UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

COMMISSIONERS:

Kristine L. Svinicki, Chairman
Jeff Baran
Annie Caputo
David A. Wright

In the Matter of	)	
	)	Docket No. 11006361
DEPARTMENT OF ENERGY	)	
	)	License No. XSNM3810
(Export of 93.35% Enriched Uranium)	)	

CLI-20-02

MEMORANDUM AND ORDER

The U.S. Department of Energy, National Nuclear Security Administration (DOE/NNSA) seeks to export 4.455 kilograms of uranium-235 in 4.772 kilograms of uranium with a maximum enrichment of 93.35%. This highly enriched uranium (HEU) would be exported to Belgium—specifically to the Institute for Radioelements (IRE)—over a period ending in 2022. NorthStar Medical Radioisotopes, LLC (NorthStar), Nuclear Threat Initiative (NTI), Curium US LLC (Curium), and Dr. Alan J. Kuperman (Dr. Kuperman) (all four collectively, Petitioners) request leave to intervene and a hearing on the export license application filed by DOE/NNSA.[1] For the

[1] *See NorthStar Medical Radioisotopes, LLC Request for Hearing* (Aug. 26, 2019) (ADAMS accession no. ML19241A501) (NorthStar Request); *Petition to Intervene and Request for Hearing of Nuclear Threat Initiative* (Sept. 11, 2019) (ML19254C538) (NTI Petition); *Petition to Intervene and Request for Hearing of Curium US LLC* (Sept. 13, 2019) (ML19256E839) (Curium Petition); *Petition of Alan J. Kuperman for Leave to Intervene and Request for Hearing* (Sept. 19, 2019) (ML19262G478) (Kuperman Petition).

reasons discussed below, we deny the Petitioners' requests for hearing and direct issuance of the requested license.

I. BACKGROUND

In August 2019, DOE/NNSA submitted to the NRC a license applicationto export HEU to IRE for the production of medical isotopes.[2] The HEU first would be sent to Framatome in France to fabricate targets for medical isotope production. The application states that these targets will then be irradiated in the High Flux Research Reactor (HFR) in the Netherlands, the Belgian Reactor 2 (BR-2) Research Reactor, the LVR-15 Research Reactor in Czechia, and the MARIA Research Reactor in Poland. The irradiated targets would be transferred to IRE, which will extract molybdenum-99 (Mo-99) and iodine-131 (I-131). IRE will use the extracted Mo-99 and I-131 to produce radiopharmaceuticals that it sells globally, including for patient use in the United States.

The original application provided a target timeframe for shipment dates between October 2019 and March 2020, and it included a cover letter stating that the application covered the total estimated quantity of HEU "required by IRE to sustain Mo-99 and I-131 production" from the fourth quarter of calendar year 2020 through the projected completion of IRE's conversion to a low-enriched uranium (LEU) program in the second quarter of calendar year 2022. In September 2019, DOE/NNSA amended its application with a new proposed expiration date of December 31, 2021, to reflect that actual shipment dates would be determined on a rolling basis based on market conditions.[3]

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[2] Export License Application from U.S. Department of Energy National Nuclear Security Administration, XSNM3810 (Aug. 5, 2019) (ML19213A204).

[3] Export License Application from U.S. Department of Energy National Nuclear Security Administration, XSNM3810 (Sept. 3, 2019) (ML19246A247) (Amended Application).

Consistent with the Atomic Energy Act of 1954, as amended (AEA), and our regulations, the NRC staff forwarded the application to the Department of State to receive the views of the Executive Branch.[4] The NRC completed its consultation with the Executive Branch concerning this export license application on February 11, 2020.[5]

Our regulations provide any person with the opportunity to request a hearing or submit a petition for leave to intervene on an export license application within 30 days of NRC notice of the application.[6] All four Petitioners timely submitted their requests.[7] DOE/NNSA did not file an answer to these requests. The NRC also received four letters providing views on the export license application; these letters were placed in the adjudicatory docket and served on the litigants.[8] NorthStar, Curium, and NTI filed a combined response to the letter from IRE.[9] Curium also filed a motion asking the Commission to order DOE/NNSA to show cause as to

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[4] *See* 42 U.S.C. § 2155; 10 C.F.R. § 110.41.

[5] Where permitted, this order includes pertinent information derived from the NRC's consultation with the Executive Branch. However, because this consultation process included the exchange of proprietary information, these documents are not publicly available, pursuant to 10 C.F.R. § 110.72.

[6] 10 C.F.R. § 110.82(c).

[7] Throughout this decision, we will typically refer to the Petitioners collectively in addressing their arguments, except where an argument is made by only one petitioner.

[8] Letter from Denise McGovern, Acting Secretary, NRC, to Mary Anne Heino, Lantheus Medical Imaging (Sept. 20, 2019) (ML19263E194) (Lantheus Letter); Letter from Annette Vietti-Cook, Secretary, NRC, to Erich Kollegger, National Institute of Radioelements (Oct. 4, 2019) (ML19277D318) (IRE Letter); Letter from, Annette Vietti-Cook, Secretary, NRC, to Senator Roy Blunt and Congresswoman Ann Wagner (Oct. 7, 2019) (ML19280C599); Letter from Annette Vietti-Cook, Secretary, NRC, to Sven Van den Berghe and Eric van Walle, Belgian Nuclear Research Centre (Oct. 17, 2019) (ML19290H611). As discussed further, *infra*, NRC regulations encourage members of the public to submit written comments regarding export and import license applications. *See* 10 C.F.R. § 110.81.

[9] *Response to Institute for Radioelements September 26, 2019 Letter to the Commission* (Oct. 10, 2019) (ML19283D150).

why its application should not be terminated for lack of participation in the hearing process (or, in the alternative, to admit the unopposed petitions to intervene).[10]

As discussed below, we deny the requests for a hearing. We first address Curium's motion to show cause and clarify the status of the four letters received by the NRC on the application. We then consider the standards in 10 C.F.R. § 110.84 to determine whether any of the four hearing requests should be granted and conclude that a hearing is not in the public interest and would not assist us in making the requisite statutory determinations in this proceeding. Finally, we find the requisite statutory criteria in the AEA satisfied based on the existing record and direct the issuance of the license.

To provide context for our discussion of the application and the various issues raised, we briefly summarize the provisions of the American Medical Isotopes Production Act of 2012 (AMIPA), which the Petitioners cite. AMIPA amended § 134 of the AEA to include a sunset provision prohibiting the issuance of a license to export HEU for the purposes of medical isotope production after January 2, 2020.[11] However, AMIPA permits the Secretary of Energy to delay the sunset provision by up to six years, by certifying that there is an insufficient global supply of Mo-99 produced without the use of HEU available to satisfy the domestic market and that the export of U.S.-origin HEU is the most effective temporary means to increase the supply of Mo-99 to the domestic market.[12] On January 2, 2020, the Secretary of Energy made this

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[10] *Curium U.S. LLC Motion for Order to Show Cause as to Why the License Application Should Not be Terminated* (Nov. 6, 2019) (ML19310E574) (Curium Motion). DOE/NNSA responded, asking us to strike or deny Curium's motion. *Motion to Strike or in the Alternative to Deny Curium's Motion for Order to Show Cause* (Nov. 15, 2019) (ML19319A988). Curium requested that we deny DOE's motion. *Curium Response to DOE's Motion to Strike or in the Alternative to Deny Curium's Motion for Order to Show Cause* (Nov. 20, 2019) (ML19324G862).

[11] 42 U.S.C. § 2160d(c)-(h).

[12] *Id*. § 2160d(d).

certification, thereby delaying AMIPA's sunset provision by no more than two years.[13] Thus, AMIPA does not currently preclude the NRC from issuing this export license.

