

The Logistics of Lifesaving

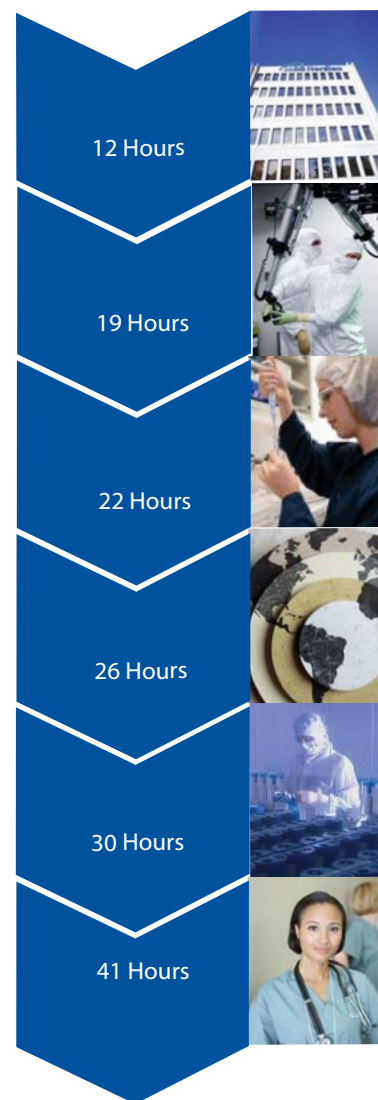
An insider's look at how a sophisticated logistics and supply chain network ensures timely, accurate delivery of critical medical isotopes

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As the staff of a frenzied Emergency Department in a major metropolitan hospital works intensely to treat a rising tide of incoming patients, they are informed of yet another patient en route – a 57-year old male suffering from suspected cardiac distress. The harried team readies themselves for their next case. Interns quickly prepare a cardiac room, while the charge nurse alerts the cardiac team that their expertise might soon be needed.

The doors swing open and EMTs rush the patient into the room. Organized chaos reigns as the ED team swarms the pale man on the gurney, taking vital signs, drawing blood for an enzyme screening, and starting an electrocardiogram. In the hallway, the charge nurse intercepts the man's wife, kindly guiding her to a nearby waiting room. Barking orders for labs, the attending doctor hurries to diagnose his patient. Pale, sweating, short of breath, and complaining of chest pain, the man exhibits possible signs of myocardial infarction (MI)...but is it truly a heart attack? With non-specific ECG results and no indication of MI from the enzyme screen, the physician makes a decision.

"Send him up to Radiology and get me a molecular imaging scan," he orders. "I need to quickly confirm his cardiac status."



Surviving the “Golden Hour”

Logistics and supply chain networks come into play when thinking about cardiac care. They ensure hospitals and doctors have the lifesaving tools on which they depend to diagnose and treat disease. Without networks in place that provide for continual replenishment of critical products, such as medical isotopes, timely access to state-of-the-art medical technologies would be limited at best.

According to the American Heart Association, heart disease kills one person every 34 seconds – or more than 2,500 people per day – making it the leading cause of death in the U.S. In the case of a heart attack, receiving proper diagnosis and treatment during the first 60 minutes – the so-called “Golden Hour” – dramatically increases a patient’s odds of survival while decreasing the likelihood of serious damage to heart tissues. But with the variety of conditions that can masquerade as a heart attack, making the correct diagnosis is challenging.

With the patient’s life and future good health hanging in the balance, doctors and hospitals today can ill afford a misdiagnosis. However, new advances

in cardiac molecular imaging are minimizing the risk that a heart attack goes unnoticed, or worse, is misdiagnosed. When compared to other modalities, medical isotopes used for molecular imaging help better determine if tissue, such as heart muscle, is actually viable with sufficient perfusion. Other imaging options may be limited primarily to anatomical considerations making an accurate diagnosis more difficult. Improved cardiac molecular imaging technologies, such as Single Photon Emission Computed Tomography (SPECT) and Positron Emission Tomography (PET), help doctors to more swiftly and accurately diagnose cardiac events in hospitals worldwide.

