

September 6, 2019

Chairman Kristine L. Svinicki
U.S. Nuclear Regulatory Commission
Mail Stop O-16 B33
Washington, D.C. 20555-0001

Reference: Export License Application from U.S. Department of Energy National Nuclear Security Administration, XSNM 3810, September 3, 2019 (Supersedes ML19213A204); ML19246A247

Dear Chairman Svinicki:

I write to support the referenced application, the approval of which would strengthen the security of supply of medical isotopes -- specifically Molybdenum-99 (Mo-99), Xenon-133 and Iodine-131 -- to U.S. patients while the Institute of Radioelements (IRE) completes its conversion from High Enriched Uranium (HEU) to Low Enriched Uranium (LEU) targets.

Lantheus Medical Imaging, Inc. (Lantheus) has been a pioneer in nuclear medicine and medical imaging for more than 60 years. We are an established manufacturer of radiopharmaceutical products used to image and diagnose heart disease, cancer, and other diseases in order to enhance patient care.

Since 2009, Lantheus has been an industry leader in the conversion to LEU medical imaging isotopes. In September 2009, we testified before the House Energy and Commerce Committee in support of the American Medical Isotopes Production Act, which eventually became law on January 2, 2013. In addition, we were the first U.S. company to:

- obtain approval for the use of LEU Mo-99 in our Technetium generators (September 2010);
- commercially manufacture Technetium generators using only LEU Mo-99 (December 2010); and
- commercially manufacture Technetium generators that produce non-HEU Technetium doses eligible for the CMS \$10 add-on payment per dose (January 2013)

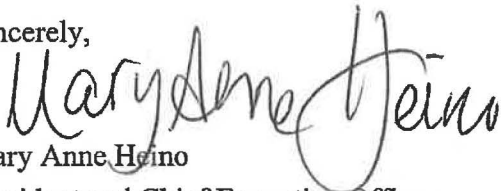
Lantheus has been, and continues to be, strongly supportive of the global conversion of medical isotope production from HEU to LEU targets. We believe this goal is now virtually at hand, as IRE - one of our three international Mo-99 suppliers - is in the final stages of LEU conversion.

During the past two years, the international medical radioisotope supply chain has faced production challenges at both ANSTO Health (Australia) and NTP Radioisotopes Pty. (South Africa), leading to intermittent international and U.S. supply shortages. As I write, neither of these two key suppliers to the U.S. market are able to produce Mo-99 at full capacity. In addition, NTP is currently unable to produce I-131.

We believe that your approval of the referenced export license is a necessary and prudent step, especially in light of ANSTO and NTP's production challenges. An approved export license will permit the Department of Energy to provide additional HEU to IRE as needed so that IRE can continue to be a key supplier of critical medical isotopes for U.S. patients. The license will enable IRE to complete its conversion from HEU to LEU targets, and allow customers sufficient time to obtain necessary regulatory approvals for LEU Mo-99 produced by IRE in all relevant jurisdictions, without jeopardizing global supply or patient outcomes during this transition period to full conversion.

Please feel free to contact me with any questions you may have.

Sincerely,

A handwritten signature in dark ink, appearing to read "Mary Anne Heino". The signature is fluid and cursive, with the first name "Mary" and last name "Heino" being the most prominent parts.

Mary Anne Heino

President and Chief Executive Officer

Copy: Secretary, U.S. Nuclear Regulatory Commission



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Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attention: Rulemaking and Adjudications Staff

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Dear Secretary:

Enclosed is a letter from Lantheus Medical Imaging President and CEO Mary Ann Heino to NRC Chairman Kristine Svnicki supporting approval of the referenced export license application.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Duffy", is written over a faint, larger version of the same signature.

Michael P. Duffy
Senior Vice-President and General Counsel

Enclosure: as stated

Docket, Hearing

From: Goldman, Ira N <Ira.Goldman@lantheus.com>
Sent: Thursday, September 12, 2019 12:54 PM
To: Docket, Hearing
Subject: [External_Sender] Lantheus Medical Imaging Letter re: Export License XSNM 3810 (ML19246A247)
Attachments: Chairman - K. Svinicki - US Nuclear Reg Comm.pdf; Secretary - US Nuclear Reg Comm.pdf

Ira N. Goldman
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