II. CURIUM'S MOTION TO SHOW CAUSE

Curium has filed a motion requesting that we either order DOE/NNSA to show cause why its license application should not be terminated, or in the alternative, grant the petitions to intervene in this proceeding.[14] Curium argues that the lack of a response by DOE/NNSA to the hearing requests amounts to a "choice to not participate" in this proceeding or an "abandon[ment]" of the license application, precluding development of an administrative record.[15] As a result, Curium asserts the only support for the application comes in the form of *ex parte* communications on which the Commission may not rely.[16]

The public participation procedures in Part 110 provide for three types of pre-hearing filings—written comments under § 110.81; hearing requests and intervention petitions under

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[13] Exports of U.S.-Origin Highly Enriched Uranium for Medical Isotope Production: Certification of Insufficient Supplies of Non-Highly Enriched Uranium (HEU)-Based Molybdenum-99 for United States Domestic Demand, 85 Fed. Reg. 3362 (Jan. 21, 2020) (Certification of Insufficient Supplies). At the time we received the hearing requests, the certification delaying AMIPA's sunset provision had not yet been issued.

[14] Curium Motion at 1.

[15] *Id.* at 5-6.

[16] *Id.* at 3-5. The asserted *ex parte* communications referenced in the Curium Motion are three of the four letters received by the NRC regarding this export license application, including letters from: (1) Lantheus Medical Imaging, Inc., expressing support for approval of the license application; (2) IRE, stating that the requests for a hearing filed by NorthStar, Curium and NTI "are either not in accordance with the facts, or misinterpreting IRE's intentions"; and (3) SCK-CEN, the Belgian Nuclear Research Centre that operates the BR-2 research reactor identified as an intermediary in the license application, responding to an alleged "false statement" in Curium's hearing request. Prior to the receipt of SCK-CEN's letter, Curium had filed a correction on the docket for this statement. *See Curium Correction to Declaration of Roy W. Brown* (Oct. 1, 2019) (ML19274B999); *see also* Curium Motion at 4, n.11. Curium's motion does not refer to the letter received from Senator Blunt and Representative Wagner, which expressed support for Curium's request for a public hearing.

§ 110.82; and answers and replies to hearing requests and intervention petitions under § 110.83.[17] Part 110 does not contemplate pre-hearing motions, and Curium has not provided a convincing reason for us to entertain one here.[18] Consequently, we take no action on the Curium Motion (or the subsequent responses prompted by that motion).

On Curium's specific points, DOE/NNSA's choice not to respond to the petitions has no effect on the status of the license application, our review of that application, or our consideration of the petitions. Under the AEA and the Nuclear Non-Proliferation Act of 1978 (NNPA), we are responsible for making a decision on an export license application based upon the applicable statutory requirements, regardless of whether an applicant chooses to file a response to a hearing request or petition for leave to intervene.[19] While the AEA requires that we establish public participation procedures in export license proceedings, our regulations provide an applicant, such as DOE, the opportunity to answer a hearing request or intervention petition but do not require that an answer be submitted.[20]

With respect to Curium's arguments that 10 C.F.R. § 2.347 and associated NRC case law bar us from considering the letters commenting on the export application, the provisions of 10 C.F.R. Part 2, including § 2.347, do not apply to Part 110 hearing requests.[21] And Part 110

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[17] "Procedural requests," such as the request for an extension of time to file a hearing request that Curium submitted and obtained in this proceeding, are also permitted. 10 C.F.R. § 110.88; *Request for Extension of Time to File a Hearing Request* (Aug. 28, 2019) (ML19240B461).

[18] Curium's response to DOE's motion to strike Curium's motion references 10 C.F.R. § 110.109, "Motions and requests," but this section only applies *after* we have granted a hearing in a Part 110 proceeding. 10 C.F.R. pt. 110, subpt. I, "Hearings."

[19] *See* 42 U.S.C. § 2155(b)(1); 10 C.F.R. § 110.45(a).

[20] 42 U.S.C. § 2155a(b); 10 C.F.R. § 110.83(a).

[21] *See* 10 C.F.R. § 110.80 ("The procedures in this part [i.e. Part 110] will constitute the exclusive basis for hearings on export and import license applications."); *id.* § 2.1 ("This part

expressly invites submission of written comments from members of the public on export applications.[22] We consider all four letters received as written comments submitted properly under 10 C.F.R. § 110.81(b). We also consider the collective response to IRE's letter as a written comment.[23] These comments have been considered in the course of this decision and, as appropriate, this order responds to the comments.[24]

III. HEARING REQUESTS

A. Standards

We allow for public hearings in nuclear export licensing proceedings when we find that such a hearing will be in the public interest and will assist us in making the statutory determinations required by the AEA.[25] Hearing requests and intervention petitions must, at minimum, explain how these standards are satisfied and set forth the issues sought to be raised.[26] Those seeking a hearing may also assert that their interests may be affected by the issuance of the license and, if doing so, must specify "both the facts pertaining to [the] interest

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governs the conduct of all proceedings, other than export and import licensing proceedings described in part 110.").

[22] *See* 10 C.F.R. § 110.81. Specifically, our regulations state that written comments should be submitted within thirty days after public notice of receipt of the application and addressed to the Secretary. *Id.* § 110.81(b). Here, because DOE/NNSA submitted its amended application on September 3, 2019, written comments submitted on or before October 3, 2019, fell within this thirty-day time period. Each of the four letters in question was timely received.

[23] Curium argues that NRC regulations do not provide a means for hearing requestors to respond to comments (Curium Motion at 4). We note that nothing in § 110.81 precludes the submission of a comment in response to another comment (as the Petitioners have done in this case, in response to IRE's letter), and we retain the discretion to consider such comments, as appropriate, even if filed after the 30-day deadline in § 110.81(b).

[24] 10 C.F.R. § 110.81(a).

[25] *Id.* § 110.84(a); *see also Edlow International Co.* (Export of 93.20% Enriched Uranium), CLI-17-3, 85 NRC 44, 48 (2017).

[26] 10 C.F.R. § 110.82(b).

and how it may be affected."[27] If a petitioner does assert an interest that may be affected, when taking action on that petition the Commission will consider the nature of the alleged interest; how that issue relates to the issuance or denial; and the possible effect of any order on that interest, including whether the relief requested is within the Commission's authority and, if so, whether granting relief would redress the alleged injury.[28]

As we have previously explained, nothing in the AEA or NNPA "suggests that the Commission must hold a hearing if a member of the public requesting a hearing has standing—or as AEA § 189 puts it, 'an interest which may be affected.'"[29] However, we have found that entities with an affected interest are more likely "to contribute to our decisionmaking, show that a hearing would be in the public interest, and assist us in making the statutory determinations."[30] When considering whether a petitioner could assist in making these determinations, we look for the petitioner to show "how a hearing would bring new information to light" and analyze whether any of the Petitioners has sufficiently asserted or established an interest that may be affected by the issuance of the license as set forth in § 110.84(b).[31]

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[27] *Id.* § 110.82(b)(4).

[28] *Id.* § 110.84(b).

[29] *U.S. Department of Energy* (Plutonium Export License), CLI-04-17, 59 NRC 357, 367 (2004).

[30] *Edlow International Co.*, CLI-17-3, 85 NRC at 48 n.10 (citing *U.S. Department of Energy*, CLI-04-17, 59 NRC at 367).

[31] *Diversified Scientific Services, Inc.* (Export of Low-Level Waste), CLI-19-2, 89 NRC 229, 232-33 (2019) (citing *U.S. Department of Energy* (Export of 93.20% Enriched Uranium), CLI-16-15, 84 NRC 53, 58 n.25 (2016)).

