WRITTEN STATEMENT

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UNITED STATES NUCLEAR REGULATORY COMMISSION

TO THE

SENATE COMMITTEE ON

ENERGY AND NATURAL RESOURCES

AMERICAN MEDICAL ISOTOPE PRODUCTION ACT OF 2011

Mr. Chairman and Members of the Committee on Energy and Natural Resources, thank you for inviting me to participate in this hearing today. As Director of the Nuclear Regulatory Commission's (NRC) Office of International Programs, I am pleased to have this opportunity to discuss NRC's licensing requirements for the exportation of highly enriched uranium (HEU) for the production of medical isotopes. My focus today will be on NRC's regulatory framework for licensing the export of HEU.

Framework for the Export of HEU

I want to describe the NRC's process in detail so that the Committee on Energy and Natural Resources has an understanding of the framework in which the export of HEU from the United States is taking place. The Atomic Energy Act of 1954, as amended, (AEA) grants the NRC exclusive jurisdiction to license civilian exports and imports of source, special nuclear, and byproduct materials to and from the United States. The NRC's regulations governing such exports and imports are set forth in Title 10 of the Code of Federal Regulations, Part 110, "Export and Import of Nuclear Equipment and Material."

Since 2005, the NRC has licensed seven exports of HEU to Canada and Belgium for fabrication of fuel or targets for the production of medical isotopes. The export licenses to Belgium

authorized export of HEU for fabrication of fuel for reactors that produce, among other things, medical isotopes and the export licenses to Canada authorized HEU as targets or for the fabrication of targets that are used in the National Research Universal (NRU) reactor for the production of medical isotopes. Of the seven licenses issued since 2005, there is only one active license. Currently, there are two pending applications from Canada and France for the export of HEU. For additional information on HEU export licenses issued by the NRC over the past five years, please see the attached table.

Prior to issuing a license for the export of HEU for the production of medical isotopes, the NRC works closely with the Executive Branch to ensure that the export is consistent with applicable U.S. non-proliferation laws and policies and is not otherwise inimical to the common defense and security of the United States. HEU may only be exported to countries that have in place an agreement for cooperation with the United States in accordance with section 123 of the AEA. These agreements set out the broad framework under which exports such as this may be authorized.

Even when the United States has in place an agreement for cooperation with a country, the Commission must determine, on a case-by-case basis, whether an individual export to that country meets the applicable export licensing criteria in Sections 127 and 128 of the AEA, as codified in the Commission regulations at 10 CFR § 110.42(a). Based on its evaluation, the NRC may impose additional requirements as conditions to the export license.

Among other criteria, section 110.42(a)(3) requires the NRC to evaluate the adequacy of the physical protection measures in the country requesting the HEU. The physical protection guidelines are established by the International Atomic Energy Agency and are published in INFCIRC/225/Rev. 4, June 1999, “The Physical Protection of Nuclear Material and Nuclear Facilities.” The NRC participates in U.S. government physical protection bilateral visits to

countries requesting HEU to confirm that the country's implementation of physical protection methods and procedures for U.S.-origin HEU is consistent with these international guidelines. The delegations conducting the physical protection visits include staff from the NRC; National Nuclear Security Administration (NNSA); Department of Energy (DOE); Department of State; and Department of Defense.

Any licensee authorized to export HEU is responsible for compliance with all applicable requirements of Title 10 of the Code of Federal Regulations, including NRC's regulations related to transportation and packaging. Since 2005, all transportation of HEU has been conducted by DOE's Office of Secure Transportation in accordance with the DOE requirements and directives. These measures meet and exceed NRC and Department of Transportation regulations in this area.

For all HEU export license applications, the NRC would, as it did for each of the seven prior HEU applications, request the Executive Branch's judgment on the proposed export, including whether the proposed export would be inimical to the common defense and security of the United States or otherwise significant for nuclear explosive purposes, and whether the export would comply with the terms of the applicable agreement for cooperation. In the seven prior cases, the Executive Branch determined that the export would not be inimical to the common defense and security, would take place pursuant to the applicable agreement for cooperation, and were consistent with the provisions of the AEA.

In the Energy Policy Act of 1992, Congress amended the AEA to require the NRC to adopt additional, more stringent criteria specifically for licensing exports of HEU. These criteria were designed to discourage the use of HEU and encourage the development and use of low-enriched uranium alternatives. Under Section 134 of the AEA, the NRC may issue a license for the export of HEU to be used as a fuel or target in a nuclear research or test reactor only if, in

addition to meeting the other AEA requirements for exports of special nuclear material, the NRC determines that:

(1) There is no alternative nuclear reactor fuel or target enriched to a lesser percent than the proposed export that can be used in the foreign reactor;

(2) The proposed recipient of the 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 HEU; and

(3) The U.S. Government is actively developing an alternative nuclear reactor fuel or target that can be used in that reactor.

