

Before the  
UNITED STATES NUCLEAR REGULATORY COMMISSION  
Washington, D.C. 20555

In the Matter of )  
Institute for Radioelements ) Docket No. 11006361  
(Export of 93.35% Enriched Uranium) License No. XSNM3810  
\_\_\_\_\_)

**NORTHSTAR MEDICAL RADIOISOTOPES, LLC**  
**REQUEST FOR HEARING**

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Pursuant to 42 U.S.C. 2239(a), 42 U.S.C. 2155a and 10 C.F.R. 110, Subparts H and I, NorthStar Medical Radioisotopes, LLC ("NorthStar" or "Petitioner") hereby respectfully requests a public, oral hearing before the Commission to with respect to the following pending license application:

The Application of Institute for Radioelement ("Applicant" or "IRE") for a license to export 4.772 kilograms of 93.35% highly enriched uranium ("HEU") to the Framatome facility in Romans, France for use in the fabrication of targets and subsequent target

irradiation in the High Flux Research Reactor in the Netherlands, the BR-2 Reactor in Belgium, the LVR-15 Research Reactor in Czechia, and the Maria Research Reactor in Poland, dated July 31, 2019 and published in ADAMS on August 5, 2019.

A full and open public hearing before the Commission would be in the public interest and will assist the Commission in making its statutory determinations by providing the Commission with relevant oral and written testimony addressing the issues and concerns raised by Applicant's pending license application.<sup>1</sup>

#### **I. Petitioner's Interest**

NorthStar is a privately held nuclear medicine technology company committed to providing reliable and environmentally friendly radioisotope supply solutions to meet patient needs and advance clinical research. NorthStar's corporate headquarters' physical address and telephone are as follows: 1800 Gateway Boulevard, Beloit, WI 53511; (608) 313-8000.

NorthStar achieved USFDA approval of its RadioGenix System (technetium Tc 99m generator) in February 2018 and subsequently entered the market producing non-HEU molybdenum-99 ("Mo-99") in

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<sup>1</sup> See 42 U.S.C. 2239(a), 42 U.S.C. 2155a and 10 C.F.R. 110.84.

the US. NorthStar is the first domestic producer of this critical radioisotope in the United States in almost 30 years and thus became the first success under the American Medical Isotopes Production Act of 2012 ("AMIPA").

NorthStar, like other market participants that have converted production operations from HEU Mo-99 or use non-HEU methodologies, have direct financial interests that have been undermined by IRE's failure to convert and would be directly affected by the Commission's decision related to Applicant's pending license application.

At great expense, time and effort, market participants around the world have converted to LEU or have established non-uranium methodologies in order to meet both the US' nonproliferation centered policy goal of eliminating the exportation of HEU and establishing a dependable domestic supply of medical isotopes. Petitioner is aware of a twenty percent loss of production when production converts from HEU to LEU. Absent a hearing, NorthStar, which has been responsible and responsive to the US government's policy goals and legal requirements, will continue to be forced to participate in an unfair and unbalanced market as a result of IRE's failure to convert.

## II. Background

### a. IRE has failed to convert.

IRE is the last market participant to fully convert operations to non-uranium processes or low enriched uranium (LEU). IRE currently has an active HEU export license valid through October 31, 2019.<sup>2</sup>

During its presentation at the July 2019 Organization for Economic Cooperation and Development ("OECD") meeting, IRE stated that while it is continuing to move forward with its LEU conversion, their facilities will not be fully converted by Q1 2020 and projected the completion of their LEU conversion would occur in mid to late 2020.<sup>3</sup> IRE has also stated that while its Mo-99 production would be converted by mid to late 2020, it still requires HEU for its Iodine 131 ("I-131") production.

### b. US policy and law concerning HEU.

The US has consistently endeavored to eliminate the export of HEU, reduce nuclear security risks and promote a reliable domestic supply of Mo-99.

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<sup>2</sup> See IRE Export License No. XSNM3795, Docket No. 11006315 (Issued Oct. 12, 2018) (attached).

<sup>3</sup> See IRE "LEU Conversion Update" Presentation, OECD Meeting, Slide 4 (July 9, 2019) (attached).

