

Revised November 19, 2009
Molybdenum 99 (Mo 99) Shortage / Technetium 99m (Tc 99m) Supply
Frequently-Asked Questions - EXTERNAL

Q1. What was Covidien's role in the additional June, 2010, cycle added by the BR2 reactor in Belgium?

A. Covidien was actively engaged with the Belgian Nuclear Research Centre SCK-CEN Board of Directors during its decision making process and is providing significant funding to support the added BR2 cycle.

Q2. What access will Covidien have to the additional Mo 99 supply from BR2 in June, 2010?

A. Covidien will receive a significant portion of the Mo 99 produced by BR2 in June, helping tremendously to offset the lack of supply from the High Flux Reactor (HFR) during that time.

Q3. Are there other initiatives between Covidien and the BR2 reactor?

A. Yes. Covidien has secured an additional target position in the BR2 reactor that will increase output throughout the period that HFR is off line in 2010, allowing additional generator production to improve patient access to Tc 99m for critical procedures.

Q4. Will Covidien have access to Mo 99 produced by the OSIRIS reactor in France during the HFR shutdown?

A. Yes, as a result of our long-standing arrangement with the IRE Mo 99 processing facility, we will receive Mo 99 produced by the OSIRIS reactor when needed to supplement other suppliers.

Q5. Recent reports indicate there will now be only a few weeks of reduced Mo 99 production capacity during the HFR shutdown in 2010. Do you agree with this assessment?

A. The recent decision by the SCK-CEN Board of Directors to add a BR2 reactor cycle combined with the French government's decision to delay a routine maintenance cycle by two months have improved the outlook for 2010. It is important to note, however, that some overlap of the additional BR2 cycle and the extended OSIRIS availability will occur. There will also be brief periods of required routine maintenance for BR2 while the HFR is off line; OSIRIS will not have capacity to completely offset the lack of BR2 production during those periods.

Our assessment of the current 2010 calendar indicates several weeks where Mo 99 production will be diminished. As we have done throughout this critical shortage, Covidien will continue to obtain Mo 99 from all available sources as 2010 unfolds. We will also keep you informed when the situation changes to assist with your immediate, short-term and long-term planning.

Q6. Can you provide details about the proposed Pallas reactor in the Netherlands?

A. The Dutch government recently announced it supports construction of a new nuclear reactor for medical isotopes to replace the current HFR in Petten. The Nuclear Research and Consultancy Group (NRG), which operates the reactor in Petten, has plans to build a new modern reactor in the Netherlands that will be called 'Pallas'.²

Q7. What is Covidien's position related to the proposed Pallas reactor?

A. We support replacement of the HFR with a new Pallas reactor based on LEU technology. Covidien is a member of the steering committee for the project and readily provides our expertise as needed. We are focused on maximizing patient access to important medical isotopes, and applaud the Dutch Cabinet's decision to develop plans that help ensure long-term reliable and continuous supply of Mo 99.

Q8. What is the expected lifespan of the HFR in Petten once the 2010 repairs are complete?

A. According to NRG, the operational life span of the HFR extends until after 2015. NRG is working on the design and construction of a new nuclear reactor, Pallas, which is targeted to replace HFR.³

Q9. Do you believe the Canadian NRU reactor will truly return to service?

A. AECL, operator of the NRU reactor, continues to state the repairs will be completed by first quarter of 2010 with a return to service at that time.¹

Q10. How can individual clinicians in the U.S. positively impact this situation?

A. It is very important to maximize the availability of technetium 99m (Tc 99m) for patients by using as much as possible in procedures rather than allowing it to decay on the shelf. Covidien – through its U.S. Mallinckrodt Inc. radiopharmacies – recently implemented Tc 99m conservation policies designed to encourage unit dose customers to adjust their ordering practices to a more “just in time” approach. To illustrate the benefits to Tc 99m conservation, consider how ordering habits can affect supply:

- A department orders a 30mCi dose of Tc 99m calibrated for use at 2:00 p.m.
- The order requests a delivery on the first morning run at 6:00 a.m., requiring 75mCi of Tc 99m to meet the 30mCi dose requirement.
- Conversely, if the same order was placed for delivery at noon—ample time to meet the procedural need at 2:00 p.m.—only 38mCi of Tc 99m would be needed to meet the 30mCi target.
- This is a Tc 99m savings of 37mCi –enough activity for one bone or cardiac imaging dose, and up to five or six doses for certain other nuclear studies. That's ONE MORE PATIENT—maybe more--who can benefit from a nuclear medicine procedure.