B. Hearing Requests Asserting an Interest That May Be Affected

Three of the Petitioners—NorthStar, Curium, and Dr. Kuperman—expressly assert that they have an interest that will be affected by this proceeding.[32] NorthStar states that it is a nuclear medicine technology company that produces Mo-99 without the use of HEU—"the first domestic producer of this critical radioisotope in the United States in almost 30 years" and "the first success under [AMIPA]."[33] NorthStar also states that it is similar to other market participants that have converted from HEU Mo-99 production at "great expense, time and effort" and that, like other similarly situated market participants, it has "direct financial interests that have been undermined by IRE's failure to convert" from HEU to LEU or non-uranium processes.[34] NorthStar seeks a hearing because it believes that IRE benefits from an "unfair and unbalanced market," given that other producers of medical isotopes have incurred expense to convert their operations in furtherance of U.S. non-proliferation goals.[35]

Curium similarly asserts an interest as an economic competitor of IRE. Curium states that it and its affiliate companies "constitute the world's largest supplier of [Technetium-99m] generators and the largest producer and user of Mo-99."[36] Similar to NorthStar, Curium asserts that through "great expense, time and effort," it has converted from HEU to LEU targets for medical isotope production, despite "incurring significant commercial impacts." Curium states

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[32] Although NTI asserts that it has "standing to request a hearing" (NTI Petition at 2), the petition itself does not assert an interest that may be affected by the issuance of the license or reference the factors in § 110.84(b). Rather, NTI generally argues that its experience and expertise in matters of non-proliferation make it uniquely qualified to contribute to our decision-making. *Id.* at 2-4. As such, we do not analyze NTI's petition under § 110.84(b).

[33] NorthStar Request at 2-3.

[34] *Id.* at 3.

[35] *Id*. at 3-4.

[36] Curium Petition at 10.

that approval of this export license "will effectively be punishing Curium and other world suppliers" who have similarly done so in furtherance of U.S. non-proliferation policy.[37]

Lastly, Dr. Kuperman asserts an interest as a Coordinator of the Nuclear Proliferation Prevention Project (NPPP), editor, author, and former staffer in the U.S. Congress with significant professional experience in nuclear non-proliferation policy, including the minimization of the use and export of HEU.[38] Dr. Kuperman states that he has "important institutional interests that would be directly affected by the outcome of this proceeding." Namely, he states that given his active involvement in "public information and education programs" on topics such as nuclear terrorism, non-proliferation, and the use of HEU, his "ability to carry out these functions would be significantly and adversely impaired by the absence of a full, open, and independent review" by the Commission of this license application.[39]

With respect to Dr. Kuperman's request for a hearing, simply asserting an "institutional interest in providing information to the public" is insufficient to show an affected interest.[40] Although we acknowledge Dr. Kuperman's extensive knowledge and professional experience in this area, this interest is not one that may be affected by this proceeding.

NorthStar and Curium articulate the nature of their respective interests as direct economic competitors of IRE who, through significant efforts, do not use HEU to produce

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[37] *Id.* at 2, 11.

[38] Kuperman Petition at 2-3. Dr. Kuperman also notes that he has been a frequent participant in NRC export license proceedings dating back to 2001. *Id.* at 3-4.

[39] *Id.* at 4-5.

[40] *See, e.g.*, *Edlow International Co.*, CLI-17-3, 85 NRC at 49 n.15 (citing *Transnuclear, Inc.* (Export of 93.15% Enriched Uranium), CLI-94-1, 39 NRC 1 (1994)); *U.S. Department of Energy*, CLI-16-15, 84 NRC at 58.

medical radioisotopes. Both assert that IRE is the last market participant to fully do so and should not continue to enjoy this economic advantage over its competitors.[41]

We look to the factors in § 110.84(b) when considering whether the affected interests asserted by NorthStar and Curium sufficiently demonstrate an interest within the meaning of that section.[42] As to "whether the relief requested is within the Commission's authority,"[43] we do not have the authority to make *market-based* determinations on whether to foreclose U.S.-origin HEU exports for the purposes of medical isotope production. Rather, through AMIPA Congress gave authority to the Secretaries of Energy and Health and Human Services (HHS)—not the NRC—to make that determination.[44] Our role in the licensing of such exports is to ensure that all applicable statutory criteria governing the export—none of which include consideration of economic or market-based interests—are satisfied. Further, AMIPA's now-extended sunset provision does not preclude issuance of this license.[45] We therefore conclude that NorthStar

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[41] NorthStar Request at 4; Curium Petition at 12.

[42] At the outset, we note that the "nature of the alleged interest" (10 C.F.R. § 110.84(b)(1))—*unfair* competitive disadvantage through IRE's continued use of HEU—is addressed by AMIPA itself. Since its passage, AMIPA has included a provision allowing for the Secretary of Energy to extend its sunset provision. While we recognize the efforts of those who have converted from the use of HEU, the plain language of the statute has always contemplated that the AMIPA sunset date on HEU exports could be extended. But as we previously acknowledged, we note that both petitions were filed well before it was clear that the Secretary of Energy would extend AMIPA's sunset provision.

[43] 10 C.F.R. § 110.84(b)(3).

[44] *See* 42 U.S.C. § 2160d(f) (authorizing the Secretaries of Energy and HHS to jointly certify that there is a sufficient supply of Mo-99 to meet the needs of U.S. patients without the export of U.S.-origin HEU, thereby causing the AMIPA sunset provision to go into effect).

[45] To the extent that NorthStar and Curium (and other Petitioners) argue that the export of HEU is *unnecessary or excessive*, and therefore "inimical to the common defense and security or would constitute an unreasonable risk to the health and safety of the public" (42 U.S.C. § 2077(c)(2)), we address such arguments in section IV.D. when making the required statutory finding.

and Curium, as direct economic competitors of IRE, do not demonstrate an interest within the meaning of § 110.84(b).

C. Whether a Hearing Would Be in the Public Interest or Assist in Making Statutory Determinations

Even if the Petitioners had demonstrated an interest under the standards in § 110.84(b), we would only order a hearing on this export application if the Petitioners had sufficiently demonstrated that a hearing would be in the public interest and would assist in making the statutory determinations required by the AEA.[46] All the Petitioners have raised substantive arguments that either directly or implicitly assert the application fails to meet certain statutory requirements. Given the number of petitions and overlap in these arguments, and for the sake of simplicity, we address the Petitioners' arguments in section IV of this order in conjunction with analyzing each statutory criterion. Before doing so, however, we clarify the lens through which we view these hearing requests in this proceeding.

First, our regulations require that we determine whether a hearing would be in the public interest.[47] We note that this particular license application has been filed against the backdrop of a certification by the Secretary of Energy that there is currently an insufficient global supply of Mo-99 produced without the use of HEU available to satisfy the needs of the U.S. market. The Executive Branch also has provided its view that there is currently considerable risk and uncertainty in this supply chain and that IRE is a critical supplier to the U.S. market for medical isotopes. In export proceedings, we must be persuaded by the Petitioners that holding a hearing would result in the acquisition of new information that will assist in making statutory

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[46] *See U.S. Department of Energy*, CLI-04-17, 59 NRC at 366 ("Even if the Petitioners had shown standing, we would not order a hearing on this export application.").

[47] 10 C.F.R. § 110.84(a)(1).

determinations concerning this application that we otherwise could not make based on the existing record.

Each Petitioner has claimed, to varying degrees, that they have made this demonstration. NorthStar argues that its oral and written testimony in a hearing would allow us to be "fully briefed" on its concerns and "permit an open dialogue" although it provides no specifics on what information it would offer that is not already included in its hearing request.[48] Dr. Kuperman emphasizes his "broad experience and expertise in technical and policy matters" directly relevant to the application and argues that he would bring "perspectives that are presently lacking and are pivotal to an understanding" of its factual and legal issues.[49] But he similarly does not specify what new information he would provide at a hearing that is not already raised in his petition.[50]

NTI argues that it is uniquely qualified, as a "leading global authority on nuclear non-proliferation," to provide us with information on the proliferation risks associated with civilian HEU exports.[51] NTI further asserts that through its staff (which consists of "former leaders of U.S. government nuclear policy"), it can "make available to the Commission centuries of collective experience" and an "unprecedented amount of understanding" on the global non-proliferation environment.[52] Curium similarly argues that it can "uniquely contribute" to our decisionmaking in this proceeding because it can provide "specific technical and business information" in "significant detail" (including expressing a willingness to provide us with

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[48] NorthStar Request at 12.

[49] Kuperman Petition at 20.

[50] *Id.*

[51] NTI Petition at 2, 4.

[52] *Id.* at 4.

proprietary, non-public information, as appropriate) in support of the alleged deficiencies with the application.[53]

In our view these latter two petitioners express more fully and with greater particularity the kinds of information each petitioner is capable of elucidating, and we acknowledge their expertise in this field and willingness to do so. However, these petitioners have already provided robust discussion and detailed analyses, and we have ample information in the existing record to assess the merits of the issues they have raised in making our licensing determination.