There are approximately 15 million molecular medicine procedures performed annually in the U.S. alone, of which 45% involve cardiac imaging. With this rising demand comes increased pressure on suppliers of critical cardiac imaging isotopes. Without an adequate and continuous supply of isotopes, patients cannot undergo these much needed molecular imaging procedures. As one of the world’s top suppliers of essential isotopes, MDS Nordion has made it a priority to ensure that its global supply chain meets its customers’ needs rapidly, which in turn helps

improve odds that patients will indeed survive the “Golden Hour”.

A Puzzle of Complexity

By their very nature, medical isotopes present a complex series of supply chain challenges. Not only must the half-life of the isotopes – the time interval required to decay to half of its initial value – be taken into account, but stringent regulatory, security, and safety requirements must also be considered. As a result, unlike consumer goods inventories that can be warehoused until needed, medical isotopes are generally delivered via Just-In-Time (JIT) logistics systems.

“Bar none, this is the most heavily regulated industry in the world,” says Chris Wagner, Senior Vice-President of Sales and Marketing at MDS Nordion in Ottawa Canada. “Isotopes have a very narrow window of usability and must be delivered to customers before that window would close. By also adding layer upon layer of strict regulatory requirements, it quickly becomes a very complicated proposition. There is simply no room for mistakes.”

Building on a half-century’s worth of experience, MDS Nordion has successfully deployed an integrated, global, JIT supply chain network that effectively ensures all of these

considerations are met. Like an intricate puzzle with interlocking pieces, this highly tuned network leverages the strong bonds formed between a multitude of players, including forecasting, production, scheduling, purchasing, suppliers, transportation carriers, and a number of diverse domestic and international regulatory agencies, in order to deliver the right quantity of isotopes to the right place at the right time. And as with any puzzle, each piece is dependent on the next in order to form the whole picture.

“Market globalization means that our supply chain network now stretches around the world, from our center of operations in Ottawa and Vancouver, Canada to hospitals as far away as Japan,” Wagner notes. “The success or failure of our supply chain relies on total co-ordination between each node in the network where medical isotopes are processed from raw materials to individual molecular imaging doses. Maintaining positive, productive intradepartmental and interagency working relationships is critical in any JIT operation because any disruptions in the system could result in patients not receiving needed treatment.”

MDS Nordion is one of only a handful of organizations with the ability to successfully operate such a complex and sophisticated logistics network. Based on JIT best practices and industry-proven Good Manufacturing Practice (GMP) principles, MDS Nordion has established its global logistics and supply chain network as the industry’s best.

The complexity surrounding the logistics of medical isotopes can be difficult to grasp. To provide insight and perspective, a step-by-step example of the route a medical isotope follows, from production to a patient in the U.S. will help address the complexities of this process.

Two Days in the Life of Mo-99

Eighty-eight percent of all cardiac diagnostic procedures in the U.S. use Molybdenum-99 (Mo-99). Timely delivery of this valuable isotope is essential given its half-life of only 2.5 days or 66 hours. Imagine a load of ice shipped without a cooler that is melting as it travels through the logistics network. Medical isotopes, with their short half-lives, are much the same. They too melt away by losing activity over time. In order to limit decay, MDS Nordion’s JIT supply

chain and logistics network must function at peak efficiency, meeting strict delivery deadlines to ensure that customers realize the optimum benefits from this product. Without an ongoing and highly reliable shipping process to maintain a constant supply, it would be only a few short days before the entire supply chain is depleted.

0 Hour: Mo-99 has been successfully harvested from a nuclear reactor by technicians at the raw-material supplier and is packaged and readied for transport to the MDS Nordion processing facility. While multiple lines of communication between the suppliers’ team and the processing facility are confirming that Mo-99 is ready for delivery, transportation planners are double-checking for any traffic delays that might impede its journey. Any transportation interruptions must be accounted for and the network schedule adjusted accordingly; with the clock ticking, every minute counts. The transport team gives the carrier the green light and Mo-99 begins its race against time.

+12 Hours: Mo-99’s arrival at the MDS Nordion processing facility is greeted with a flurry of activity. Technicians clad in protective gear descend rapidly on the shipment, carefully moving it to a “hot cell” – a

special containment unit designed to shield workers from radiation exposure. Once in the hot cell, a technician swiftly works to process Mo-99 quickly and efficiently for use as a pharmaceutical ingredient, so that it can continue on its fast-paced journey to the customer.

