



February 12, 2008

Opening Remarks

To the Standing Committee on Health

“Medical Isotope Supply Assurance to Canada and the World”

Introduction

- Good morning, my name is Grant Malkoske, Vice President, Strategic Technologies at MDS Nordion and accompanying me is David McInnes, Vice President, International Relations.
- MDS Nordion is an Ottawa-based life sciences company with over 700 employees at locations in Laval, Vancouver and Belgium.
- We welcome the opportunity to appear before you today to provide our perspective on the 2007 medical isotope supply shortage caused by the NRU reactor shutdown.
- This event had a significant impact on medical isotope production and our ability to supply medical isotopes to the nuclear medicine community and in turn, that community’s ability to supply to hospitals, physicians and patients.

Medical isotope supply chain

- As you may be aware, we appeared before the Standing Committee on Natural Resources last week. As we stated, there is a sequence of steps in the medical isotope supply chain that ends with hospitals.
- These steps involve; a reactor, a processor, a radiopharmaceutical manufacturer and a hospital and/or radiopharmacy.
- The AECL-NRU reactor is our primary source of medical isotopes.
- MDS Nordion is the processor of these medical isotopes at our facility in Ottawa.

- It is important to note that MDS Nordion is not the direct supplier of radiopharmaceuticals to hospitals.
- We distribute medical isotopes, which are Active Pharmaceutical Ingredients, to our customers - radiopharmaceutical companies – all of whom are based outside of Canada.
- Our customers, in turn, manufacture radiopharmaceuticals and distribute them to hospitals and radiopharmacies in Canada and worldwide.
- There are two American companies who are our customers and supply all of Canada's radiopharmaceutical products.
- Canadian-produced medical isotopes are responsible for supplying a total of over 50% of the world's medical isotopes, some 60,000 procedures per day – 5,000 in Canada.

Reactor suppliers

- One important aspect in this supply picture is the global production capacity.
- NRU is the most reliable reactor in the world for medical isotope production. Its supply reliability exceeds 97%.
- There are only three other sources to call upon for back-up supply: South Africa, Belgium and the Netherlands.
- If one of these reactors goes off-line, NRU can quickly ramp up to meet 100% of the additional demand.
- However, the reverse is not true as we saw last November/December.
- If NRU is off-line for more than 7 days, no other foreign reactor or combination of foreign reactors can fully fill the supply gap left by NRU.
- Even with the world's other reactors ramping up to capacity, there was still approximately a 35% total global shortage in medical isotopes. That gap would have persisted had the NRU reactor remained off-line.

Chronology of initial key dates during the NRU outage

- On the evening of November 21st, we were informed that NRU would not be restarting after its scheduled shutdown.
- We immediately initiated our contingency protocol for such emergencies.
- With only two days of inventory remaining, we began notifying affected customers, radiopharmaceutical manufacturers. We remained in close contact with them over the course of the outage period.
- On the morning of November 22nd in a meeting with AECL, we were informed of the potential extent of the NRU outage. We advised AECL that this outage would cause a shortage of global supply of approximately 30%.
- In the afternoon of November 22nd, we attended a regularly scheduled meeting arranged by AECL with Natural Resources Canada and ourselves. At that meeting we reiterated the estimated impact of this outage on global supply.
- On November 23rd, we contacted our other suppliers in South Africa, Belgium and the Netherlands in an attempt to source back-up supply. Virtually every day, we remained in contact with these suppliers.
- It is important to note at this point, it was not clear when the NRU reactor would resume isotope production. The information provided by AECL was in constant flux with regards to resolution options and restart schedules.
- By late November, AECL advised us they were working toward an early December restart. Based on that information, we then issued a press release.
- Starting on December 5th government officials from several departments sought regular briefings from us to update them.
- Later that led to discussions by departmental officials from Natural Resources Canada and Health Canada to involve us in the development of a communication protocol should any such supply event occur again.

Additional steps to facilitate back-up supply

- In addition to repeatedly requesting additional medical isotopes from our back-up suppliers, we took a number of steps to facilitate extra supply

- We obtained U.S. Food and Drug Administration approval to combine any available back-up supply in any proportion.
- We contacted the Belgium nuclear regulator to validate the shortage crisis and enable special dispensation for increasing processing limits at the Belgian processing facility.
- We shipped licensed containers to all our suppliers to facilitate immediate shipments should any material become available.
- In addition to seeking back-up supply, on December 3rd we also initiated a meeting with all of the world's suppliers to make an unprecedented request that they share their regular supplies. They refused.
- Despite persistent attempts to source back-up supply, we were only able to get a marginal amount of isotopes from abroad, about 20% of what we needed.
- All back-up supply received by MDS Nordion prior to the time that Bill C-38 was passed on December 12th came from South Africa; we were not able to get any back-up supply from Europe.

Steps to direct supply to Canada

- Although the global medical isotope supply shortage turned out to be about 35%, the shortage varied from country to country.
- In Canada's case, it was about 65% because the NRU reactor is the primary source in our supply chain. And, as we have learned from the nuclear medicine community, the shortage was more acute in certain regions.
- The reason for the geographic variation depended upon where each hospital obtained its finished radiopharmaceuticals.
- Our customer, U.S.-based Bristol-Myers Squibb, was – and is – the largest supplier of finished radiopharmaceuticals to Canada.
- We prevailed upon Bristol-Myers Squibb to ensure that Canada receive its fair share of available finished radiopharmaceuticals.
- They informed us that, in fact, Canada did receive its fair share of the limited supply of medical isotopes then available over the course of the NRU outage period.

Going forward

- In summary, Madam Chair, we believe we acted swiftly and worked diligently to address the medical isotope supply shortage caused by this outage.
- However, the reality is that there is no source of back-up supply that can fulfill the worldwide gap that NRU creates as a result of an extended shutdown.
- Clearly it is imperative that government, industry and the nuclear medicine community collectively find a long-term solution for the reliable supply of isotopes from Canada.
- Thank you and we are available for your questions.