medicine), the source of the radiation is within the body and the image is created by using arrays of very sophisticated Geiger-counter-like sensors to identify the location and characteristics of the organ which captures the radioactive substance.

Importantly, the radioactive substances do not last long in the body and are rendered safe by a process known as “decay.” Physicists measure this by calculating “half-lives” of the material, which is the time it takes for one-half of the material to become non-radioactive. Half-lives for different radioactive materials range from millionths of a second to thousands of years; the ones used in medical imaging are typically in the range of six hours. Today, there are more than 100 different nuclear medicine procedures that uniquely provide information about nearly every major organ system within the body.

Currently, more than 70 percent of all procedures within nuclear medicine are based upon technetium-99m (Nuclear Energy Agency 2000), a radionuclide produced by individual generators (Molybdenum-99/Technetium-99m Generator) that use molybdenum produced in reactors alongside those that generate nuclear energy. The most prominent suppliers have been Canada’s NRU Chalk River plant (40 percent) and the Netherlands’ High Flux Reactor in Petten (35 percent). At the very heart of all nuclear medicine procedures is the need for year-round, reliable availability of radionuclides. The consistent availability of these radionuclides has been compromised by repeated interruptions since 2007.²

Today’s Supply of Radionuclides
In November 2007, Atomic Energy of Canada Limited (AECL) announced that it would close down operations at its NRU Chalk River plant for routine maintenance. This was a medically important issue because the plant is the primary (though not only) producer of medical isotopes used in North America. Immediately following this closure, several hospitals reported a 20-30 percent shortage in the most commonly used isotope, Technetium 99M. Recently, Chalk River has experienced similar problems and has announced that the production of medical radioisotopes would be suspended for nearly three months.³

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Exploring Alternate Solutions
As outlined above, current world supply is dependent upon multiple international laboratories, including one in Canada and four in Europe. Many of the disruptions have been caused by lack of cross-plant coordination of routine maintenance among the producers, with as many as three plants off-line at the same time. International attention has forced better coordination and a significant interest in expanding production capacity. This has included discussion of harnessing the research reactor at the University of Missouri (MURR).

The U.S.-based National Radionuclide Production Enhancement (NRPE) Program has been established to address the problem and identify solutions. Program officials have noted that MURR currently provides reactor-produced radionuclides for therapeutic applications. However, it has a low-power (10MW) reactor that allows it to produce only relatively small quantities of radionuclides at a low specific activity (a few radioactive atoms and a much greater number of non-radioactive atoms), effectively limiting their use.

How U.S. Suppliers Are Coping
Covidien, a major U.S. supplier, obtains most of its isotopes from the High Flux Reactor in Petten, the Netherlands. This has provided some insulation from the effects of the Canadian shutdown for Covidien’s clients. However, that may change in July 2009 when the Dutch reactor goes off-line for a four-week maintenance shutdown, leaving many providers to consider how best to manage ongoing demand for these radionuclides in the absence of their routine availability.

Privately held Lantheus Medical Imaging of Massachusetts, which processes isotopes for medical use, has relied upon the Chalk River plant for the bulk of its supply. In May 2009, the company made arrangements with other radionuclide suppliers to help their customers cope with the impact of the shutdown.

What Physicians Can Do
Nuclear physicians are adopting a number of different strategies to ensure that patients are not harmed by the ongoing Mo-99/Tc-99m supply shortage. These strategies have included:
1. Lowering the dose of Tc-99m-based radiopharmaceuticals
2. Eluting (or flushing) the generator more often to maximize the activity of Tc-99m extracted, thereby improving yield
3. Opening imaging departments on Saturdays to shorten the length of nuclear decay in between use of the radionuclide
4. Rescheduling examinations

In some cases, standard bone scan procedures using Tc-99m have been replaced by fluorine-18 FDG PET scans, and Thallium has been substituted for the current Technetium-based nuclides for cardiac evaluation.

NIA’s Perspective
By far the most commonly used isotope containing Tc-99m is commercially known as Cardiolite and is used in conjunction with a variety of Nuclear Cardiology procedures. It is important to note that when NIA issues pre-procedure authorization for a Nuclear Cardiology study, the authorization is not specific to a certain radioisotope. This allows the service provider flexibility in selecting the isotope that is available and/or most appropriate for the given study. This is particularly important as a significant number of Nuclear Cardiology studies are alternatively performed using Thallium rather than Cardiolite. Many industry leaders believe these isotopes to be of essentially equal value.

The 2007 shortage prompted National Imaging Associates (NIA) to notify our service providers and health plans of this flexibility within our authorization process (as outlined above), and, as predicted, many examinations were simply performed using an alternative isotope (such as Thallium). Some procedures were cancelled as providers identified alternate diagnostic examinations. It is to be expected that some were rescheduled.

It is worth noting that the NIA Call Center, along with our online verification system at www.RadMD.com, processes more than 3 million pre-procedure reviews annually. We did not record a statistically significant drop in utilization during the prior period of radionuclide shortage. Additionally, NIA did not observe any noticeable pent-up demand at the conclusion of the 2007 shortage.
Summary Observations

• It is reasonable for the health care industry to expect periodic shortages for the next several years, especially until there is greater coordination across all existing plants and/or until additional consistent supply becomes available.
• The communication and coordination of scheduled reactor maintenance by producers will help to ensure a continued, uninterrupted supply.
• Most Technetium-based studies (cardiac) can be performed with alternate radionuclides (e.g., Thallium), which are not in short supply.
• Nuclear physicians are adopting a number of different strategies to ensure that patients are not harmed by the ongoing Mo-99/Tc-99m supply shortage.

For more information or to learn more about NIA, contact your NIA representative or call 1-877-NIA-9762.

3. Since January 2007, there have been five periods of serious disruption to supplies, including a month outage at Chalk River to fix safety back-up systems and a six-month shutdown of the Petten reactor from August 2008 after corroded pipes were discovered in its primary cooling circuit.