This more thoughtful ordering approach has resulted in **hundreds of additional patient doses daily**. Similar efforts are encouraged industry wide. We appreciate the nuclear medicine community's willingness to carefully schedule patients, providing greater access to those most critically in need of this vital isotope. We are still boosting production of thallous chloride TI 201 injection for those procedures where it can be a clinically appropriate substitute.

Q11. How can individual clinicians in Europe, Canada, Latin America and Asia/Pacific positively impact this situation?

A. In a collaborative effort to maximize patient access to critical nuclear medicine procedures, we encourage physicians to plan for the most efficient use of Tc 99m. These efforts are encouraged industry wide. We appreciate the nuclear medicine community's willingness to carefully schedule patients, providing greater access to those most critically in need of this vital isotope. We continue to boost production of alternative isotopes such as thallous chloride TI 201 and other products for those procedures where either can be a clinically appropriate substitute.

Q12. How will supply projections work by week in the U.S. and Canada?

A. The calendar below details anticipated Covidien generator and unit dose (UD) Tc 99m supply to the overall U.S., Canadian and Latin American markets through November 2009. NOTE: Daily projections are based on current information and subject to change.

NOVEMBER							DECEMBER							JANUARY						
S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S
1	2	3	4	5	6	7			1	2	3	4	5						1	2
8	9	10	11	12	13	14	6	7	8	9	10	11	12	3	4	5	6	7	8	9
15	16	17	18	19	20	21	13	14	15	16	17	18	19	10	11	12	13	14	15	16
22	23	24	25	26	27	28	20	21	22	23	24	25	26	17	18	19	20	21	22	23
29	30						27	28	29	30	31			24	25	26	27	28	29	30
														31						
Generator standing orders met with some extra; minimal Tc-99m UD impact							Majority of generator standing orders met but no extra; some Tc-99m UD impact							Shortage to generator standing orders, significant Tc-99m shortage and UD impact						

Q13. How will supply projections work by week in Europe, the Middle East and Africa (EMEA)?

A. The calendar below details anticipated Covidien Mo 99/Tc 99m generator deliveries to the overall EMEA markets through December 2009. NOTE: Daily projections are based on current information and subject to change. Calendar Mo-99/Tc-99m generator deliveries.*

Calendar Mo-99/Tc-99m generator deliveries*

NOVEMBER							DECEMBER							JANUARY						
S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S
1	2	3	4	5	6	7			1	2	3	4	5						1	2
8	9	10	11	12	13	14	6	7	8	9	10	11	12	3	4	5	6	7	8	9
15	16	17	18	19	20	21	13	14	15	16	17	18	19	10	11	12	13	14	15	16
22	23	24	25	26	27	28	20	21	22	23	24	25	26	17	18	19	20	21	22	23
29	30						27	28	29	30	31			24	25	26	27	28	29	30
														31						

- Standing orders are expected to be met, with extra supply likely
- Standing orders are expected to be met, some shortages likely
- Significant Tc-99m shortages to be expected

* assuming delivery one working day after shipment

Q14. Why is there currently a shortage of Mo 99 supply?

A. On May 18, 2009, the National Research Universal (NRU) reactor in Chalk River, Ontario—operated by Atomic Energy of Canada Limited (AECL)—was taken offline for immediate repair after a heavy water leak was found at the base of the reactor vessel. On August 12 AECL announced the NRU shutdown would extend into first quarter 2010.¹

Q15. What does this shutdown mean for medical imaging procedures?

A. The NRU reactor is one of the world’s major molybdenum 99 (Mo 99) supply sources; Mo 99 is the raw material used to produce a key isotope used in medical imaging procedures. According to AECL, the reactor normally supplies about 50 percent of the Mo 99 used globally for diagnostic nuclear medicine studies. The U.S. and Canadian medical communities are most affected by the current shortage.

