November 6, 2019

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
BEFORE THE COMMISSION

In the Matter of	)	
	)	
U.S. DEPARTMENT OF ENERGY	)	Docket No. 110-06361
	)	
(Export of 93.35% Enriched Uranium)	)	License No. XSNM3810
	)	

MOTION FOR ORDER TO SHOW CAUSE
AS TO WHY THE LICENSE APPLICATION SHOULD NOT BE TERMINATED

I. INTRODUCTION

Due to the United States Department of Energy's ("DOE" or "Applicant") intentional decision not to participate in the Nuclear Regulatory Commission ("NRC") hearing process to defend its above-captioned export license application ("Application"), and the entirely Petitioner[1]-based record before the Commission showing a number of legal and factual deficiencies in the Application, Curium U.S. LLC ("Curium") respectfully requests that the Commission issue an order for DOE to show cause as to why its Application should not be terminated, or in the alternative, admit the unopposed petitions to intervene in this proceeding.

While Curium believes that a hearing remains the best forum to address the significant questions raised by the Application, the NRC must also consider whether DOE's unwillingness to engage in the hearing process—a process that it is not exempt from under the Atomic Energy Act—and respond to the questions of law and fact raised by the Petitioners, throws into doubt DOE's willingness to substantively support the Application and the NRC's ability to grant the Application based on the one-sided record before the agency in this proceeding.

[1] Curium, Nuclear Threat Initiative, NorthStar Medical Radioisotopes, LLC ("NorthStar"), and Dr. Alan J. Kuperman are each a "Petitioner" and together comprise the "Petitioners."

II. BACKGROUND

On August 5, 2019, DOE filed an export license application to ship 4.772 kilograms of 93.35% high-enriched uranium ("HEU") to Europe for target fabrication and irradiation in four research reactors, each located in a different European country.[2] The Application provided that the HEU would be used to support Molybdenum-99 ("Mo-99") and Iodine-131 ("I-131") production by the Institute for Radioelements ("IRE").[3]

Thereafter, four parties timely filed petitions to intervene and requests for hearing ("Petitions") challenging the Application: Curium, Nuclear Threat Initiative, NorthStar, and Dr. Alan J. Kuperman. The last of these Petitions was filed and served on September 19, 2019. The Petitions raise genuine disputes with the Application on material issues of law and fact, including as to whether the export is inimical to the common defense and security, satisfies a real need by the medical community, and meets basic requirements set forth in 10 C.F.R. § 110.42.

NRC regulations provide that the Applicant can reply to a Petition within 30 days of its service.[4] This means that the latest possible point for DOE to provide an Answer to the final Petition submitted was October 21, 2019. Amazingly, weeks past this date, DOE has remained completely silent as to its Application. Instead, the only defense for the Application has come in the form of *ex parte* communications, in circumvention of the NRC's well-established hearing process.

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[2] Application to Export Enriched Uranium to the Institute for Radioelements for Use in the Production of Medical Isotopes (License No. XSNM3810) (Docket No. 110-06361) (Accession No. ML19213A204) (posted Aug. 5, 2019) ("Application"). The Application was amended on September 3, 2019 (Accession No. ML19246A247).

[3] Application at 4 (cover letter).

[4] Per the requirements of 10 C.F.R. §§ 110.89 and 2.305, service of all Petitions upon the Applicant was provided through the NRC E-Filing system.

III. DOE HAS PROVIDED INSUFFICIENT INFORMATION TO SUPPORT THE GRANTING OF A LICENSE

A. DOE's Application Does Not Satisfy NRC Licensing Requirements

In order to grant a license, the NRC must make an independent finding that an application satisfies all the requirements of 10 C.F.R. § 110.42, the Atomic Energy Act, and NRC policy. Pursuant to 10 C.F.R. § 2.325, the applicant bears the burden of proof as to all of these findings. Moreover, the agency cannot plug any holes as part of its review; instead the applicant itself has to put forward evidence to support any required findings.[5]

Yet against these requirements, DOE put forward a sparsely populated three-page form, with a one-page cover letter. Among the many deficiencies with this Application identified by the Petitions, this form letter does not explain why the export is "justified" under NRC policy,[6] contains no analysis of the requirements of 10 C.F.R. § 110.42, and purports to export HEU for uses that are on their face barred under 10 C.F.R. § 110.42(a)(9)(i).[7] DOE, as a key driver in the transition from HEU to Low-Enriched Uranium ("LEU") for medical isotope production, should have been well aware of the controversial nature of the proposed export. Yet even after multiple Petitions were filed challenging the Application, DOE has done nothing to substantiate its Application.