Therefore, having reviewed all four petitions and the record before us, we conclude that granting a hearing in this proceeding would not be in the public interest or assist in our statutory decisionmaking. Holding a hearing to acquire additional information beyond what has been already provided thus far is unnecessary. As discussed in greater detail below, we find that the application satisfies all applicable statutory criteria based on the existing record. We therefore deny all four hearing requests and address their substantive arguments in conjunction with our analysis of the requisite statutory and regulatory determinations.

IV. STATUTORY AND REGULATORY DETERMINATIONS

In accordance with AEA § 126,[54] the NRC requested the views of the Executive Branch on the export application. The Executive Branch communicated its judgment that the proposed export satisfies all applicable statutory requirements and would not be inimical to the common defense and security of the United States. The Executive Branch confirmed that the proposed export to France and subsequent use in Belgium, Czechia, the Netherlands, and Poland would take place pursuant to the U.S. - Euratom Agreement for Cooperation in the Peaceful Uses of

[53] Curium Petition at 24-26.

[54] 42 U.S.C. § 2155.

Nuclear Energy. It recommended that the NRC make the requisite statutory findings and issue the requested license with the understanding that the actual shipments of HEU will be limited to what is needed by IRE year-by-year.

With Executive Branch views in hand, we must determine whether the statutory requirements are met. In order to grant an export license for HEU, we must find that the proposed export satisfies the following statutory provisions:

- The non-proliferation criteria in AEA § 127;[55]
- The additional non-proliferation criteria in AEA § 128, if the export includes a non-nuclear weapons state (here, Belgium, the Netherlands, Poland, and Czechia);[56]
- The further restrictions on exports of HEU to be used as a fuel or target in a nuclear research or test reactor, codified in AEA § 134 (the "Schumer Amendment");[57] and
- The requirement, under AEA § 57c(2), that the proposed export will not be "inimical to the common defense and security" of the United States.[58]

We address each in turn.

A. Section 127 Criteria

Section 127 of the AEA lists five applicable nonproliferation criteria that govern exports of special nuclear material.[59] None of these criteria are the subject of any of the petitions or

[55] *Id.* § 2156; *see also* 10 C.F.R. § 110.42(a)(1)-(5).

[56] 42 U.S.C. § 2157; *see also* 10 C.F.R. § 110.42(a)(6).

[57] 42 U.S.C. § 2160d; *see also* 10 C.F.R. § 110.42(a)(9).

[58] 42 U.S.C. § 2077(c)(2); *see also* 10 C.F.R. § 110.42(a)(8). Additionally, the export must be under the terms of an agreement for cooperation (a "123 agreement"). *See* AEA § 123, 42 U.S.C. § 2153; 10 C.F.R. § 110.42(a)(7). As confirmed by the Executive Branch, this proposed export would take place in accordance with the terms of the U.S. - Euratom Agreement for Cooperation in the Peaceful Uses of Nuclear Energy.

[59] 42 U.S.C. § 2156; *see also* 10 C.F.R. § 110.42(a)(1)-(5). In abbreviated form, the five criteria relevant to DOE/NNSA's export application are as follows:

comments. We have reviewed the Executive Branch's views, which contain assurances that the five criteria of section 127 will be met. Based on these views and our review of the application, we find that these non-proliferation criteria are satisfied.

B. Section 128 Criterion

Section 128 of the AEA requires that any recipient of special nuclear material that is a non-nuclear weapon state party to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) must have full-scope International Atomic Energy Agency (IAEA) safeguards with respect to all peaceful nuclear activities carried out in that state.[60] Belgium, Czechia, the Netherlands, and Poland have placed all of their peaceful nuclear activities under IAEA safeguards.[61] We therefore find that this additional non-proliferation criterion is satisfied.

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(1) [International Atomic Energy Agency] safeguards will be applied with respect to any such material proposed to be exported.

(2) No material proposed to be exported will be used for any nuclear explosive device or for research on or development of any nuclear explosive device;

(3) Adequate physical security measures will be maintained with respect to such material proposed to be exported and to any special nuclear material used in or produced through the use thereof;

(4) No material proposed to be exported will be re-transferred to jurisdiction of any other nation or group of nations unless the prior approval of the United States is obtained for such re-transfer;

(5) No material proposed to be exported and no special nuclear material produced through the use of such material will be reprocessed, and no irradiated fuel elements containing such material removed from a reactor shall be altered in form or content, unless the prior approval of the United States is obtained.

[60] 42 U.S.C. § 2157; *see also* 10 C.F.R. § 110.42(a)(6).

[61] Section 128's additional criteria do not apply to France because it is a nuclear-weapon state party to the NPT.

C. Section 134 Criteria

Section 134(a) of the AEA requires the NRC to make the following additional findings before authorizing an application to export HEU:

> (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 the reactor;
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> (2) the proposed recipient of that uranium has provided assurances that, whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use that alternative in lieu of highly enriched uranium; and
>
> (3) the United States Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.[62]

According to the Executive Branch, Argonne National Laboratory (ANL) has confirmed that no currently available LEU target exists that IRE can use in its production facility for all proposed isotope production, and IRE intends to convert its production facility once such a target can be used. ANL has similarly confirmed that no alternative target currently exists that IRE can use for medical isotope production at the BR-2, LVR-15, HFR, or MARIA research reactors and that once such a target can be used, the relevant parties will use it. DOE/NNSA is cooperating with IRE to convert IRE's facility to use LEU targets. The Executive Branch communicated that, based on current estimates, IRE should finish converting its facility to use LEU targets by June 2022, at which point it will be able to use LEU targets.

The petitions and comments primarily focus on § 134(a)'s first criterion but raise points about the third criterion as well.

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 the reactor

Pursuant to § 134(h)(3) and our implementing regulations, a target "can be used" in a nuclear research or test reactor if—

> (A) The . . . target has been qualified by the Reduced Enrichment Research and Test Reactor Program of [DOE]; and

[62] 42 U.S.C. § 2160d; *see also* 10 C.F.R. § 110.42(a)(9).

> (B) use of the . . . target will permit the large majority of ongoing and planned experiments and medical isotope production to be conducted in the reactor without a large percentage increase in the total cost of operating the reactor.[63]

The Petitioners have raised several arguments about this criterion to the effect that the NRC cannot make this finding because an alternative target exists that can be used in either IRE's facility or the various reactors. As explained below, however, we do not agree that there are "alternative targets" that "can be used," as that term is understood, at the IRE facility.

a. Individual Isotopes

IRE intends to use the requested HEU to produce Mo-99 and I-131. According to IRE's written comment, its conversion for Mo-99 production should be complete by the end of 2020, but IRE will not have finished converting to LEU targets for I-131 production until the second quarter of calendar year 2022.[64] The Executive Branch views have confirmed these statements. Thus, during the period covered by this application, IRE could produce one of the medical isotopes with LEU targets but not the other.

The Petitioners maintain that we cannot find § 134(a)(1) to be satisfied because IRE will have completed the conversion of its facility to the use of LEU targets for Mo-99 production prior to using the HEU exported from this application.[65] They note that at a July 2019 Organisation for Economic Co-operation and Development (OECD)-Nuclear Energy Agency presentation, IRE publicly stated that it "expects to complete the conversion" from HEU to LEU targets for its Mo-99 production process "by the third quarter of calendar year 2020."[66] The Petitioners argue

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[63] 42 U.S.C. § 2160d(h)(3); *see also* 10 C.F.R. § 110.42(a)(9)(iii).

[64] IRE Letter at 2. The IRE Letter states that this 2022 date is based on obtaining regulatory approvals for the radiopharmaceuticals derived from the I-131. *Id.*

[65] NorthStar Request at 9-10; Kuperman Petition at 16-18.

[66] Kuperman Petition at 16; NorthStar Request at 9-10.

that during the proposed export license term, an alternative lesser-enriched target will exist that can be used within the meaning of § 134(a)(1).