With only five major Mo 99 reactors around the globe, and the Chalk River facility producing roughly half of the world’s supply, the situation means Mo 99 will be in short supply during the repair period. Limited Mo 99 supply means reduced technetium 99m (Tc 99m) generator production and a shared inability to fully meet demand for nuclear imaging requests.

Q16. Why is there a planned 2010 shutdown at the HFR?

A. HFR is scheduled to go offline in mid-February, and expected to be shut down for 22 to 26 weeks for extensive planned maintenance work by government directive.² In 2009, the Dutch government granted permission for HFR to continue operation (inclusive of periodic maintenance) only until March 1, 2010. Covidien will continue bolstering our arrangements with the remaining online reactors in the coming months to obtain the maximum Mo 99 available, doing everything possible to minimize patient impact during this shutdown.

In an effort to maximize patient access to Tc 99m, the five Mo 99 reactors share maintenance schedules and coordinate scheduling required maintenance and refueling, and also processing of other targets to meet contractual obligations. The 2010 shutdown has been scheduled for months. Regulatory obligations demand these maintenance schedules occur as scheduled without deviation—even in situations where global supply would be further challenged.

At Covidien, we understand that even planned shutdowns can negatively impact patient care and are doing everything possible to minimize disruption. Even with the numerous global efforts and collaborations now underway, though, there will be challenges meeting full market need.

Q17. How will you deal with the potentially overlapping extended shutdowns of both the NRU reactor and HFR?

A. We anticipated the possibility of an unplanned overlap in reactor shutdowns early next year, which now appears likely. Our efforts continue toward maximizing Mo 99 supply arrangements with all viable sources. Based on the expected status of NRU and HFR in 2010, we estimate intermittent ability to fully meet existing customer orders (pre-NRU shutdown) mixed with periods of more severe shortages for technetium 99m (Tc 99m) generators. This variability will be due to already scheduled shutdowns of the remaining Mo 99 reactors from which we anticipate securing supply during that time.

Q18. What is Chalk River and who operates the facility?

A. The NRU reactor is a Canadian nuclear-research facility located near Chalk River, Ontario, and sometimes referred to simply as “Chalk River” or “CRL”. The facility is operated by the AECL, and according to the company the reactor normally supplies about 50 percent of the Mo 99 used globally for diagnostic nuclear medicine studies. The majority of its Mo 99 supply is normally sold to MDS Nordion who, after processing, provides a significant percentage to Lantheus Medical Imaging, a lesser amount to Covidien and some to other international customers.

Q19. Is this the first time there has been a Mo 99 shortage?

A. No. During the past three years, different reactors have been offline unexpectedly for extended periods of time, creating Mo 99 shortages. Routine maintenance shutdowns, however, are coordinated well in advance and generally do not create shortages.

Q20. Is the NRU shutdown affecting the European supply chain for Mo 99?

A. The overall usage of Tc 99m in Europe is considerably less due to fewer Tc 99m-based procedures than in the United States. Covidien is taking a thoughtful approach to equalizing global patient access to this isotope to the extent possible, keeping in mind isotope decay and other factors.

Q21. Does Covidien own the HFR in Petten?

A. No, the HFR is owned by the Joint Research Center (JRC) of the European Union and operated by the Nuclear Research and consultancy Group (NRG). Covidien has targets that are irradiated at the HFR to produce Mo 99.

Covidien does own two manufacturing sites across the street from the HFR; one processes irradiated uranium targets to produce Mo 99, and the second processes the Mo 99 into Tc 99m generators that are distributed in Europe, the Middle East and Africa, as well as areas in the Asia-Pacific region.

Q22. How are you progressing with the new generator line at the Maryland Heights manufacturing facility?

A. The new generator line being installed at our Maryland Heights facility is on schedule. We expect to complete installation and have the new line up and running in early 2012. This new generator line will provide a more robust and reliable supply of Tc 99m to customers and their patients.

Q23. Do you expect generator production or delivery delays due to the increased volume of generator orders?