*i. 42 U.S.C. 2160d.*

To facilitate its commitment to meet its export policy goals, Congress placed further restrictions on HEU exports. Among other considerations, the Atomic Energy Act restricts the export of HEU if there is "an alternative nuclear reactor fuel or target enriched in the isotope 235 to a lesser percent than the proposed export that can be used in the reactor."<sup>4</sup> This restriction emphasizes the US' policy goal of eliminating the use of HEU and incentivizing market participants to convert to non-HEU means of production.

*ii. The American Medical Isotopes Production Act of 2012 prohibits the continued exportation of US-origin HEU.*

The American Medical Isotopes Production Act of 2012 ("AMIPA"), enacted January 3, 2013, included a Medical Production License Sunset provision.<sup>5</sup> Specifically, AMIPA states that 7 years after the date of its enactment the Commission may not issue a license for the export of HEU from the US for the purposes of medical isotope production if there is a finding through joint

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<sup>4</sup> See The American Medical Isotopes Production Act of 2012 amended Section 134 of the Atomic Energy Act 42 U.S.C. 2160d(a), "...the Commission may issue a license for the export of highly enriched uranium to be used as a fuel or target in a nuclear research or test reactor only if, in addition to any other requirement of this chapter, the Commission determines that—(1) there is no alternative nuclear reactor fuel or target enriched in the isotope 235 to a lesser percent than the proposed export, that can be used in that reactor."

<sup>5</sup> See 42 U.S.C. 2160d(c).

certification by the Secretary of Energy and the Secretary of Health and Human Services that there is a sufficient supply of non-HEU produced Mo-99 available to meet the domestic needs of US patients, and it is no longer necessary to export US-origin HEU for the purposes of medical isotope production in order to meet domestic US patient needs.<sup>6</sup> The effective date of the Medical Production License Sunset provision is January 2, 2020.<sup>7</sup>

If issued by the Commission, IRE's recent application would permit for 5 months of HEU exportation (October 2019 through March 2020) which would be used to support 2.5 years of additional HEU production. An additional 2.5 years of production goes well beyond both Applicant's projected conversion date and runs afoul of the effective date of the export license sunset provision provided by AMIPA.<sup>8</sup> The issuance of another export license will continue to incentivize Applicant to continue delaying its conversion completion and, subsequently, continue to adversely affect other marketplace participants that have duly converted.

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<sup>6</sup> See 42 U.S.C. 2160d(f).

<sup>7</sup> See 42 U.S.C. 2160d(c); 42 U.S.C. 2160d(f) (2).

<sup>8</sup> See IRE Export License Application No. XSNM3810, Docket No. 11006361 (Received by NRC Aug. 5, 2019), "This application covers...production from the 4th quarter of 2020 through the projected completion of the LEU conversion program in the 2nd quarter of 2022" or 2.5 years."

### III. Petitioner's Contentions

Petitioner contends that the market supply for both non-HEU Mo-99 and I-131 are capable of meeting domestic market demands, IRE's application requests more HEU than required for production, IRE's application is inconsistent with stated conversion timeline and the Commission's issuance of a license to Applicant is contrary to the policy goals of AMIPA and the ongoing endeavors of the Department of Energy.

- a. The proposed HEU Exports are not required to meet current market demand.

The supply and demand standards set forth by AMIPA are met by the current marketplace and the need for continued exportation of US-origin HEU for the production of Mo-99 is no longer substantiated.

The OECD estimates the global Mo-99 usage to be 9,400 Ci per week.<sup>9</sup> Currently, based on OECD published figures, both the Mo-99 market weekly maximum production capacity and weekly average production exceed the global demand.<sup>10</sup>

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<sup>9</sup> See OECD, *The Supply of Medical Radioisotopes, 2018 Medical Isotope Demand and Capacity Projection for the 2018-2023 Period* at 8-9, 29 (2018) (attached).

<sup>10</sup> See *id.*

Moreover, the 1-131 market's maximum capacity surpasses the global demand and utilization rates significantly. Current market conditions provide an ample supply of I-131 exceeding market demand and the market would surpass global demand without any IRE sourced I-131 being taken into consideration. Notably, there are other non-HEU based methodologies (neutron capture on a Tellurium target) that produce I-131 which are used by other market participants, including domestic producers, and would be available as an alternative to IRE HEU sourced I-131.

b. The proposed export quantity is in excess of what is required to meet Applicant's production capacity.

