



February 7, 2008

Opening Remarks

To the Standing Committee on Natural Resources

“Medical Isotope Supply Assurance”

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.
- Thank you for the invitation to appear before you on this important matter.
- I would like to mention up front that we were unable, regrettably, to have our remarks translated in French due to the short notice we were given to appear.
- MDS Nordion is an Ottawa-based life sciences company with over 700 employees at locations in Laval, Vancouver and Belgium.
- As a leading supplier of medical isotopes, we welcome this opportunity to provide our perspective on the 2007 isotope supply shortage event.
- 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.
- This event has significantly damaged Canada’s global reputation as a supplier to the nuclear medicine community and ours as well.
- *I would like to cover 3 key points:*
 1. *Our role in the medical isotope supply chain;*
 2. *Why AECL’s NRU unplanned outage was serious;*
 3. *The steps we took to respond to the outage and to source alternative, foreign supply of medical isotopes.*

Medical isotope supply chain

- It is important to understand that there is a sequence of steps in the medical isotope supply chain before patients are actually treated in the hospital. 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 to hospitals.
- We distribute medical isotopes 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.
- Every day, NRU and MDS Nordion-produced medical isotopes enable some 5,000 nuclear medicine diagnostic tests and cancer therapies to be performed in Canada, alone.
- 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.

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 35% total global shortage in medical isotopes. That gap would have persisted if 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.
- At that point it was not clear when the reactor would resume isotope production. It is important to understand that the information we were provided was in constant flux with regards to resolution options and restart schedules.
- Nonetheless we immediately initiated our contingency protocol for such emergencies.
- With only two days of inventory remaining, we immediately began notifying affected customers. 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.

Sourcing Back-up

- Over the course of the outage event, we were in daily contact with these isotope suppliers.
- We also took a series of additional steps to try to facilitate isotope 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.
- 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 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.

Going forward

- 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.