A. No issues are expected that would result in delivery delays for Covidien's Tc 99m generators.

Q24. Is it possible to purchase more Mo 99 from another reactor?

A. There are only five major global reactors used for the production of Mo 99: one in Canada, three in Europe and one in South Africa.

At Covidien, we are working to secure additional Mo 99 supply and minimize patient-care impact, specifically:

- Requesting more frequent productions from the HFR by processing more targets, likely resulting in increased Mo 99 output
- Boosting output by increasing our target irradiation positions, maximizing our Mo 99 processing plant production
- Ordering additional Mo 99 from our other three suppliers in Europe and South Africa
- On a global basis, fairly distributing supply to reach as many patients as we can
- Significantly boosting our production of Tl 201 for use as an alternative to Tc 99m where clinically appropriate

Q25. What is Covidien doing to help customers and patients through the global Mo 99 shortage?

A. We understand any reactor shutdown or slowdown is stressful for our customers and, most importantly, to their patients. Covidien is committed to investing in supply chain diversification and providing new solutions to address the limited and fragile global Mo 99 supply chain. Covidien is working to minimize patient-care disruption and is taking steps to increase the availability of Tc 99m, as noted in question 24 above.

Q26. How quickly can Covidien respond to requests for additional generators in the U.S.?

A. Under normal circumstances, with full availability of Mo 99 supply, it takes two weeks to start filling any increases in standing orders. With a significant global shortage underway, and with 40 to 50 percent of the Mo 99 supply removed from the market almost instantaneously, any timeline for filling orders is impacted dramatically. Covidien Customer Service is maintaining a

list of requests, which will be filled as supply allows and according to our distribution priorities to reach as many patients as possible.

Q27. How quickly can Covidien respond to requests for additional generators in Canada?

A. During this worldwide shortage, we are doing our utmost to accept new standing order contracts within our regular timeframe of two weeks. Depending on the weekly supply, we also try to fill any new orders received.

Q28. Will Covidien be able to meet the extra demand for generator production?

A. With the Canadian reactor shutdown, no one company can meet 100 percent of customer demand. While the raw material supply situation continues to evolve, we are hopeful it will change for the better. In the meantime, we are building our generator production schedules with continued delay possibilities in mind, including working with our partners at the other reactors to secure additional Mo 99 supply. Our goal is to minimize patient-care impact, specifically:

- Requesting more frequent productions from the HFR by processing more targets, likely resulting in increased Mo 99 output
- Boosting output by increasing our target irradiation positions and maximizing our Mo 99 processing plant production
- Ordering additional Mo 99 from our other three suppliers in Europe and South Africa
- On a global basis, fairly distributing supply to reach as many patients as we can

Q29. How can Covidien positively affect the supply chain of Mo 99 long term?

A. Covidien has begun implementing a number of proactive steps to diversify its Mo 99 supply chain and aid the industry. This includes investing more than \$100 million in production upgrades during recent years, including \$60 million directed toward our Maryland Heights, MO, manufacturing facility.

We are committed to transitioning from using highly enriched uranium (HEU) to low-enriched uranium (LEU). That effort is underway and Covidien is investing in current production and processing, and pursuing new LEU solution-based technology through our agreement with The Babcock & Wilcox Company (B&W).

Covidien continues to assess developing LEU target technology for Petten and supports the replacement of the HFR, including the possible construction of a new Pallas reactor based on all LEU technology. We are also open to exploring other LEU opportunities.

Covidien also champions efforts to address current Mo 99 reactor maintenance issues, as diversification of supply is critical to long-term reliable supply and transitioning from HEU to LEU.

Q30. Can other reactors be brought online, even for the short term?

A. Typically, bringing a new reactor online takes years of planning, regulatory approvals, licenses, construction and testing. Even converting an existing reactor to produce medical isotopes such as Mo 99 is a time-intensive, costly process. Additionally, facilities must be available to process the targets.

In short, bringing a nuclear reactor online for medical isotopes is a complex regulatory process that cannot be accelerated—even during times of extreme global supply shortage.

Q31. Are there alternatives to using Tc 99m for patient procedures?