*i. IRE Production Figures*

The proposed export quantity of 4.7 kilograms is in excess of what is required to meet Applicant's production capacity of I-131. IRE has requested 4.7 kilograms of HEU to sustain 130 weeks of production for both Mo-99 and 1-131.<sup>11</sup> 4.7 kilograms of HEU would supply IRE with 954 6-day curies of Mo-99 per week.<sup>12</sup> This

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<sup>11</sup> See IRE Export License Application No. XSNM3810, Docket No. 11006361 (Received by NRC Aug. 5, 2019).

<sup>12</sup> This figure assumes:

1. This HEU would be used over a 130-week period
2. You can produce, on average, about 26.4 Ci of Mo-99 (six-day) per gram of HEU in targets;
3. 4,700 g of U spread over 130 weeks (through Q2 2022) would produce 954 Ci (six-day) per week

Equation:  $4,700 \text{ g} \times 26.4 \text{ Ci per g} = 124,080 \text{ Ci (six-day)}$



would represent about 24% of their current average production of ~4,000 6-day curies per week.<sup>13</sup>

Applicant still requires HEU to produce I-131. In order to meet IRE's current weekly production of I-131 of ~400 6-day curies over a 130-week period, IRE would only require 559 grams or 0.559 kilograms of uranium (HEU).<sup>14</sup> Therefore, after meeting its current weekly production of I-131 throughout the 130-week period delineated in its license application, IRE would have an excess of 4.141 kilograms to use for the continued fabrication of Mo-99 produced with HEU.

*ii. The proposed export application creates discrepancies concerning Applicant's conversion timeline.*

The proposed exports application provides inconsistent figures and production timelines. On the basis of IRE's statements and accompanying presentation during the 2019 OECD meeting, the industry was left with the impression that IRE's Mo-99

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<sup>13</sup> See OECD, *The Supply of Medical Radioisotopes, 2018 Medical Isotope Demand and Capacity Projection for the 2018-2023 Period* (2018) (attached).

<sup>14</sup> This figure assumes:

1. 1 gram of uranium (LEU) will produce roughly 77 Ci of I-131.
2. HEU production of I-131 has about 20% higher yield or 92.4 curies per g of HEU.
3. IRE is producing 400 curies per week of I-131.

Equation:  $400 \text{ Ci per week} / 92.4 \text{ Ci per g} = 4.3 \text{ grams of HEU needed}$   
 $4.3 \text{ grams HEU} \times 130 \text{ weeks} = 559 \text{ grams or } 0.559 \text{ kg}$

production would be fully converted by mid to late 2020.<sup>15</sup>

As explained through the production figures in above paragraph (b)(i) the amount of HEU requested by IRE clearly exceeds its current I-131 production capacity leaving IRE with more than 4 kilograms to be used for non-I-131 production. If IRE intends to have its Mo-99 production converted by mid to late 2020, it is unclear why Applicant needs an additional 4 kilograms to sustain I-131 through Q2 of 2022.

Additionally, in accordance with the export restrictions set forth in 42 U.S.C. 2160d(a)(1), because Applicant has one production line dedicated to LEU Mo-99 production, the requested export of HEU for Mo-99 production through 2022 is unwarranted.

If granted a hearing, Petitioner seeks clarification of the discrepancy between IRE's statements at the OECD meeting and subsequent export request.

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<sup>15</sup> See IRE "LEU Conversion Update" Presentation, OECD Meeting, Slide 4 (July 9, 2019) (attached).

c. Issuance of Applicant's pending license application is contrary to the policy goals of AMIPA and the endeavors of the Department of Energy.

The proposed exports would be inconsistent with the Department of Energy's ongoing efforts to establish a reliable domestic source of non-HEU Mo-99. As a means of facilitating the goals set forth by AMIPA, the Department of Energy ("DOE") has spent hundreds of millions of dollars implementing, funding and administering cooperative agreement programs to establish a domestic source of Mo-99.

The issuance of another export license to IRE will continue to negatively affect US companies that have been both responsible and responsive to the policy goals of the US government and financially assisted through DOE. Clearly, the intent of the US through years of law making and subsequent program-aide was not to continually foster the ability of foreign companies to undermine both US companies who have found new means of producing non-uranium Mo-99 or have duly complied with conversion to non-HEU production.

**IV. Petitioner's Request for an Oral Hearing for an Oral Hearing.**

An oral hearing before the Commission to address Petitioner's interests and concerns with Applicant's pending license application would be in the public interest and will assist the Commission in making its statutory determinations. Petitioner's oral and written testimony will allow the Commission to be fully briefed on Petitioner's concerns and permit an open dialogue between the affected and the Commission to fully address all relevant issues and questions.