Dr. Kuperman notes that the application requests HEU to produce Mo-99 and I-131 from the fourth quarter of 2020 through the second quarter of calendar year 2022.[67] Dr. Kuperman argues that if IRE is able to convert to LEU targets for Mo-99 production by the third quarter of 2020, it would be able to "produce Mo-99 continuously [using only LEU targets thereafter] without further export of HEU."[68] Thus, Dr. Kuperman asserts, beginning in the fourth quarter of 2020, an alternative LEU target will exist and criterion one cannot be satisfied. NorthStar likewise argues that an alternative target that IRE can use in its production process exists because IRE will run two production lines—one dedicated to HEU targets and one dedicated to LEU targets—during the time period this application covers.[69]

Both NorthStar and Dr. Kuperman essentially claim that if IRE can produce any amount of Mo-99 with LEU targets, an alternative target exists for Mo-99 production and thus we could then only find the § 134(a)(1) criterion to be met with regard to HEU for I-131 production but not for Mo-99 production.

The Petitioners' arguments conflict with the § 134 definition of the phrase "can be used." A target "can be used" if use of the target will permit the "*large majority* of ongoing and planned . . . *medical isotope* production to be conducted."[70] The definition of "can be used" in § 134 refers to the "large majority" of planned "medical isotope production" *generally* produced; it does

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[67] Kuperman Petition at 16; *see also* Letter from Becky G. Eddy, National Nuclear Security Administration, to David Skeen, NRC (July 31, 2019) (ML19213A204). Based on the information submitted, the requested HEU will not support medical isotope production before the fourth quarter of 2020. *See id.*

[68] Kuperman Petition at 16.

[69] NorthStar Request at 10.

[70] 42 U.S.C. § 2160d(h)(3)(B) (emphasis added); 10 C.F.R. § 110.42(a)(9)(iii)(B).

not refer to the "large majority" of medical isotope production broken down by individual isotopes or otherwise indicate that we must apply the "large majority" criterion isotope to isotope.

This construction not only is supported by the text but also is reasonable from a technical perspective. Medical radioisotopes are produced through irradiation of a target. The irradiation process naturally produces not just one radioisotope but a wide variety of radioisotopes, including both Mo-99 and I-131. Thus, if a producer irradiates an HEU target to produce I-131, post-irradiation that target will also contain Mo-99. Applying § 134 on an isotope-to-isotope basis would mean producers must isolate collection of particular radioisotopes produced with an HEU target (i.e., in this case, I-131) and discard the others produced with that same target (i.e., Mo-99). This result is not reasonable, given both the language of § 134 as well as congressional intent reflected in the statutory framework to ensure an adequate supply of medical isotopes.

The technical realities of medical isotope production are clearly illustrated by the proposed HEU export. We are informed through Executive Branch views that any HEU used would produce both Mo-99 and I-131. According to IRE timeline estimates that are regularly monitored by DOE/NNSA, all of IRE's global Mo-99 regulatory validations will be completed by mid-2020 (and the first LEU-based Mo-99 from IRE could be shipped to U.S. customers as early as March or April 2020). However, the transition to LEU-produced Mo-99 to meet 100 percent of the production planned to satisfy supply is dependent on regulatory approval timelines for LEU-produced I-131. The regulatory approvals for LEU-produced I-131 are expected to be complete by June 2022. For these reasons, IRE will need to maintain operations of one HEU production line to produce I-131, which also will result in Mo-99, until all LEU I-131 validations are complete. IRE will therefore continue to run one LEU and one HEU production line during the transition to 100 percent LEU-based production for both isotopes.

The language "large majority of . . . medical isotope production" likewise does not call for parsing the relative amounts of the two medical isotopes IRE produces. If a producer plans to produce multiple medical isotopes to meet demand but cannot use an alternative target to produce one of those medical isotopes, then an essential part of the planned production as a whole is disrupted at the production facility. Thus, by definition, the producer will be unable to produce a "large majority" of the planned medical isotopes. In sum, we find that IRE's ability to use LEU targets for only Mo-99 production does not mean that an alternative target currently exists that "can be used," as § 134 defines that phrase, in IRE's production facility.

We therefore do not construe § 134(a)(1) as requiring us to determine whether alternative targets exist for each isotope the producer plans to collect. Rather, when determining whether an alternative target "can be used," we find that the best interpretation of § 134(a)(1) is to look at the planned medical isotope production in its entirety and then to determine whether the ultimate consignee could produce a large majority of those isotopes with an alternative target.

b. Tellurium

The Petitioners also note that other producers "use non-uranium-target based methodologies to produce I-131," in particular "neutron capture on a [t]ellurium [(Te)] target."[71] The Executive Branch views confirm that IRE cannot use Te targets as an alternative for HEU targets for I-131 production. While I-131 can be produced in different ways, there is no practical way IRE could produce I-131 without uranium targets (e.g., neutron capture with a Te target) within a timeframe that would support patient demand and supply. These alternative methods would require IRE to develop an entirely new technology, as well as apply for and receive the requisite regulatory approvals. Therefore, qualifying I-131 produced from a new neutron-

[71] Curium Petition at 18; Brown Declaration at 13; NorthStar Request at 8.

capture target process would require a much longer transition period than completing the current LEU-based I-131 regulatory approval schedule.

c. Reactors

Curium and NTI together assert that alternative targets can be used within the meaning of § 134(a)(1) in the irradiating reactors—that is, the MARIA, HFR, BR-2, and LVR-15 research reactors.[72] Curium points to its own use of LEU targets in these reactors and argues that its targets "meet the 'can be used' requirement,"[73] and NTI, similarly, points to the routine use of LEU targets in the relevant reactors.[74] Both Petitioners argue that, because of the use of LEU targets in those reactors, we cannot make the finding that there is no alternative target.[75]

As previously noted, a target "can be used" if its use "will permit the large majority of ongoing and planned . . . medical isotope production to be conducted in the reactor."[76] To properly interpret the statute, a key phrase in the definition is "planned . . . medical isotope production." That language refers to the medical isotopes the ultimate end user plans to produce with the requested material. To be able to produce medical isotopes, however, that producer must be able to use the relevant targets in its production facility. Thus, the question is not simply whether an alternative target exists that the reactor operators can place in the reactor that will still allow safe operation during the irradiation process. Rather, the question is whether

[72] Curium Petition at 22; Brown Declaration at 13; NTI Petition at 8.

[73] Curium Petition at 22 ("The MARIA reactor in Poland can and does use 'alternative' LEU targets. Curium knows this because it itself uses LEU targets in that reactor."); Brown Declaration at 13 ("Curium has been using LEU targets in these reactors since 2017.").

[74] NTI Petition at 8.

[75] Curium Petition at 21-23; NTI Petition at 8.

[76] 42 U.S.C. § 2160d(h)(3)(b); 10 C.F.R. § 110.42(a)(9)(iii)(B).

an alternative target exists that the reactor operators can safely place in the reactor *and* from which the medical isotope producer can collect medical isotopes.

Here, IRE will carry out the planned medical isotope production. While Curium and other producers may have LEU targets that they can safely place in the MARIA Research Reactor, the HFR, and the BR-2 Research Reactor, those targets cannot be used in this instance, as § 134 defines that phrase, because IRE cannot use them. Because the LEU targets mentioned by Curium and NTI cannot be used by IRE, they are not alternatives that prevent § 134(a)(1) from being met.

Curium essentially argues that, because Curium itself has an LEU target that Curium can use in these reactors to produce medical isotopes, we cannot find § 134(a)(1) satisfied for another producer such as IRE. This interpretation seemingly could jeopardize the supply of medical isotopes and undermine the statutory objective of maintaining a reliable supply of medical isotopes during the LEU conversion process. And section 134(a)(1) has not previously been construed in this manner.[77] Thus, Curium's reading is not supported by the statute, policy, or our past practice.

In sum, none of the arguments raised by the Petitioners with respect to the existence of an alternative target that can be used in either IRE's facility or the various reactors demonstrate that the criterion in § 134(a)(1) is not met for this proposed export. Consequently, based on the administrative record before us, including the Executive Branch views, we find that consistent with § 134(a)(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 the reactor.