More recently, in the Energy Policy Act of 2005, Congress further amended the AEA by adding a new section 134b., “Medical Isotope Production," in which Congress continued to encourage the eventual end of reliance on HEU targets in the production of medical radioisotopes. In the new AEA section 134b., Congress lifted certain restrictions on exports of HEU to Canada, France, Belgium, Germany, and The Netherlands for the production of medical radioisotopes if the recipient country supplies an assurance letter to the United States that the HEU will be used solely for medical isotope production, and if the NRC determines that the HEU will only be irradiated in a reactor that uses alternative fuel or is the subject of an agreement with the United States to convert to alternative fuel when such fuel can be used in the reactor.

The NRC is mindful of the importance of the supply of medical isotopes for diagnostic and therapeutic medical procedures. Therefore, the NRC carries out this export licensing regime in an efficient and effective manner. Our regulations require notice of the application to the public and the opportunity to request a hearing on whether the export is consistent with our regulations. We also accept and review written comments even when a hearing is not

requested. Once the various views are obtained, we then reach a carefully considered decision in accordance with non-proliferation policies, laws and regulations.

Conclusion

The NRC's exclusive jurisdiction to authorize the export HEU for production of radiopharmaceuticals for diagnostic and therapeutic procedures is regulatory in nature and exercised only in accordance with the statutory framework and Congressional policies established in the Atomic Energy Act. In carrying out its regulatory responsibilities, the NRC works effectively with the Executive Branch, the recipient countries, the public, exporters and importers to assure the exports will not be inimical to the common defense and security and are consistent with policies to use alternatives to HEU when appropriate.

Again, I appreciate the opportunity to participate today and look forward to answering any questions the Committee may have.

Table Summarizing NRC Authorized Exports of

HEU

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Office of International Programs

These tables should not be relied on as an official agency record. The official files for each license are located in NRC's Agencywide Documents Access and Management System (ADAMS) accessible through the NRC's Public web site.

LicenseNumber	Applicant	Commodity	Destination	EndUse	Fabricator	Issued	Expires
XSNM3369	DOE- ORNL*	HEU, 93.35% as metal pieces - 15.5 kg	Canada	Target matl to produce medical isotopes - NRU Reactor		15-Apr-05	31-Dec-05
XSNM3192	Transnuclear	HEU, 93.34%, as metal; 32.4 kg	Belgium	BR-2 Research Reactor - fuel	France-CERCA	3-Aug-05	Withdrawn
XSNM3427	DOE- ORNL*	HEU, 93.15% as metal; 15.50 kg	Canada	NRU - Target matl		14-Apr-06	31-Dec-06
XSNM3404	DOE- ORNL*	HEU, 93.15% as metal pieces - 85.5 kg	Belgium	Reload Fuel - BR2 Research Reactor	France-CERCA	3-May-06	31-Dec-07
XSNM3473	DOE- ORNL*	HEU, 93.35%, as broken metal pieces - 15.50 kg	Canada	NRU - Target matl		17-Jan-07	31-Jan-08
XSNM3504	DOE- ORNL*	HEU, 93.35%, as as broken metal pieces - 15.50 kg	Canada	NRU - Target matl		19-Oct-07	28-Feb-08
XSNM3060/03	BXWT	HEU, 93.6% as U02, fabricated targets	Canada	Amend to: 1) transfer license from Transnuclear, Inc. to BXW Technologies, Inc.; 2) update list of "Other Parties to Export"; & 3) extend expiration date		22-Jul-08	Withdrawn
XSNM3545	DOE- ORNL*	HEU, 93.35% as broken metal	Canada	For fabrication of targets used in production of medical isotopes at NRU Reactor		4-Nov-08	28-Feb-09
XSNM3622	DOE- ORNL*	HEU, 93.95% as metal - 93.5 kg	Belgium	Reload fuel - BR2	France-CERCA	6-Nov-10	1-Jun-12
XSNM3623	DOE- ORNL*	HEU, 92.95% as metal - 17.5 kg	Canada	Target materials - NRU		Pending	
XSNM3633	DOE- ORNL*	HEU, 93.95% as metal - 116.00 kg	France	Reload Fuel - Institut Laue - Langevin (ILL) High Flux Reactor(HFR)	France-CERCA	Pending	
HEU exported solely for medical isotope production							
HEU exported as fuel for research and test reactors							

*Department of Energy - Oak Ridge National Laboratoy (DOE - ORNL).