**V. Relief Requested**

For the reasons set forth above, the Petitioner respectfully requests an oral hearing before the Commission in regard to License No. XSNM3810 Docket No. 11006361.

Respectfully submitted,

/s/ Signed (electronically) by Steve Merrick

President & CEO

1800 Gateway Blvd

Beloit, WI 53511

smerrick@northstarnm.com

Dated: 26 August 2019

## Request for Hearing References

1. IRE Export License No. XSNM3795, Docket No. 11006315 (Issued Oct. 12, 2018), Footnote 2.
2. IRE LEU Conversion Update Presentation, OECD Meeting (July 9, 2019), Footnotes 3 and 15.
3. OECD, The Supply of Medical Radioisotopes, 2018 Medical Isotope Demand and Capacity Projection for the 2018-2023 Period (2018), Footnotes 9, 10 and 13.

**EXPORT LICENSE**

NRC FORM 250  
(10-07)

**UNITED STATES OF AMERICA**  
**Nuclear Regulatory Commission**  
**Washington, D.C. 20555**

**NRC LICENSE NO.:** XSNM3795

Page 1 of 4

**NRC DOCKET NO.:** 11006315

**LICENSE EXPIRES:** October 31, 2019

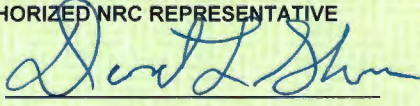
Pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 and the regulations of the U.S. Nuclear Regulatory Commission (NRC) issued pursuant thereto, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued to the licensee authorizing the export of the materials and/or production or utilization facilities listed below, subject to the terms and conditions herein.

| LICENSEE   | ULTIMATE CONSIGNEE(S) IN FOREIGN COUNTRY(IES)   |
|--|---|
| U. S. Department of Energy (DOE)<br>National Nuclear Security Administration (NNSA)<br>Y-12 National Security Complex<br>301 Bear Creek Road<br>Oak Ridge, TN 37831<br><br>Attn: Becky G. Eddy | Institute for Radioelements (IRE)<br>Avenue de l'Esperance 1<br>B-6220 Fleurus<br>Belgium<br><br>(for medical isotope production) |

| INTERMEDIATE CONSIGNEE(S) IN FOREIGN COUNTRY(IES) | OTHER U.S. PARTY(IES) TO EXPORT |
|---|---------------------------------|
| See pages 3 and 4                                 | See page 3                      |

|  |   |
|--|---|
| <b>APPLICANT'S REFERENCE NO.:</b> IRE-EU19 | <b>ULTIMATE DESTINATION(S):</b> Belgium |
|--|---|

| QUANTITY(IES)   | DESCRIPTION OF MATERIAL(S) OR FACILITY(IES)  |
|-----------------|--|
| 3.304 kilograms | Uranium, enriched to 93.2 WGT % maximum, containing 3.07 kilograms of uranium-235, in the form of unalloyed broken metal.<br><br>Conditions 3, 4, 6, and 7 on page 2 of this license apply to this export. |

|   |  |
|---|--|
| <p>Neither this license nor any right under this license shall be assigned or otherwise transferred in violation of the provisions of the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974.</p> <p>This license is subject to the right of recapture or control by Section 108 of the Atomic Energy Act of 1954, as amended, and to all of the other provisions of said Acts, now or hereafter in effect and to all valid rules and regulations of the NRC.</p> | <p align="center"><b>THIS LICENSE IS INVALID UNLESS SIGNED BELOW<br/>BY AUTHORIZED NRC REPRESENTATIVE</b></p> <p><b>SIGNATURE:</b> </p> <p><b>NAME AND TITLE:</b> David L. Skeen, Deputy Director<br/>Office of International Programs</p> <p><b>DATE OF ISSUANCE:</b> <b>OCT 12 2018</b></p> |
|---|--|

