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United States Nuclear Regulatory Commission
*Protecting People and the Environment*

# NRC NEWS

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**Chairman Allison M. Macfarlane**
**Prepared Remarks at American Nuclear Society**
**8th International Conference on Isotopes**
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**Chicago, Illinois**

Good morning. It's a pleasure to be here and I appreciate the invitation to join in this very timely discussion. The potential development of domestic medical isotope production capability in the United States raises a number of interesting regulatory issues that the NRC anticipates and is working to address. Our efforts in this area require focused collaboration with other federal and state agencies.

For the past two decades, the United States has relied on imported radioisotopes to perform approximately 50,000 life-saving medical procedures daily. Multiple global shortages of medical isotopes have underscored the need for prompt action to ensure a reliable domestic supply.

Today, I'd like to update you on what the NRC is doing to prepare for possible licensing and oversight of medical isotope production facilities – and discuss how our export licensing role helps facilitate continued isotope production overseas. I'd also like to discuss some of the complexities associated with regulating medical isotope production, and address how our safety and security mission characterizes our ongoing coordination efforts inside and outside the agency.

The NRC fulfills its mission to protect public health and safety – in part – by ensuring that civilian uses of radioactive materials are safe and secure. Following the issuance of a national policy objective in 2011 to establish a reliable domestic supply of Molybdenum-99 (Mo-99) without the use of highly-enriched uranium (HEU), the NRC began preparing for several potential medical isotope production construction and operating license applications, likely proposing to use several different technologies. This has necessitated broad coordination across the various technical disciplines of the NRC staff and our Agreement State partners.

At the same time, on a policy level, our agency is also participating in government-wide coordination efforts led by the Office of Science and Technology Policy (OSTP) and other Federal agencies.

From the beginning, this work has required careful analysis, with plenty of technical nuances that are keeping our scientific and engineering team fully engaged. Each potential isotope production

technology comes with its own set of licensing considerations. Within the NRC's regulatory structure, the technology dictates what type of licensing process we'd use.

For example, isotope production involving uranium requires a construction permit, making the licensing process similar to that of a power reactor. For isotopes produced in an accelerator that do not involve the fission of uranium, the approval process may be different.

Some facilities may ultimately fall under the regulatory purview of one of the 37 Agreement States.

With the passage of the Energy Policy Act of 2005, the NRC assumed a role in regulating accelerator production of medical isotopes. The Act placed certain radioactive material produced in particle accelerators under the NRC's regulatory authority by expanding the definition of byproduct material.

From a policy standpoint, there are pros and cons to each possible technology. Isotopes produced domestically using uranium would be identical to those currently produced internationally, making it possible to use existing generator facilities to create radiopharmaceuticals. Yet, only two generator facilities currently operate in the U.S.

By contrast, accelerator-produced isotopes have low specific activity and would require different types of generator technologies. This has the potential to make the production more widespread and the isotopes more accessible.

As an independent regulator, the NRC is focused on the safety and security of potential facilities. For example, each technology may have associated unique radiation protection considerations. The NRC staff and comparable experts in the Agreement States will continue to train a sharp eye on these implications in the future.

I think a side-by-side comparison of isotope production facilities illustrates the diversity of possible paths that licensing could take in the United States. Let's consider, for example, the SHINE Medical Technologies and NorthStar Medical Radioisotopes facilities. Both companies propose to build facilities in Wisconsin, less than 20 miles from one another. Both designs use accelerators, but SHINE's technology includes fissioning low-enriched uranium (LEU), while NorthStar's uses non-radioactive isotopes of molybdenum.

The NRC staff recently began an extensive technical evaluation of the SHINE design, and determined that the irradiation units should be licensed as utilization facilities under 10 CFR Part 50, rather than with a special nuclear materials license under Part 70, because of the similarity of the systems to those of research and test reactors. By contrast, NorthStar, because it wouldn't use uranium and would be located in an Agreement State, would fall under Wisconsin's jurisdiction – and would be licensed under Wisconsin's rules. If the NorthStar facility were built in a non-Agreement State, it would fall under NRC Part 30 byproduct material oversight.

I'm throwing all these CFR "Parts" out there to give you a sense of the technical complexities associated with licensing a wide variety of potential designs. Because of the number of possible paths forward, we've been strongly encouraging companies to communicate with us early in the process to share information about their technologies and potential plans. Later today, I'll be speaking at the

annual meeting of the Organization of Agreement States a few miles from here. This is one of many areas of active engagement the NRC has with the States. For example, we've been in regular contact with the State of Wisconsin as we explore issues related to SHINE and NorthStar.