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[77] *See, e.g.*, XSNM3795 at 3-4 (Oct. 31, 2018) (ML18285A367) (permitting the export of HEU for medical isotope production and permitting IRE to irradiate the HEU targets in the MARIA Research Reactor, the HRF, and the BR-2 Research Reactor in 2018, one year after Curium says it began using LEU targets in the MARIA Research Reactor, the HFR, and the BR-2 Research Reactor).

2. The proposed recipient of that uranium has provided assurances that, whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use the alternative in lieu of highly enriched uranium

No concerns were raised by the Petitioners about this criterion. The Executive Branch confirmed that the requisite assurances have been received from all recipients regarding this criterion. Based on the Executive Branch views, we find this criterion satisfied.

3. The United States Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

The Petitioners contend that DOE/NNSA failed to demonstrate the existence of a program "actively developing an alternative LEU target for use by IRE in" the irradiating reactors.[78] Curium argues that while DOE controls these efforts, its focus has been on converting reactor *fuel* rather than targets for these reactors.[79] NTI likewise states that neither Poland nor Czechia "is part of a U.S. government program to develop an alternative nuclear reactor fuel or target for those reactors."[80]

An active program satisfies § 134(a)(3) if it leads to the development of an LEU target that can be used to produce medical isotopes. From a technical perspective, the reactors that irradiate targets, such as the LVR-15 and MARIA Research Reactors, can irradiate LEU and HEU targets interchangeably. In other words, targets do not need to be specifically designed to work in each reactor (for irradiation purposes), and they generally work in all reactors.

This is not the case for medical isotope producers such as IRE, which, without conversion, could not accommodate the use of LEU targets if they were originally designed to use HEU targets to produce medical isotopes. Each medical isotope producer uses a unique target design that is specific to its production and chemical processing. The specific shape and

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[78] Curium Petition at 23; Brown Declaration at 14; NTI Petition at 8-9.

[79] Curium Petition at 23.

[80] NTI Petition at 9.

cladding specifications of targets are two attributes that vary significantly among different medical isotope producers. These attributes are closely connected to the required chemical processing of the targets following irradiation so that a pure, medically-qualified product is achieved at the end of a series of processing steps. In general, therefore, targets are not interchangeable among different chemical processing configurations, and such configurations are not easily changed without extensive re-design work, testing, and subsequent regulatory approval.

Curium argues that our prior decision in *Transnuclear, Inc.*[81] demonstrates that the active program must be "geared to developing LEU targets *for . . . specific reactors*."[82] Although our discussion of § 134(a)(3) in *Transnuclear* did variously refer to "the development of LEU targets for use in the [MAPLE] reactors," the issue in that case was not whether an active LEU conversion program must focus on specific reactors. Rather, the issue before us in *Transnuclear* was whether, at that time, there existed an active program at all for developing LEU targets for production of medical isotopes by the planned MAPLE project, including the MAPLE reactors (for irradiating the targets) and associated processing facility (for extracting the targets).[83] Thus, the issue presented in this proceeding was not before us in *Transnuclear*.

In sum, to satisfy the § 134(a)(3) criterion for a particular export, DOE must have an active program to develop an LEU target that can be used for medical isotope production. In its views on the application, the Executive Branch confirmed that DOE has an active program to

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[81] *Transnuclear, Inc.* (Export of 93.3% Enriched Uranium), CLI-99-20, 49 NRC 469 (1999).

[82] Curium Petition at 23.

[83] *See Transnuclear, Inc.*, CLI-99-20, 49 NRC at 475 ("The participants' written responses to these questions, as well as presentations made at the June 16 public meeting, furnished new information and evidence of a currently active program at ANL for the development of LEU targets for use in the MAPLE *project*." (emphasis added)).

work closely with IRE for conversion of Mo-99 and I-131 production. Accordingly, we find the § 134(a)(3) criterion to be met for the proposed export.

D. Section 57—Noninimicality Finding

To issue a license, we must determine under § 57c.(2) of the AEA that the proposed export, in addition to meeting the other export requirements, will not be "inimical to the common defense and security" of the United States.[84] Here, the Petitioners raise several arguments that can be grouped in three main categories of inimicality concerns with this proposed export. First, the Petitioners argue that this export is not needed and that other medical isotope producers can meet international Mo-99 and I-131 demand.[85] Second, the Petitioners assert that DOE/NNSA has requested too much HEU in the application.[86] Finally, the Petitioners argue that the proposed shipment is an attempt to circumvent AMIPA's statutory prohibition on the export of HEU.[87]

The AEA's inimicality test pre-dates the enactment of the NNPA. As explained in the NNPA's legislative history, the addition of specific licensing criteria, discussed above, did not replace or render obsolete the pre-existing inimicality test.[88] Yet the NNPA's drafters noted that "in the absence of unusual circumstances," if a proposed export satisfied the NNPA's non-

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[84] 42 U.S.C. § 2077(c)(2); *see also* 10 C.F.R. § 110.42(a)(8).

[85] NorthStar Request at 7-8; NTI Petition at 7; Curium Petition at 16-18; Brown Declaration at 11-13.

[86] NorthStar Request at 8-10; Curium Petition at 18-21; Brown Declaration at 9-11; Kuperman Petition at 16-18. We note that unnecessary HEU exports (e.g., if demand can be met by other producers using alternative material or if too much HEU is requested) pose an increased risk of diversion and weapons proliferation that would not exist but for the export, which in turn raises inimicality concerns for the U.S. common defense and security.

[87] NTI Petition at 7; Curium Petition at 21; Brown Declaration at 7-9.

[88] H.R. REP. NO. 95-587, at 21 (1977).

proliferation criteria, then it would likewise satisfy "the common defense and security standard."[89] In *Natural Resources Defense Council, Inc. v. NRC*, the Court of Appeals for the District of Columbia Circuit noted this legislative history and explained that we generally "need not look beyond the non-proliferation safeguards in determining whether the common defense and security standard is met."[90] When determining whether any "unusual circumstances" exist with respect to a proposed export, we give "great weight" to the Executive Branch's judgments.[91] This approach is woven into the fabric of the NNPA itself, which requires various Executive Branch departments to be closely involved in the export licensing process.[92] The NNPA and NRC regulations also require the NRC to make an independent technical finding that the export meets all applicable requirements.[93] With this background in mind, we turn to the Petitioners' three inimicality concerns, which some of the Petitioners argue constitute "unusual circumstances."

1. Medical Isotope Supply

The Petitioners argue that actors besides IRE can meet international demand for Mo-99 and I-131 without using HEU, making this proposed export inimical to the common defense and security.[94] Noting the inherent risks of exporting HEU,[95] Curium and NTI argue that Commission

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[89] *Id.*

[90] 647 F.2d 1345, 1363 (D.C. Cir. 1981); *see also U.S. Department of Energy*, CLI-04-17, 59 NRC at 374.

[91] *See U.S. Department of Energy*, CLI-04-17, 59 NRC at 376.

[92] 42 U.S.C. § 2155.

[93] *Id.*; 10 C.F.R. § 110.45.

[94] Curium Petition at 16-18; Brown Declaration at 11-13; NorthStar Request at 7-8; and NTI Petition at 7.

[95] Curium Petition at 16-17; NTI Petition at 6.

policy requires us to apply a strict balancing test weighing the risk posed by the export against "significant need."[96] Curium and NorthStar also assert that the proposed export is unnecessary to meet international demand based on internal market projections and an OECD report.[97]

In the view of the Executive Branch, however, approval of this export license is necessary to meet demand. Moreover, Lantheus and IRE dispute Curium's, NorthStar's, and NTI's statements that others could meet demand if we were to deny this license.[98]

The Petitioners have presented us with a variety of arguments that other producers can meet medical isotope demand by using non-HEU targets if this license is denied and that this export is therefore unnecessary. However, the Secretary of Energy has certified, pursuant to AMIPA, that additional HEU exports are necessary at this time to satisfy domestic patient needs for Mo-99. We will not second-guess findings concerning medical isotope demand and supply that have been made by DOE pursuant to express statutory authority.[99] Consistent with our statutory role, we defer to the judgment of the Secretary of Energy that there is currently an insufficient supply of Mo-99 to satisfy U.S. demand.