**U.S. NUCLEAR REGULATORY COMMISSION  
EXPORT LICENSE**

**LICENSE NUMBER: XSNM3795**  
Page 2 of 4

**Conditions**

- Condition 1:** Reserved
- Condition 2:** Reserved
- Condition 3:** This license covers only the nuclear content of the material.
- Condition 4:** The material to be exported under this license shall be shipped in accordance with the physical protection requirements for special nuclear material in 10 CFR Part 71 and 10 CFR Part 73.
- Condition 5:** Reserved
- Condition 6:** This license authorizes export only and does not authorize the receipt, physical possession, or use of the nuclear material.
- Condition 7:** The shipper shall complete and submit a DOE/NRC Form 741 for each shipment of uranium, thorium, and plutonium (i.e., source or special nuclear material) exported under this license.
- Condition 8:** Reserved
-

**OTHER U.S. PARTY(IES) TO EXPORT:**

1. Consolidated Nuclear Security (CNS) L.L.C.  
301 Bear Creek Road  
Oak Ridge, TN 37831

(DOE/NNSA supplier/transport contractor)

2. TN Americas LLC  
7135 Minstrel Way Suite 300  
Columbia, MD 21045

(transporter)

**INTERMEDIATE CONSIGNEE(S) IN FOREIGN COUNTRY(IES):**

1. Framatome  
54 Avenue De La Déportation  
ZI Les Bérauds  
26104 Romans Sur Isère  
France

(target fabrication)

2. TN International  
1, rue des Herons  
78180 Montigny-le-Bretonneux  
France

(transporter)

3. Studiecentrum Voor Kernenergie (SCK-CEN)  
BR-2 Research Reactor  
Boeretang 200  
BE-2400 Mol  
Belgium

(target irradiation)



**INTERMEDIATE CONSIGNEE(S) IN FOREIGN COUNTRY(IES): (Cont'd)**

4. Nuclear Research and Consultancy Group (NRG)  
HFR Research Reactor  
Westerduinweg 3  
1755 LE Petten  
The Netherlands

(target irradiation)

5. Nuclear Research Institute, Rez, plc  
LVR-15 Research Reactor  
Husinec – Rez 130  
Cz-250 68 Rez  
Czech Republic

(target irradiation)

6. National Center for Nuclear Research  
Maria Research Reactor  
Andrzej Soltan 7  
05-400 Otwock-Swierk  
Poland

(target irradiation)



# IRE LEU conversion update

OECD-NEA AD-HOC Lite 09-07-2019



Excellence dedicated to nuclear medicine, healthcare and environment

# Specific LEU conversion challenges

- Safety improvements required
  - Chemical process modifications
  - Production equipment modifications
  - Production environment updates : hot cells and ancillaries
  
- 3 processes to convert
  - Mo-99
  - I-131
  - Xe-133
  
- Product validation not under direct IRE control

# Status

- **QUALITY : Mo-99 pharmaceutical validation at IRE**
  - Validation runs successfully completed
  - Samples shipped for customer validations
  - Customer validations ongoing
- **Drug Master File**
  - submission end of August
- **Final safety demonstration**
  - In worst case conditions - ongoing
  - Approval required by federal agency for nuclear control (FANC)

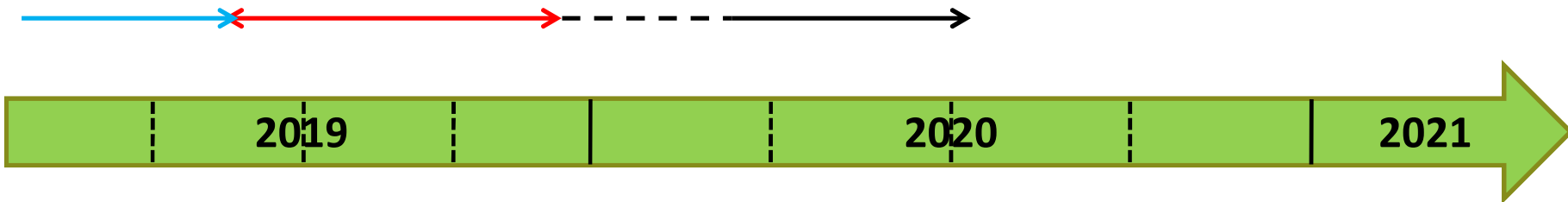


# Planning

**Validation & approvals**

**HEU Phase out**

**Mo-99 ; Xe-133 timeline**



**I-131 timeline**





**IRE**

**RE** Elit  
Environment & Lifescience Technology

©

**Excellence dedicated to nuclear medicine, healthcare and environment**

# The Supply of Medical Radioisotopes

2018 Medical Isotope Demand  
and Capacity Projection for the  
2018-2023 Period

## Chapter 2. Demand update

In 2011, the NEA released a study with the results of a global survey of future demand for  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$  (NEA, 2011), based on an assessment by an expert advisory group. The study anticipated  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$  demand growth up to 2030 in both mature and emerging markets, with stronger growth forecast in emerging markets.