B. *Ex Parte* Communications Cannot Sustain the Application In DOE's Stead

The only defense of the Application on the docket comes in the form of three *ex parte* letters by parties that have not otherwise tried to participate in the proceeding, including the

[5] *Curators of the Univ. of Missouri*, CLI-95-1, 41 NRC 71, 121 (1995); *Nuclear Innovation N. Am. LLC* (S. Texas Project, Units 3 & 4), LBP-14-3, 79 NRC 267, 278 (2014), *aff'd*, CLI-15-7, 81 NRC 481, 499 (2015).
[6] Curium Petition at 17 (Accession No. ML19256E839) (citing *NRC Use of High-Enriched Uranium (HEU) in Research Reactors*, 47 Fed. Reg. 37,007, at 37,008 (1982)).
[7] *See* Curium Petition at 22-23.

beneficiary of DOE's license request.[8] The general rule is that these off-the-record communications "carry no weight in adjudicatory proceedings."[9] Simply adding them to the hearing docket does not render them legitimate. Pursuant to 10 C.F.R. § 2.347(b), neither the Commission nor its staff may "entertain . . . any ex parte communication relevant to the merits of the proceeding." Moreover, NRC regulations do not provide a path forward as to how to respond to such communications, as Petitioners may only respond to Answers filed pursuant to the requirements of 10 C.F.R. Parts 2 and 110.

Of these three *ex parte* communications,[10] only the two letters by Lantheus and IRE touch on the subject matter of the proceeding.[11] It is worth noting, however, that both letters support a key proposition raised by Petitioners—that both IRE and its supply chain partners are on the verge of attaining approval for LEU-based Mo-99 production[12]—undercutting any need for HEU for Mo-99 production during the period of use stated in the Application (4th Quarter of 2020 through the 2nd Quarter of CY 2022).[13] This leaves at best a technical dispute as to the

[8] The Petitioners responded to the *ex parte* communications by reemphasizing that a hearing is the proper forum for addressing any concerns. *See* Petitioners' Response to Institute for Radioelements September 26, 2019 Letter to the Commission (Oct. 10, 2019) (Accession No. ML19283D150).

[9] *Pub. Serv. Co. of Indiana, Inc.* (Marble Hill Nuclear Generating Station, Units 1 & 2), 7 NRC 179, 191 (1978).

[10] Lantheus Medical Imaging *Ex Parte* Letter to NRC Commission (Sept. 6, 2019) (Accession No. ML19263E194) ("Lantheus *Ex Parte* Letter"); IRE *Ex Parte* Letter to NRC Commission (Sept. 26, 2019) (Accession No. ML19277D318) ("IRE *Ex Parte* Letter"); Belgian Nuclear Research Centre *Ex Parte* Letter to NRC Commission (Oct. 3, 2019) (Accession No. ML19290H611) ("BNRC *Ex Parte* Letter").

[11] The BNRC *Ex Parte* Letter commented on an accidental erroneous statement near the end of the Declaration of Roy Brown supporting the Curium Petition. Curium had already filed a correction of this statement by the time the BNRC Letter was written (Accession No. ML19274B999). In any event, the erroneous statement in the Declaration has no bearing on the contentions raised in the Petition.

[12] *See, e.g.*, IRE *Ex Parte* Letter at 2 ("The conversion to the 99Mo produced from LEU will be possible for all lRE's customers when they have received approval from their respective pharmaceutical authorities. This point should be reached at the end of 2020, and IRE has enough stock of HEU until then."); Lantheus *Ex Parte* Letter at 1 ("IRE - one of our three international Mo-99 suppliers - is in the final stages of LEU conversion.").

[13] Application at 4 (cover letter). IRE further asserts that *past* shutdowns at the NTP Radioisotopes SOC Ltd. ("NTP") and Australian Nuclear Science and Technology Organisation ("ANSTO") reactors somehow support a need for HEU exports *in the future*. IRE *Ex Parte* Letter at 2-3. However, IRE thereafter acknowledges that by the end of 2020 (the point at which IRE would first use the exported HEU) these irradiation sources should have largely returned to operation. *See id*. Moreover, a lack of irradiation sources is distinct from the long-term conversion from HEU to LEU targets. Curium Petition at 20.

need for HEU for I-131 production. The unsupported assertions provided in the IRE *Ex Parte* Letter as to I-131 production, however, cannot contest the detailed analyses provided in the Petitions.[14] Moreover, even presuming a need for I-131, IRE should not be allowed to alter the playing field in its favor as to Mo-99 production based on a supposed need for HEU only for I-131 production and outside the scope of a contested hearing.[15]

As a result, these improperly filed assertions simply cannot contribute to the record the Commission can use to reach a decision. Reliance on *ex parte* communications—especially here, when they form the basis of the entire defense of the Application—renders the public's right to a hearing "effectively nullified" as there is no proper way for the Petitioners or the Commission to judge their merits or effectively respond.[16]

IV. DOE'S INACTION CHALLENGES THE INTEGRITY OF THE HEARING PROCESS

"Hearings serve an important function in our licensing process by ensuring that our regulatory decisions are thoroughly vetted and transparent."[17] Their important role necessitates that the underlying hearing process "produce an informed adjudicatory record that supports agency decision making."[18]

DOE's inaction here purposefully precludes development of such a record. And any answer now would be significantly untimely. DOE is well-versed in administrative law and NRC litigation, and its choice to not participate—without any reason provided on the record—

[14] For example, IRE asserts that one gram of Uranium-235 generates approximately 5 Ci of I-131. Both Curium and NorthStar provide calculations, however, explaining that 1 gram of HEU will produce roughly 93 Ci of I-131. *See* Curium Petition, Expert Declaration of Roy Brown ¶ 31; NorthStar Petition at 9 n.14.