+19 Hours: The processing crew signals the transport team that its work is nearly complete, and Mo-99 will soon be ready for the next leg of its trip. Transportation logistics specialists immediately begin placing confirmatory calls and sending emails, finalizing arrangements for Mo-99's departure. A quick call to the charter air carrier confirms flight times and the destination. A check is also made of current weather conditions, ensuring there will be no weather-related delays. As a fail-safe, a second plane is on standby, minimizing chances of mechanical failure affecting the schedule.

The processing team alerts the transportation leader that its work is finished; Mo-99 is packaged and labeled, final shipping papers prepared and signed, and the package is raced to the waiting aircraft. As precious moments tick away, the shipment is

loaded into the cargo bay before finally taking off.

+22 Hours: Although much of MDS Nordion's work is complete, logistics personnel are still laboring furiously to smooth Mo-99's arrival in the U.S. With a myriad of regulatory agencies, including Customs and Border Protection, Department of Transportation, Nuclear Regulatory Commission, and other respective agencies involved, coordinating Mo-99's journey from Canada is no small feat. An MDS Nordion customs' and logistics' specialists work meticulously to see that all documentation is absolutely accurate and in place, such as customs clearance forms, cargo manifests, bills of lading, and invoices, averting a potential paperwork bottleneck. Additionally, arrangements are checked and double-checked to confirm the shipment meets all regulatory requirements for not just one, but each country.

To streamline and simplify international deliveries, MDS Nordion works with customs' specialists and agents from regulatory bodies around the world. Through an educational seminar series, agency personnel learn more about the product, how it is used, and what safety and security precautions are in place. By hosting these seminars, MDS Nordion ensures that there are clear channels of communication

between its team and all agencies involved, minimizing confusion and preventing cross-border delays.

+30 Hours: As Mo-99's flight touches down on U.S. soil, all of the advance groundwork laid by MDS Nordion is paying off – the shipment is checked quickly and clears customs in only 30 minutes. The journey continues with transportation to the U.S. radiopharmaceutical manufacturer who will complete Mo-99's processing.

Mo-99's true value lies hidden beneath its surface – a derivative radioisotope called Technetium-99 (Tc-99m). In the final radiopharmaceutical manufacturing phase, Mo-99 will be processed one final time into a number of Mo-99/Tc-99m generators, sometimes called a "Molycow". It is from this Mo-99/Tc-99m generator, that the Tc-99m is harvested to make molecular imaging agent patient doses.

The manufacturing team moves swiftly but precisely as they rush to produce these Mo-99/Tc-99m generators; with just a few precious hours remaining, wasted time is a luxury the team cannot afford. Custom-made generator shipping containers, built to stringent specifications set by regulatory agencies such as the

Canadian Nuclear Safety Commission, the Nuclear Regulatory Commission, and the Department of Transportation, not only protect the isotopes they house, but also the people coming into contact with them throughout the supply chain. While the manufacturing team loads the generator shipping containers, transportation agents are calling ahead to hospitals, clinics, and radiopharmacies who await their delivery. Once the needed molecular imaging doses arrive at customer designated sites, staff is available to prepare the necessary molecular imaging doses for delivery and patient use.

+41 Hours: At the hospital, the molecular imaging team quickly signs for the containers which hold the Tc-99m patient doses, before speeding them to Radiology. There, they will be used to administer molecular imaging scans. Mo-99's journey is complete.

A Life Preserved

A doctor steps into the hushed waiting room. Gently grasping the elbow of a frightened-looking woman seated in the corner, he carefully helps her to her feet and escorts her into the hall. She searches his face with worried eyes as he delivers the words she has been praying all morning to hear.

"We just received the results of your husband's molecular imaging scans and now know what's happened. We have a treatment plan I think will work, and your husband will be just fine."

As a global life-sciences leader, MDS Nordion is dedicated to making a difference in the lives of patients. By deploying and maintaining a world-class global supply chain and logistics' network that is founded on industry best practices, and proven JIT principles, physicians and hospitals can rest assured they will have the life-saving tools needed to prevent, diagnose and treat disease.