In a subsequent report, “A Supply and Demand Update of the Molybdenum-99 Market” (NEA, 2012a), the NEA estimated global  $^{99}\text{Mo}$  demand at 10 000 6-day curies  $^{99}\text{Mo}$  per week<sup>1</sup> at end of processing (EOP). This demand was lower than the previous estimate of 12 000 6-day curies  $^{99}\text{Mo}$  per week EOP and the difference primarily resulted from a number of changes that occurred in the market as a consequence of the 2009-2010 global supply shortages. Those changes included: better use of available  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ , more efficient elution of  $^{99\text{m}}\text{Tc}$  generators, adjustments to patient scheduling, and some increased use of substitute diagnostic tests/isotopes. Some of those changes continued to be implemented in the market after the end of the 2009-2010  $^{99\text{m}}\text{Tc}$  supply shortage.

The April 2014 report, “Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$  Market, 2015-2020” (NEA, 2014), used as a starting point the NEA 2012 estimate of 10 000 6-day curies  $^{99}\text{Mo}$  EOP per week from processors, but with modified annual demand growth rates of 0.5% for mature markets and 5% for developing markets. This change was based on information provided at that time by supply chain participants.

The August 2015 report, “The Supply of Medical Radioisotopes: 2015 Medical Isotope Supply Review:  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$  Market Demand and Production Capacity Projection 2015-2020” (NEA, 2015), introduced an adjusted demand estimate of 9 000 6-day curies  $^{99}\text{Mo}$  EOP per week from processors. This was based on a new set of data that was collected by the NEA from supply chain participants on capacity utilisation for each operating quarter of the period 2012 to 2014. The data along with the actual operational periods for each facility (e.g. the actual number of operational days) provided useful information, as it included known periods when the supply chain had been stressed due to a number of facilities suffering outage periods at the same time.

The reasons behind that market demand estimate being lower than in earlier reports were not clear. The continuation of some of the measures mentioned previously to increase efficiency of use of  $^{99\text{m}}\text{Tc}$  at the nuclear pharmacy and in the clinic, combined with some reduction in average injected dose due to some technical improvements in gamma cameras, as well as some procedure protocol changes may have played some role. Also, in a market where full cost recovery (FCR) pricing continues to be implemented in steps along the supply chain, with the result of steadily and substantially increased prices, it would be understandable that efficiency of use of materials was a priority for all supply chain participants who have an objective of minimising costs.

This report builds upon the same approach as the April 2017 report; it is based upon analysis of the same supply chain data set, but now for the period from 2012 to 2017. Estimated market growth rates in this report have been kept unchanged at 0.5% for

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1. A 6-day curie is the measurement of the remaining radioactivity of  $^{99}\text{Mo}$  six days after it leaves the processing facility (i.e. at the end of processing – EOP). In International System (SI) Units, 1 Ci is equal to 37 Giga becquerels.



mature markets and 5% for developing markets during the forecast period. At the end of 2014, mature markets were estimated to account for 84% of the global demand for  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ , while emerging markets accounted for 16%.

The latest available data has been analysed to determine the level of recent market demand as described above, with reported global utilisation capacity being taken as a surrogate for the demand in the market. The data set is not 100% complete; again in this report, one processor did not provide the requested data. For the purposes of this report, the market demand for  $^{99}\text{Mo}$  activity has been held at 9 000 6-day curies  $^{99}\text{Mo}$  EOP per week EOP based upon a starting reference time point of the end of 2014. This means that with the growth rates used in this report, the market demand at the beginning of 2018 has increased and is estimated to be approximately 9 400 6-day curies  $^{99}\text{Mo}$  per week, a total increase of approximately 4.5% since the end of 2014.

The latest analysis does not fully confirm nor disprove this level of estimated market growth during the period. The latest data for 2017 does however reconfirm that recent global demand for  $^{99}\text{Mo}$  is close to a level of 9 400 6-day curies  $^{99}\text{Mo}$  EOP per week, with some demand fluctuations seen at a quarterly level.