As with nuclear power plants or any of the other facilities we regulate, a complete, high-quality license application is essential for a timely review. Our staff has been conducting extensive outreach to help ensure that potential licensees understand our regulatory requirements. It's also important to emphasize that the NRC allocates resources and staff for future work in large measure based on information we receive from the industry regarding planned application submittals. We therefore urge licensees to give us design-mature information as soon as possible and realistic timeframes so we can plan accordingly.

So far, we've received ten letters of intent from potential applicants, and our staff has the necessary resources to review them. The Commission has approved publication of a Direct Final Rule as one step of the staff's proposed path forward for addressing the construction permit application from SHINE. Others are not as far along in the process.

In the past year, the NRC has conducted seven public meetings to facilitate discussion with possible licensees and other interested parties, and to answer questions about our regulatory process. And as I alluded to earlier, our staff is coordinating effectively both within the agency, in the form of a staff working group, and outside the agency – as part of OSTP's working group, with the States, and as appropriate, individually with the Food and Drug Administration and the National Nuclear Security Administration.

With the exception of the generator manufacturers and the radio-pharmacies, the only contribution that the U.S. currently makes to the global supply chain involves the export of uranium needed by other countries for use as fuel and/or targets in research reactors and medical isotope production facilities. Even though it appears likely that U.S. efforts to develop domestic suppliers of medical isotopes could bear fruit in the coming years, our country remains entirely dependent on international supply chains.

As the agency charged with licensing exports of uranium for use in research reactors and medical isotope production facilities overseas, the NRC plays a critical role in ensuring continued reliability of international isotope supply. As I'm sure you're aware, Canada is one of the major suppliers to the United States, and we highly value our cooperation with Ramzi and his team at the Canadian Nuclear Safety Commission.

The Atomic Energy Act sets forth the criteria that must be met for licensing exports of most nuclear materials. It shouldn't be surprising that exports of HEU are subject to the highest level of review and the most stringent criteria. I would note that concerns about exports of HEU are not new, and the NRC actually went on record in a 1982 policy statement supporting broader U.S. policy to reduce or eliminate the use of HEU in research and test reactors to prevent the proliferation of nuclear weapons.

The NRC's export licensing mandate is an important example of how the U.S. implements fundamental non-proliferation objectives by only allowing exports of nuclear materials to countries that provide and sustain commitments to peaceful use. To ensure safe and secure transfer and use of any proposed exports of special nuclear material (LEU to HEU) from the United States, our process

requires us to consult on a case-by-case basis with the Departments of State and Energy to verify that the recipient countries and referenced facilities meet required treaty and agreement obligations.

As part of their nonproliferation commitments, government authorities of countries requesting shipments of HEU must provide assurances that the destination facilities are legitimately licensed to receive, possess, and use the material as proposed. They must demonstrate that the facilities will maintain adequate physical protection measures and will not retransfer the material or use it in another application without first obtaining the prior consent of the U.S. Government.

Countries must also demonstrate that it hasn't yet been possible to convert their facilities to either LEU fuel or targets, and commit to doing so as soon as technically and economically feasible. In addition to requiring approval by the Executive Branch, each license application to export HEU requires my review and that of my Commission colleagues.

The NRC recognizes the critical importance to the medical community of reliable supplies of Mo-99 and supports efforts underway in various countries to replace aging facilities and ultimately move to non-HEU based supplies. The NRC has also joined other U.S. Government agencies in participating in the Organization for Economic Coordination and Development's Nuclear Energy Agency High-Level Group on the Security of Supply of Medical Radioisotopes.

I believe that the continued efforts to promote global recognition and consensus regarding the need to minimize and eventually phase out use of HEU for medical isotope production should be applauded. They make the world safer. In the meantime, the NRC will continue to perform the essential task of maintaining the stringent controls established to protect and account for HEU consistent with U.S. laws and our associated regulatory requirements.

The Commission is mindful of the fact that the availability of medical isotopes, regardless of where or how they are produced, enables people to receive medical treatments. At the same time, the NRC's responsibility is to ensure that all NRC and Agreement State-licensed facilities operate safely and securely and we intend to apply the same rigorous oversight with respect to isotope production.

The NRC is fully supportive of efforts to ensure a reliable supply of medical isotopes consistent with U.S. Government non-proliferation objectives. We have an outstanding staff that can analyze the technical complexities associated with licensing a variety of potential designs, and we've made sure that resources are available to effectively address incoming applications.

And as possible domestic isotope production continues to evolve in the United States, the NRC remains committed to upholding its export license obligations. This important aspect of the agency's work helps ensure a stable worldwide isotope supply.

I greatly appreciate the opportunity to speak with you today, and I look forward to your questions and our discussion.

Thank you.