[15] *See* Curium Petition at 21 n. 23 (suggesting that at a minimum, any NRC license should be conditioned on use of HEU just for the production of I-131, and that the quantity of HEU exported should be limited to just what is necessary for I-131 production).

[16] U.*S. Lines, Inc. v. Fed. Mar. Comm'n*, 584 F.2d 519, 539 (D.C. Cir. 1978).

[17] *Tenn. Valley Auth.* (Bellefonte Nuclear Plant, Units 1 & 2), CLI-10-26, 72 NRC 474, 480 (2010).

[18] *Policy Statement, Policy on Conduct of Adjudicatory Proceedings*, 63 Fed. Reg. 41,872, 41,873 (Aug. 5, 1998).

must be presumed to be intentional. The Commission has the ability to terminate a proceeding where the applicant has "abandoned any intention" of supporting its application; and NRC adjudicatory bodies have also requested parties to show cause as to why they should not be dismissed when they fail to provide support for their own positions.[19] Such orders to show cause appear particularly appropriate when there does not appear to be "good cause" for a lack of participation, and the applicant's sincere interest in taking ownership of its case-in-chief is in doubt.[20] DOE cannot purposefully ignore the NRC's hearing process and at the same time receive the benefit of the doubt as to the sincerity of its request.

[19] *See, e.g., Puerto Rico Elec. Power Auth.* (N. Coast Nuclear Plant, Unit 1), ALAB-605, 12 NRC 153, 154 (1980) (NRC adjudicatory boards have authority to terminate proceedings where it appears that the applicant has "abandoned any intention" of supporting its application.); *Crow Butte Res., Inc.* (Marsland Expansion Area), Licensing Board Memorandum and Order (Order to Show Cause) (Oct. 22, 2014), at 3-4 (Accession No. ML14295A245) (a Licensing Board requesting a petitioner to show cause why its participation in a hearing should not be terminated for lack of effort to prosecute its contentions); *Calvert Cliffs 3 Nuclear Project, LLC, & Unistar Nuclear Operating Servs., LLC* (Calvert Cliffs Nuclear Power Plant, Unit 3), Order (To Show Cause Why The Board Should Not Grant Summary Disposition as to Contention 1, Deny Authorization to Issue the License, and Terminate this Proceeding) (Apr. 18, 2011) (Accession No. ML111080553) (seeking cause from the applicant as to why the Licensing Board should not terminate the proceeding when uncontroverted evidence exists in the record to demonstrate the applicant is ineligible to obtain an NRC license).

[20] In the *Crow Butte* Marsland proceeding identified in footnote 19, the Licensing Board in the end declined to terminate the adjudicatory proceeding because "good cause" was identified for a petitioner's delay in prosecuting its contentions—in that case, new pro-bono counsel was brought on board to support a disadvantaged community, and the delays in prosecuting contentions were not due to carelessness or a purposeful lack of interest in participating. *Crow Butte Res., Inc.* (Marsland Expansion Area), Licensing Board Memorandum and Order (Regarding Order to Show Cause) (Feb. 6, 2015), at 6-9 (Accession No. ML15037A390). It is doubtful DOE could argue the same in this proceeding.

V. CONCLUSION

For the reasons stated above, Curium respectfully requests that the Commission issue an order for DOE to show cause as to why its Application should not be terminated, or in the alternative, admit the unopposed Petitions to intervene in this proceeding.

Respectfully Submitted,

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Dated in Washington, D.C.
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CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2019 copies of the above **Motion for Order to Show Cause as to Why the License Application Should Not Be Terminated** have been served through the U.S. Nuclear Regulatory Commission E-Filing system on the participants of the above-captioned proceeding. Pursuant to 10 C.F.R. § 110.89(b) and the Memorandum of Russell E. Chazell, NRC Assistant for Rulemaking and Adjudications, to the parties in this proceeding, dated September 23, 2019, I further certify that a copy was served by email to the Executive Secretary, Department of State, at kennald@state.gov.

Respectfully Submitted,

/s/ Signed (electronically) by Amy C. Roma
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Dated in Washington, D.C.
November 6, 2019

CERTIFICATE OF COUNSEL

Pursuant to 10 C.F.R. § 2.323(b), I certify that between November 1-5, 2019, I consulted with each of the Petitioners, as well as counsel for DOE and the NRC Staff in a sincere effort to resolve the issues raised by this motion. The Petitioners Dr. Alan Kuperman and NorthStar support the motion; and Petitioner Nuclear Threat Imitative takes no position on the motion. The NRC's position is that it is not a party and does not need to be consulted, and DOE opposes the motion.

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Dated in Washington, D.C.
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