There is some evidence that the level of production needed to supply the market has increased since the end of routine NRU production in late 2016. The end of NRU production directly resulted in extending supply lines to the large US market, with increased volumes of material delivered from outside North America. The short half-life of  $^{99}\text{Mo}$  (66 hours) – the product form that is transported internationally to generator manufacturers – results in approximately 1% of the entire quantity of product shipped being lost through decay for every additional hour of distribution time. This is equivalent to a total 22.3% decay loss during 24 hours of additional distribution time.

Increases in distribution distance and time have indirectly added to the demand for product per week at the EOP time point. As an example, the actual production level at the processor point in the supply chain, at the time point EOP, must increase by 28.7% to offset a 24-hour decay loss sustained in shipping that product for 24 hours of additional distribution time. Likewise, the direct cost of production of the same product distributed for longer transport distances/times also increases proportionally. This is an example of how production capacity may need to increase for  $^{99}\text{Mo}$ , without there being an equivalent increase in the end-user demand for the final product.

### **What capacity level is required to ensure that $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ demand is met?**

The capacity level required to ensure that the market needs for  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$  are met must include some level of paid outage reserve capacity (ORC). In the HLG-MR policy principles, it was proposed that a processor should hold a sufficient level of paid ORC to replace the largest supplier of irradiated targets in their supply chain. Likewise, participants further down the supply chain should hold similar levels of ORC. This is the so-called (n-1) criterion, that is, the level of ORC required by a customer to ensure that no supply disruption occurs when their largest individual supplier has an unplanned problem.

In fact, there have been occasions over the last few years when, for some participants, the (n-2) criterion (e.g. the ability to replace their two largest suppliers) may have been a more appropriate measure. The actual levels for (n-1) and (n-2) criterion vary for each supply chain participant depending upon the diversity of their own supply chain, and the actual levels of ORC that are required may change as part of a dynamic process, for example when suppliers in different locations enter and exit the market and the supply chain length changes.

As the number of separate supply chain participants has decreased since 2012 and the market share of the remaining participants has increased, it is clear that the general level of risk associated with an (n-1) type supply problem has also increased.

Table 2. Current processors including those in transition by 2023 Revision

| Processor                                 | Targets <sup>5</sup> | Anticipated <sup>99</sup> Mo production weeks/year | Available capacity per week (6-d Ci <sup>99</sup> Mo) | Expected available capacity per year (6-d Ci <sup>99</sup> Mo) by 2023 | Expected first full year of <sup>99</sup> Mo production <sup>6</sup> | Expected year of conversion to LEU targets | Estimated end of production                 |
|---|----------------------|--|---|--|--|--|---|
| ANSTO Health                              | LEU                  | 43   | 2 150   | 92 450   | NA   | LEU  | 2057  |
| CNEA                                      | LEU                  | 46   | 400   | 18 400   | NA   | LEU  | 2027 or earlier based on RA 10 introduction |
| IRE                                       | HEU                  | 52   | 3 500   | 182 000  | NA   | 2018/2019                                  | At least until 2028                         |
| Curium <sup>1</sup>                       | LEU                  | 52   | 5 000   | 260 000  | NA   | LEU  | Not Known                                   |
| NTP                                       | LEU                  | 44   | 3 000   | 130 700  | NA   | LEU  | At least until 2030                         |
| RIAR <sup>2</sup>                         | HEU                  | 50   | 540   | 27 000   | NA   | 2018                                       | At least until 2025                         |
| KARPOV Institute <sup>2</sup>             | HEU                  | 48   | 350   | 16 800   | NA   | 2018                                       | At least until 2025                         |
| MURR/NorthStar <sup>3</sup>               | Natural Mo target    | 52   | 750   | 39 000   | 2019   | NA   | At least until 2037                         |
| ANSTO Nuclear Medicine (ANM) <sup>4</sup> | LEU                  | 43   | +1 350  | 58 050   | 2019   | LEU  | 2057  |

Notes: 1) Curium converted to LEU early 2018, 2) RIAR and KARPOV material needs to comply with specific requirements to be available in some markets, the KARPOV facility will be relicensed in 2020 to continue its operation, 3) NorthStar RadioGenix system approved by the FDA 8 February 2018, production starts 2Q 2018, 4) ANM extra processing capacity is additional and will use OPAL additional irradiation capacity, 5) HEU >20% enriched uranium, LEU <20% enriched uranium, 6) NA = not applicable