

Product Lifecycle Management in a New Era of Radiopharmaceuticals

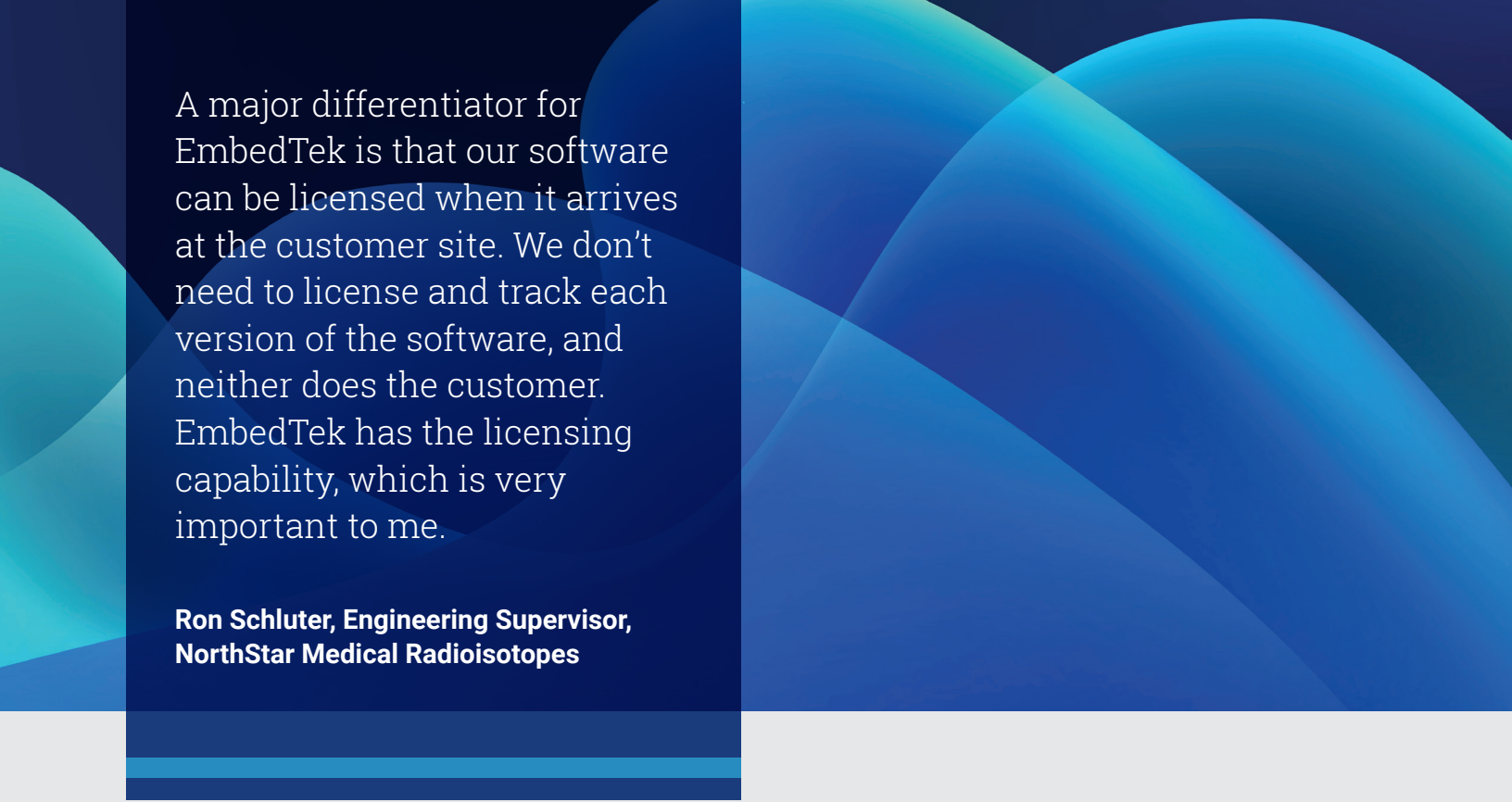
For more than a decade, EmbedTek has provided embedded computing solutions to a nuclear medicine company where success has required deep customer knowledge. The delicate nature of handling nuclear medicine called for EmbedTek to be aware of the end user application, stay updated on FDA regulations and have a comprehensive understanding of their entire supply chain. The result: a partnership that has evolved from an embedded technology provider to a true extension of the engineering team.



Photo provided by NorthStar Medical Radioisotopes

NorthStar Medical Radioisotopes, based in Beloit, Wisconsin, utilizes innovative production technologies that are defining a new era in diagnostic and therapeutic radiopharmaceuticals. Radiopharmaceuticals are used in imaging studies that help to diagnose heart disease and cancer. Radiopharmaceutical therapy (RPT) is rapidly evolving as a treatment option for patients with cancer and other serious diseases, an area where NorthStar is expanding its efforts.

NorthStar is the first company in 30 years with a program that produces, processes, and ships the highly valuable medical radioisotope molybdenum-99 (Mo-99) in the United States. Until now, Mo-99 was sourced exclusively from overseas, experienced shortages, and posed significant environmental risks because it is produced using enriched uranium-based fission processes.



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**Ron Schluter, Engineering Supervisor,
NorthStar Medical Radioisotopes**

NorthStar's non-uranium based production program produces benign and recyclable waste streams free of toxic and radioactive waste. In conjunction with a partnership with the University of Missouri Research Reactor (MURR®), these technological advances are helping to solve the U.S. radioisotope supply concerns and enabled NorthStar's integrated, efficient, and reliable Mo-99 distribution. Two facility expansion projects nearing completion in Beloit, Wisconsin, will augment current Mo-99 production and processing in Columbia, Missouri.