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[96] Curium Petition at 17 ("Therefore, the export of HEU creates an unequivocal national security risk, which must be offset at least by a significant need for the export, one that outweighs the risk associated with exporting weapons-grade uranium to many destinations across Europe." (emphasis removed)); NTI Petition at 6-7 (same).

[97] Curium Petition at 17-18; Brown Declaration at 11-13; NorthStar Request at 7-8. NTI also asserts, without citation, that it is well understood that medical isotope supplies can be fully met by current LEU or non-uranium-based methods. NTI Petition at 7.

[98] IRE Letter at 4; Lantheus Letter at 2.

[99] As required by statute (42 U.S.C. § 2160d(e)), DOE sought public comment prior to making this certification. Exports of U.S-Origin Highly Enriched Uranium for Medical Isotope Production: Sufficient or Insufficient Supplies of Non-HEU-based Molybdenum-99 for United States Domestic Demand; Request for Public Comment, 84 Fed. Reg. 65,378 (Nov. 27, 2019). Its certification has been made based on submissions received, "other publicly available healthcare data," and in coordination with the U.S. Food and Drug Administration. Certification of Insufficient Supplies, 85 Fed. Reg. at 3363.

While AMIPA's focus is on Mo-99, the radiopharmaceutical that is most widely in demand in the U.S., AMIPA also provides joint certification authority to the Secretaries of Energy and HHS that is not limited to Mo-99—specifically, the authority to jointly certify that it is *not* necessary to export U.S. origin HEU "for the purposes of medical isotope production in order to meet United States patient needs."[100] AMIPA defines "medical isotope" to include Mo-99 as well as "[I-131], xenon-133, and other radioactive materials used to produce a radiopharmaceutical for diagnostic or therapeutic procedures."[101] This joint certification under AEA § 134(f)(1)(B) was one of the statutory prerequisites for the HEU export license ban to take effect. In light of DOE's January 2 certification, the Secretaries did not make the joint certification that U.S.-origin HEU exports are unnecessary for production of medical isotopes (including I-131) to meet U.S. patient needs.

Additionally, the NRC received views from the Executive Branch on the global availability and stability of I-131 supply for the time period covered by this export license application, including impacts if the application were denied. The Executive Branch observed that the I-131 supply chain is volatile and adequate domestic and global supplies of I-131 would be at risk if IRE were unable to maintain its current production or if IRE's supply was interrupted until its conversion to LEU is complete. Thus, we disagree that the export is unnecessary because an adequate supply of Mo-99 and I-131 already exists.

2. More HEU than Necessary

Based on the same premise underlying the arguments we addressed in section C.1.a. above—that export of HEU for use in Mo-99 production is unnecessary after the date IRE is able to produce Mo-99 using LEU targets—the Petitioners claim that the application requests

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[100] 42 U.S.C. § 2160d(f)(1)(B).

[101] *Id.* § 2160d(h)(4).

more HEU than is needed for I-131 production.[102] The Petitioners calculate that based on IRE's current production level, it should only need approximately 0.5 kilograms to support I-131 production during the period covered by this application.[103] IRE disagrees with this figure.[104] The Petitioners assert that this leaves IRE with an excess of four kilograms of HEU over what IRE will need for I-131 production.[105] Curium maintains that this indicates that IRE intends to stockpile HEU for future use, and "incentivize[s] IRE to continue delaying it Mo-99 LEU target conversion."[106] Similarly, NorthStar argues that "it is unclear why [IRE] needs an additional 4 kilograms to sustain I-131 production through [quarter two] of 2022."[107] Dr. Kuperman also argues that the maximum amount of HEU we may authorize for export is significantly smaller than the amount requested because the HEU can only permissibly be used for I-131 production after IRE converts to LEU targets for Mo-99.[108]

As we discussed above, the production processes for Mo-99 and I-131 production are inseparable. We find that the total amount of HEU requested for export is sufficiently supported by the application and Executive Branch views. The total amount of HEU requested for export is approximately the same as the amount of HEU the Petitioners' estimate would go toward supporting the production of Mo-99 once IRE begins producing Mo-99 using LEU targets (i.e.,

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[102] Curium Petition at 18-21; Brown Declaration at 9-11; NorthStar Request at 8-10.

[103] Curium Petition at 19-20; Brown Declaration at 9-10; NorthStar Request at 8-9.

[104] IRE Letter at 2.

[105] Curium Petition at 19-21; NorthStar Request at 8-10.

[106] Curium Petition 20-21; Brown Declaration at 11.

[107] NorthStar Request at 10.

[108] Kuperman Petition at 17-18.

approximately 4 kilograms) combined with the amount of HEU that the Petitioners estimated would be needed for I-131 production after that transition period.

Specifically, the Executive Branch confirmed that ANL has conducted calculations that assumed that IRE will continue production of 3,000 6-day Curie(Ci)/Week (above IRE's normal production of 2,200 6-day Ci/Week) to satisfy global demand. The increased production rate at IRE is warranted in order to supplement the shortfall resulting from South Africa's NTP Radioisotopes producing at only 40% of its normal isotope production rates.[109]

The 4.772 kilograms of HEU requested will allow planned isotope production until full conversion to LEU targets by the end of June 2022. ANL verified this data by considering the weight in grams of each target, manufacturing efficiency, variances due to broken pieces (the form in which HEU is shipped), and IRE's proposed decrease of HEU targets and increase of LEU targets during the final transition to LEU. And the Executive Branch has stated that the 4.772-kilogram amount is considered to be a bounding amount that will be re-evaluated and adjusted by DOE/NNSA to account for current market conditions prior to any shipment(s) occurring. DOE/NNSA's amended license application contains a statement to this effect.[110] Accordingly, we direct the NRC staff to authorize an initial shipment of up to 2.0 kilograms of HEU, subject to monitoring of quantities and timing of subsequent shipments based on IRE's efforts to convert to LEU targets coupled with associated analyses of the demand for and supply of medical isotopes. We also direct the NRC staff to include a license condition requiring the licensee, by January 4, 2021, to submit a status report documenting the quantities of uranium shipped during the previous calendar year, including both the element and isotope weights for

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[109] Both IRE and Lantheus also refer to production challenges at South Africa's NTP Radioisotopes in support of the application. IRE Letter at 3; Lantheus Letter at 2.

[110] *See supra* n.3 and accompanying text (stating that actual shipment amounts "will be determined on a rolling basis based off of market conditions in support of IRE inventory and operational requirements during the transition to LEU targets").

each shipment made. This report shall also provide projections and supporting rationale for any uranium shipments that may be scheduled during the remaining license term, including estimates of both the element and isotope weights. This will provide further assurance that HEU shipment amounts are sufficiently justified—particularly in the latter half of the license term, as IRE moves closer to full LEU conversion and the now-extended AMIPA sunset provision draws nearer.

In sum, we find that the Petitioners' arguments regarding the use of HEU exclusively for I-131 do not call into question our finding that the proposed export would not be inimical to the common defense and security.

3. One-Year Limit

Dr. Kuperman argues that our recent practice and the intent of AMIPA's HEU export license ban prohibit us from issuing a license allowing the export of more than one year's worth of HEU for medical isotope production.[111] Dr. Kuperman points to our issuance of HEU export licenses for a single year's worth of HEU for medical isotope production since 2012, as well as a statement we made in a 2017 decision that "export licenses for targets for medical isotope production tend to be for only a year."[112]

We find that granting this license for more than one year's worth of HEU does not undermine the intent of AMIPA's HEU export license ban. The Secretary of Energy has made the certification necessary to delay AMIPA's HEU export license ban (at most) through January 2, 2022.[113] IRE currently plans to finish its conversion by June 2022. Given that there is

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[111] Kuperman Petition 14-15 ("The applicant apparently aims to evade U.S. law, which . . . is expected to prohibit approval of HEU export licenses for medical isotope production after January 2, 2020.").

