August 18, 2016

Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attention: Rulemaking and Adjudications

Dear Office of the Secretary,

In accordance with 10 CFR 110.81, I write to submit comments on the application (XSNM 3776, Docket No. 11006241) of the U.S. Department of Energy (DOE), National Nuclear Security Administration, received by the Commission on July 21, 2016, and published in the *Federal Register* on August 15, 2016 (81 Fed. Reg. 54133), for a 15-month license to export 7.2 kilograms (kg) of 93.20% enriched uranium metal to France for fabrication into targets to be irradiated in Europe and then processed at the Institute for Radioelements (IRE) in Belgium to produce medical isotopes.

Disturbingly, this requested export of weapons-grade, highly enriched uranium (HEU) contradicts the multilateral commitment of March 26, 2012, by four countries including Belgium and the United States.<sup>1</sup> In that pledge at the 2012 Nuclear Security Summit, regarding production of medical isotopes, "Belgium, the Netherlands, and France, in cooperation with the United States, reaffirm their determination to support conversion of European production industries to non-HEU-based processes by 2015." By switching to LEU targets, the accord promises, "the use of HEU will be completely eliminated for medical isotopes that are produced in Belgium."

At a follow-up DOE meeting of September 2015, IRE provided an update on its conversion effort, declaring that the company's "LEU target qualification" had already been "Completed!" and "All tests are successful," indicating that the company was only "Awaiting formal approval from safety authority." Occurring nearly a year ago, this presentation raised expectations that conversion from HEU targets to LEU targets would occur by the end of 2015, in compliance with the multilateral accord.

Now, however, seven months after Belgium's pledged deadline to convert from HEU to LEU targets for medical isotope production, DOE is proposing to export another 7.2 kg of HEU for IRE targets, which shows that Belgium not only has reneged on its commitment to convert completely to LEU targets by the end of 2015, but it has failed even to convert a substantial fraction of its production to LEU targets.

Indeed, as illustrated in Figure 1, IRE seeks an amount of HEU roughly equal to that in preceding export licenses prior to the company's ostensible conversion to LEU targets:

Figure 1. NRC's HEU export licenses for IRE targets

Date Approved	HEU (kg)	XSNM
September 2012	6.2	3622/01
March 2013	6.2	3729
January 2014	7.3	3729/01
February 2015	7.8	3756
(proposed)	7.2	3776

Reportedly, IRE claims that it must still use HEU targets because regulatory health authorities have yet to approve its LEU-produced medical isotopes. However, such approvals can be obtained in a matter of months, as occurred when the U.S. Food and Drug Administration approved LEU-produced medical isotopes from South Africa in March 2011,<sup>3</sup> just months after they had arrived for testing in July 2010.<sup>4</sup>

U.S. law and policy unambiguously seek to minimize and eliminate HEU exports, to reduce risks of nuclear proliferation and nuclear terrorism. In 2014, DOE reaffirmed that it "implements the long-standing U.S policy to minimize and eliminate the use of highly enriched uranium (HEU) in civilian applications by working to convert research and test reactors and isotope production facilities to the use of low enriched uranium (LEU)." This year, at the 2016 Nuclear Security Summit, the United States and 21 other countries again "pledged to make every effort to achieve further progress with regard to minimizing and eliminating the use of highly enriched uranium (HEU) in civilian applications."

If the Commission were to approve the proposed export, enabling full-scale use of HEU targets beyond 2017, IRE would have little incentive to pursue regulatory approval of its LEU-produced isotopes, which may be marginally more expensive to produce. Thus, Commission approval of the pending application would likely perpetuate unnecessary HEU commerce, directly contradictory to longstanding U.S. law and policy.

To comply with U.S. law and policy by minimizing and seeking to eliminate HEU exports for civilian applications, the Commission must not approve any more than a fraction of the proposed export of HEU for IRE targets. Reducing the amount of HEU in the proposed export license could both ensure continued near-term production of medical isotopes (using HEU targets) and incentivize IRE to obtain regulatory approval of its LEU-produced isotopes as quickly as possible. This would enable the Commission to minimize and expeditiously eliminate HEU exports for IRE, consistent with U.S. law and policy.

Thank you for consideration of these comments. I stand ready to provide further information upon request.

Sincerely,

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<sup>&</sup>lt;sup>1</sup> "Belgium-France-Netherlands-United States Joint Statement: Minimization of HEU and the Reliable Supply of Medical Radioisotopes," The White House, Office of the Press Secretary, March 26, 2012, <a href="https://www.whitehouse.gov/the-press-office/2012/03/26/belgium-france-netherlands-united-states-joint-statement-minimization-he">https://www.whitehouse.gov/the-press-office/2012/03/26/belgium-france-netherlands-united-states-joint-statement-minimization-he</a>.

<sup>&</sup>lt;sup>2</sup> Valery Host, "Recent achievements of IRE's LEU conversion project," Mo-99 Topical Meeting 2015, Boston, September 2, 2015, Slide 5, <a href="http://mo99.ne.anl.gov/2015/pdfs/presentations/S8P3">http://mo99.ne.anl.gov/2015/pdfs/presentations/S8P3</a> Host Presentation.pdf.

<sup>&</sup>lt;sup>3</sup> Clint vanSonnenberg, "FDA clears Covidien's low-enriched uranium based isotope production," *Health Imaging*, March 11, 2011, <a href="http://www.healthimaging.com/topics/molecular-imaging/fda-clears-covidiens-low-enriched-uranium-based-isotope-production">http://www.healthimaging.com/topics/molecular-imaging/fda-clears-covidiens-low-enriched-uranium-based-isotope-production</a>.

<sup>&</sup>lt;sup>4</sup> Natasha Odendaal, "First commercial-sized shipment of medical isotopes to the US," *Engineering News*, August 20, 2010, <a href="http://www.engineeringnews.co.za/article/worlds-first-commercial-sized-shipment-of-leu-mo-99-delivered-to-the-us-2010-08-20/rep\_id:4136.">http://www.engineeringnews.co.za/article/worlds-first-commercial-sized-shipment-of-leu-mo-99-delivered-to-the-us-2010-08-20/rep\_id:4136.</a>

<sup>&</sup>lt;sup>5</sup> U.S. Department of Energy, "GTRI's Convert Program: Minimizing the Use of Highly Enriched Uranium," Fact Sheet, May 29, 2014, <a href="https://nnsa.energy.gov/mediaroom/factsheets/gtri-convert">https://nnsa.energy.gov/mediaroom/factsheets/gtri-convert</a>.

<sup>&</sup>lt;sup>6</sup> "NSS 2016: Gift Basket on Minimizing and Eliminating the Use of Highly Enriched Uranium in Civilian Applications," April 1, 2016, <a href="https://www.regjeringen.no/globalassets/departementene/ud/vedlegg/fred/heu-minimization-gift-basket-for-nss-2016--final.pdf">https://www.regjeringen.no/globalassets/departementene/ud/vedlegg/fred/heu-minimization-gift-basket-for-nss-2016--final.pdf</a>.