

The Council on Radionuclides and Radiopharmaceuticals, Inc.

Michael J. Guastella, MS, MBA
Executive Director

500 North Capitol Street, NW
Suite 210
Washington, DC 20001-7407
(202) 547-6582
Fax: (202) 547-4658
michael.guastella@corar.org

October 29, 2018

Hon. Jeffrey Thamsanqa Radebe
Minister of Energy
Department of Energy
192 Visagie Street
Corner Paul Kruger & Visagie Street
Pretoria, South Africa 0001

Subject: Expeditionary Safe Return of Medical Isotope Production at NTP Needed for Patient Care

Dear Minister Radebe,

I am writing to you on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) to express our deep concern regarding the extended production interruption of molybdenum-99 (Mo-99) and Iodine -131 (I-131) at NTP Radioisotopes. CORAR is the voice of the radionuclide, radiopharmaceutical, and nuclear pharmacy industries in the United States and we strongly encourage the National Nuclear Regulator South Africa (NNR) to work with NTP, a subsidiary of Nuclear Energy Corporation South Africa (NECSA), to expeditiously complete the remaining operational testing and regulatory reviews needed to allow the NTP processing facility to safely return to full medical isotope production as quickly as possible.

The United States consumes approximately 50% of the world's supply of Mo-99 and is a significant consumer of I-131. According to the Society of Nuclear Medicine and Molecular Imaging (SNMMI), more than 20 million Americans benefit each year from nuclear medicine procedures.¹ Well over half these patients undergo diagnostic tests that rely on Technetium-99m (Tc-99m), the daughter isotope of Mo-99. In addition, many patients benefit from I-131 for both diagnostic and therapeutic indications. Therefore, patients in the United States are particularly vulnerable to shortages of both Mo-99 and I-131 as a result of the NTP production outage. Please consider that Mo-99 has a relatively short half-life (approximately 66 hours) and must be produced on a continuous basis to meet the needs of the medical community. Any interruptions in production can place patients at great risk of missing much needed, "standard of care" diagnostic tests.

NTP is one of four Mo-99 processing facilities worldwide that extract Mo-99 from uranium targets and purify it for shipment to Tc-99 generator manufacturers. NTP currently supplies about 20% of global demand for Mo-99 according to published data.² While the remaining medical isotope production supply chain has worked to minimize the impact of the decreased NTP production of Mo-99 and I-131, without the significant production capacity provided by NTP, the risk of medical isotope shortages has increased. Because the potential for medical isotope shortages corresponds closely with the

¹ Society of Nuclear Medicine and Molecular Imaging, <http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=4825>

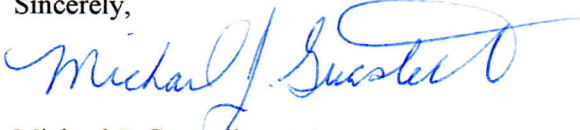
² The National Academies of Sciences Engineering Medicine, Molybdenum-99 for Medical Imaging, 2016

potential for an adverse impact on diagnostic and therapeutic treatment of patients in the United States (and elsewhere), CORAR supports and encourages efforts to enhance the production of medical isotopes.

CORAR formally requests that NNR balances the critical nuclear safety requirements of the NTP facility with the needs of the medical community and expedite the remaining operational tests and regulatory reviews necessary to return NTP to full medical isotope production as quickly as safe production of those isotopes can occur.

I would be happy to provide additional information on the Mo-99 and I-131 needs in the United States and the importance of maintaining a reliable and adequate supply of these medical isotopes for patients. The members of CORAR appreciate the opportunity to provide you with our comments, and I would like to thank you in advance for your consideration.

Sincerely,



Michael J. Guastella
Executive Director

cc: South African National Nuclear Regulator
Council on Radionuclides and Radiopharmaceuticals, Inc.
Society of Nuclear Medicine and Molecular Imaging
American Society of Nuclear Cardiology
Association of Imaging Producers & Equipment Suppliers