[112] *Id.* (quoting *Edlow International Co.*, CLI-17-3, 85 NRC at 57).

[113] Certification of Insufficient Supplies, 85 Fed. Reg. at 3363.

necessarily a several month lead time between our approval of an application and IRE's use of that material to produce medical isotopes, all the material IRE requires pre-conversion will likely be exported prior to that January 2, 2022, sunset date regardless of whether we approve the export now or in a year. Thus, granting this application would not evade compliance with AMIPA.

We have previously rejected Dr. Kuperman's argument that the amount of HEU should be limited to that necessary to provide medical isotopes for one year, in the context of HEU exports for fuel.[114] No statutory or regulatory requirement limits HEU export licenses to one year's worth of HEU. Additionally, while we have indicated that "export licenses for targets for medical isotope production tend to be for only a year," we have not adopted a one-year limit. Rather, supply terms have been appropriately specific to the circumstances surrounding each particular HEU export application.

The particular circumstances of this HEU export application support issuance of a license authorizing the export of enough HEU for multiple years' worth of medical isotope production. Due to the potential for complications as well as the volatility in the medical isotope market, significant uncertainty currently exists surrounding IRE's precise conversion schedule and HEU needs. It is reasonable for the amount of the proposed export to account for that uncertainty.

Moreover, due to the much lower quantity of material that would be exported (4.772 kilograms), the proliferation and security risks, both in transportation and end use, posed by the

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[114] *Edlow International Co.*, CLI-17-3, 85 NRC at 57; *U.S. Department of Energy*, CLI-16-15, 84 NRC at 63-64.

proposed export are much smaller than the recent prior exports that were limited to one-year supply.[115]

In addition, DOE plans to conduct a market analysis of global Mo-99 supplies every six months and to re-evaluate and adjust (if required) the amount of material in each shipment, which could potentially result in shipping smaller quantities after the first partial shipment. As part of DOE's standard processes, DOE will use qualified nuclear shipment specialists, who will conduct thorough security reviews and risk evaluations prior to any shipment made. The Executive Branch notes that these processes are intended to meet the dual goals of HEU minimization and meeting the needs of patients.

4. AMIPA's Deadline

The Petitioners also argue that the proposed export raises inimicality concerns because it authorizes HEU exports for use entirely after the date on which AMIPA would have ended our authority to issue HEU export licenses, in the absence of the Secretary of Energy's January 2, 2020, certification to delay the ban on issuance of HEU export licenses.[116] This argument is moot in light of the Secretary of Energy's certification.

For these reasons, we find that the proposed export would not be inimical to the common defense and security of the United States.

F. Additional NorthStar Argument

NorthStar argues that "[t]he proposed exports would be inconsistent with [DOE's] ongoing efforts to establish a reliable domestic source of non-HEU Mo-99."[117] NorthStar also

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[115] *See, e.g.*, *U.S. Department of Energy*, CLI-16-15, 84 NRC 53 (involving export quantities of ~130 kilograms).

[116] *See* Curium Petition at 21; Brown Declaration at 8-9; NTI Petition at 7; Kuperman Petition at 15.

[117] NorthStar Request at 11.

asserts that the United States' clear intent "was not to continually foster the ability of foreign companies to undermine both [U.S.] companies who have found new means of producing non-uranium Mo-99 or have duly complied with conversion to non-HEU production."[118]

Our review of export license applications must necessarily stay within the confines of the AEA's export licensing requirements. NorthStar does not ground its argument in any of these licensing requirements. While AEA § 134 contains provisions intended to maintain reliable domestic supplies of medical isotopes, our regulatory responsibilities in licensing and overseeing HEU exports are totally independent of U.S. domestic endeavors to develop a non-HEU medical isotope supply.[119]

V. CONCLUSION

For the reasons stated above, we find that a hearing in this matter would not be in the public interest and would not assist us in making the required statutory and regulatory determinations. We further determine that the proposed export satisfies all applicable export-licensing criteria and that issuing this export license would not be inimical to the common defense and security of the United States. Accordingly, we *deny* the Petitioners' requests for hearing and petitions to intervene and *direct* the Office of International Programs (OIP) to issue License No. XSNM3810 to DOE/NNSA for the export of up to 4.772 kilograms of HEU.

In light of the particular circumstances of this export, the license shall authorize an initial shipment of up to 2.0 kilograms of HEU, and the licensee shall determine quantities and timing

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[118] *Id.*

[119] To the extent that general concerns have been raised that issuance of a license for export of HEU results in competitive harm to a certain segment of producers, these concerns reflect congressional policy considerations underlying AEA § 134, including AMIPA, and do not bear on our decision under the AEA to issue an export license. *See* Comment from Senator Blunt and Congresswoman Wagner Regarding Export License Application of U.S. Department of Energy, National Nuclear Security Administration (XSNM3810), (Sep. 27, 2019) (ML19337C978).

of subsequent shipments by monitoring IRE's efforts to convert to LEU targets coupled with associated analyses of the demand for and supply of medical isotopes. In addition, as a condition of the license, the licensee shall submit by January 4, 2021, a status report documenting the quantities of uranium shipped during the previous calendar year including both the element and isotope weights for each shipment made. The report shall also provide projections and supporting rationale for any uranium shipments that may be scheduled during the remaining license term, including estimates of both the element and isotope weights.

IT IS SO ORDERED.

For the Commission

NRC SEAL

Annette L. Vietti-Cook

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Date: 2020.04.13 11:19:50 -04'00'

Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 13th day of April 2020.

Additional Views of Commissioner Baran

While I agree that it is not necessary to hold a hearing on this matter, I write separately because I do not subscribe to the "affected interest" analysis in the Commission's decision. In my view, it is time for the Commission to reconsider our use of the affected interest analysis in export cases. The current approach suffers from two major problems.

First, the determination of whether a petitioner has an affected interest in a proposed export has no material impact on the overall legal analysis of whether to hold a hearing. Regardless of whether an entity demonstrates that it has an affected interest, the same legal test applies: would a hearing be in the public interest and would it assist the Commission in making the statutory determinations under the Atomic Energy Act.[1] As a practical matter, the inquiry into whether a petitioner has demonstrated an affected interest serves no useful purpose.

Second, under the Commission's affected interest jurisprudence, it is seemingly impossible for a petitioner to demonstrate an affected interest. The Commission has found that a person residing within 1.5 miles of a bridge that would serve as the exit point for the export of low-level waste did not have an affected interest in that export.[2] Even living within an eighth of a mile of a port through which an export would travel was not enough to demonstrate an affected interest.[3] The Commission also decided that living near the ultimate destination of an exported reactor could not qualify as an affected interest.[4] Here, the Commission has found that

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[1] 42 U.S.C. 2155a(b).

[2] *Diversified Scientific Services, Inc.* (Export of Low-Level Waste), CLI-19-02, No. 11005323, 2019 WL 1225717, (N.R.C. March 11, 2019).

[3] *U.S. Department of Energy* (Plutonium Export License), CLI-04-17, 59 NRC 357, 364 n.11 (2004).

[4] *Westinghouse Electric Corporation* (Exports to the Philippines), CLI-80-14, 11 NRC 631 (1980).

economic competitors do not meet the test either. In fact, over the course of many years, in cases similar to this one and in cases that were very different, no petitioner has ever been able to successfully demonstrate that it had an affected interest in a proposed export.

Given the unimpressive track record of the “affected interest” inquiry, I believe the Commission should take a new approach. In future export cases, we would be better off focusing our decisions on the central question of whether a hearing is in the public interest and would assist the Commission in making the statutory determinations under the Atomic Energy Act.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
	)	
U.S. DEPARTMENT OF ENERGY	)	Docket No. 11006361
	)	
	)	License No. XSNM3810
(Export of 93.35% Enriched Uranium)	)	
	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **COMMISSION MEMORANDUM AND ORDER (CLI-20-02)**, have been served upon the following persons by Electronic Information Exchange or, as indicated by an asterisk, by electronic mail.

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[Electronically signed by Herald M. Speiser]
Office of the Secretary of the Commission

Dated at Rockville, Maryland,
this 13th day of April 2020