A. Clinicians may consider using other isotopes such as thallous chloride TI 201 injection (TI 201) when clinically appropriate. Covidien has significantly boosted production of TI 201 to help meet increased demand.

Q32. Are there plans to raise generator pricing in the near term?

A. At any given time, Tc 99m generator pricing reflects the need to invest in stabilizing the supply chain over the long term as well as to cover operating costs. Recent events, including the Chalk River and HFR shutdowns, have led to industry-wide increases to Mo 99 costs. As these costs impact our operations and ability to invest in the business, we will evaluate the impact regionally in the months ahead.

Q33. What can be done to alter reactor schedules for planned maintenance?

A. Planned maintenance and irradiation schedules follow strict timelines. Regulatory obligations demand these maintenance and operation schedules are adhered to without deviation—even in situations where global supply would be further challenged.

Q34. What is LEU conversion and why should the industry look to convert?

A. LEU conversion refers to transitioning from utilizing HEU targets. Currently, over 95 percent of global Mo 99 production depends on aging HEU reactors with inconsistent reliability, contributing to isotope shortages and impacting patient care.

LEU has the potential of addressing global security initiatives aimed at limiting possible diversion of HEU for nuclear terrorism. HEU is a weapons grade material; LEU is not.

Q35. What is the Covidien-Babcock & Wilcox (B&W) partnership?

A. Covidien and B&W are collaborating to develop solution-based reactor technology for medical isotope production. The agreement combines Covidien expertise in radiopharmaceutical production and global regulatory approvals with B&W's patented liquid phase nuclear technology. It is an initial step toward establishing a reliable large-scale, LEU based U.S. supply of medical isotopes.

Recently, the Society for Nuclear Medicine task force identified our partnership as one of the most viable U.S.-based alternatives for Mo 99 supply.

Q36. How quickly will the relationship with Babcock & Wilcox help the industry?

A. As the development progresses, B&W will build a new high-tech facility to support the program to develop solution-based reactor technology for medical isotope production. B&W anticipates the facility to be producing Mo 99 in approximately five or six years, depending on a number of factors including site selection, design, construction and regulatory approval. However, a long-term solution supporting the entire globally interdependent supply chain could take as much as 12-15 years to achieve. Thus, it is essential to ensure availability of the HEU Mo 99 supply to bridge transition to LEU and maintain global access to this isotope.

Q37. What can you tell me about the American Medical Isotopes Production Act of 2009 (AMIPA) or Markey bill in the U.S Congress?

A. On July 21, the American Medical Isotopes Production Act of 2009 (AMIPA) was introduced into the U.S. House of Representatives by Congressmen Edward Markey (Democrat-Massachusetts) and Fred Upton (Republican-Michigan). The Act would promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and

phase out the export of highly enriched uranium for the production of medical isotopes. To learn more, you may read the full bill at: <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.3276>:

Q38. How can I learn more about the Mo 99 supply situation?

A. To learn more about the current Mo 99 supply situation, please visit our website at www.covidien.com/Mo99supply . You may also visit these sites for regular updates:

- Society of Nuclear Medicine (<http://www.snm.org/>)
- FDA Drug Shortage (<http://www.fda.gov/cder/drug/shortages/>)
- Canadian Nuclear Safety Commission (<http://www.nuclearsafety.gc.ca/eng/>)
- Atomic Energy of Canada Ltd. <http://www.aecl.ca/site3.aspx>
- Association of Imaging Producers and Equipment Suppliers (European Industrial Association for Nuclear Medicine and Molecular Healthcare) <http://www.aipes-eeig.org/index.php?id=7>

1. NRU Status Report #29 - AECL provides update on NRU activities (last accessed November 19, 2009)

http://www.aecl.ca/NewsRoom/Community_Bulletins.htm

2. Government supports construction of new nuclear reactor for medical isotopes" (last accessed November 19, 2009)

<http://international.vrom.nl/pagina.html?id=44577>

3. Maintenance Stop High Flux Reactor Petten (last accessed November 19, 2009)

<http://www.nrg.eu/general/nieuws/2009/20090709en.html>