The EmbedTek team was brought on over a decade ago to provide hardware, software, and lifecycle management to one of NorthStar's industry-leading technologies, the RadioGenix® System. The RadioGenix System (technetium Tc 99m generator) is used by radiopharmacies nationwide to produce Sodium Pertechnetate Technetium-99m (Tc-99m) from Mo-99. In the U.S. alone, products labeled with Tc-99m are used in more than 40,000¹ imaging studies per day.

Reliability is Key

NorthStar's RadioGenix System is the first-of-its-kind high-tech radioisotope separation platform. Once non-uranium-based Mo-99 is produced, it is shipped in source vessels to radiopharmacies nationwide, where radiopharmacists work under stringent protocols and tight deadlines to deliver the radiopharmaceuticals to local hospitals and imaging centers.

"Reliability is key because there is a short timeline to vet the chemistry and get it out the door. Once radiopharmacies use the RadioGenix System to produce Tc-99m, the half-life is 6 hours," said Vicki Bull, Senior Strategic Sourcing Specialist for NorthStar. "The FDA requires robust traceability for everything that goes into that injection – from the computer, special software, consumable packaging, sterilization, reagents to dilute the product – everything has a lot number so if there ever is a problem down the road, we can trace it all back."

EmbedTek is uniquely suited to support NorthStar because of our holistic approach to designing embedded solutions based on customer requirements. EmbedTek engineers leverage proven technologies, commercial off-the-shelf (COTS) components, and existing supply chains where possible. Once a solution is implemented, EmbedTek provides product lifecycle management that prevents unexpected component changes, disruption to production, and increased costs.

"NorthStar Medical Radioisotopes fits the profile of other EmbedTek customers, in that their long-standing relationship with us is built on the kind of trust that is measured in consistency of work performed," said John Knepprath, Product Manager for EmbedTek. "In their business of supplying limited life cycle diagnostics to radiopharmacies, product reliability is critical."

NorthStar had a few layers of requirements for the RadioGenix System. First, the computer, monitor, touch panel, and power supply must balance performance quality within a specific size, decibel, and thermal parameters. Secondly, all components in the system must be consistent and available for 5 years to minimize changes to the product. Even a minor change or update would require a new FDA submission. And third, EmbedTek is to provide a customized system image for the .NET software framework, so NorthStar's manufacturing group doesn't have to set up the system independently.

"The goal of our manufacturing group is to minimize what we have to do in the system once we get it," said Ron Schluter, Engineering Supervisor for NorthStar. "EmbedTek also provides the safety and EMC regulatory compliance reports, which saves me a lot of work."

Controlled Updates

To comply with FDA regulations, EmbedTek manages a bill of materials (BOM) for the RadioGenix System hardware, software, and lock components for five years.

"Windows by default will install updates, so we have to come up with a way to ensure that does not happen," said Steve Paulin, Engineering Team Lead for EmbedTek. "We provide an initial system image when we release the computer. We do the setup, remove software functions that are not needed, and then every 6 months EmbedTek works with NorthStar to carefully review updates released by Microsoft."

EmbedTek assesses all updates to determine if there are fixes that can be ignored, could be productive, or are necessary. Once the impact assessment is complete, EmbedTek recommends all updates that would need to be installed as a large package, including written guidelines on managing the updates, and submits it to NorthStar for verification. If needed, EmbedTek helps with field updates to ensure all software is validated. EmbedTek also manages all software licensing by NorthStar radiopharmacy customers.

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Future Expansion

The benefit of a locked BOM is that EmbedTek always has its hand on the pulse of component availability for now and technologies coming down the pipeline for the future.

"We appreciate that NorthStar is transparent about their performance needs, requirements, any bottlenecks they are experiencing, etc.," said Christine Reese, Account Executive for EmbedTek. "Our engineers are always monitoring technology releases related to the NorthStar BOM, so when the time comes to launch a new platform, we already know what hardware could work and the software wraparound needed to achieve their goals."

Product launches and updates have occurred a few times over the past 10 years. In fact, EmbedTek has watched NorthStar grow from a company of 15 employees to 380 as they have continued to expand their technology footprint. Also, NorthStar is expanding its industry-leading position into the growing area of radiopharmaceutical therapy (RPT) to treat cancer and other serious diseases, and is poised to be the first commercial-scale producer of non-carrier added (n.c.a.) actinium-225 (Ac-225) and copper-67 (Cu-67) using electron accelerator technology.

"Our focus is to provide a spectrum of non-uranium-based radioisotopes for use in diagnosing and treating patients with cancer and other serious diseases," Schluter said. "State-of-the-art equipment, facilities, and a robust pipeline are planned to help patients in the U.S. and around the world."

1 DOE/NNSA, "NNSA's Molybdenum-99 Program: Establishing a Reliable Supply of Mo-99 Produced Without Highly Enriched Uranium", 2017

EmbedTek designs, invents, and manufactures computers, software, sensors, cameras, and displays for original equipment manufacturers. Our systems improve the quality of imaging in healthcare, simulation programs in the military, video analytics in security, and much more. Throw any challenge at us, from demanding environment and ergonomic requirements to High Level Assembly and nonstandard I/O. We'll evaluate it, carefully attack it, and solve it.