

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Part 30**

**[Docket Nos. PRM-30-65; NRC-2011-0134]**

**Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics, Inc.**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Petition for rulemaking; consideration in the rulemaking process.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) will consider the issue raised in the petition for rulemaking (PRM) submitted by Annette User, on behalf of GE Osmonics, Inc. (GE or the petitioner), in the rulemaking process. The petitioner requests that the NRC amend its regulations regarding the commercial distribution of byproduct material to allow recipients of exempt quantities of polymer (polycarbonate or polyester) track etch (PCTE) membranes that have been irradiated with mixed fission products (MFP) to commercially redistribute the material without a license. In its review of the PRM, the NRC concluded that the petitioner raised a valid issue concerning regulatory control of the commercial distribution of PCTE membranes that the NRC will consider in its rulemaking process.

**DATES:** The docket for the petition for rulemaking, PRM-30-65, is closed on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Further NRC action on the issue raised by this petition can be found on the Federal rulemaking Web site at <http://www.regulations.gov>.

You can access publicly available documents related to the petition, which the NRC possesses and are publicly available, using any of the following methods:

- **Federal e-Rulemaking Web site:** Public comments and supporting materials related to this petition can be found at <http://www.regulations.gov> by searching on the petition docket ID for PRM-30-65 or NRC-2011-0134. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668, e-mail: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** The public may examine, and have copied for a fee, publicly available documents at the NRC's PDR, Room O-1F21, 11555 Rockville Pike, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Edward M. Lohr, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0253; e-mail: [Edward.Lohr@nrc.gov](mailto:Edward.Lohr@nrc.gov).

## **SUPPLEMENTARY INFORMATION:**

### **The Petition**

On April 20, 2011, the NRC received a PRM, filed by Annette User on behalf of GE Osmonics, Inc. (ADAMS Accession No. ML120250133). The petitioner requests that the NRC amend its regulations in parts 30 and 33 of Title 10 of the *Code of Federal Regulations* (10 CFR), specifically 10 CFR 30.18, "Exempt quantities," to allow commercial distribution and redistribution of PCTE membranes that have been irradiated with MFPs and are represented by the petitioner to contain such MFPs in quantities below the exempt quantity limits for byproduct material as identified in 10 CFR 30.71, Schedule B. On June 22, 2011 (76 FR 36386), the NRC published a notice of receipt and request for comment for the PRM.

Until February 2010, GE transferred the PCTE membranes to two GE redistribution facilities located in Westborough, Massachusetts and Minnetonka, Minnesota. During GE's Texas license renewal process, the Texas Department of State Health Services advised GE that it could no longer transfer the PCTE membranes to those two facilities for commercial distribution without an exempt distribution license from the NRC. In April 2011, GE submitted such a license application to the NRC and a petition for rulemaking that was docketed as PRM-30-65. The license application was returned to GE in June 2011, with no action taken because the NRC's current regulations do not allow exempt distribution of the PCTE membranes.

The petition states that PCTE membranes are used in a wide variety of research, medical, academic, scientific, and industrial applications. In particular, PCTE membranes are used in pharmaceutical, medical device, and water filtration applications. The petitioner

believes that the requested amendments are necessary to allow distribution of the PCTE membranes to the full range of its customers.

### **Public Comments on the Petition**

The notice of receipt of the PRM invited interested persons to submit comments. The comment period closed on September 6, 2011. The NRC received one comment letter (ADAMS Accession No. ML1178A021) from a member of the public opposing the PRM, stating that the current regulations do not place an unfair burden on the petitioner and have been in place for some time.

The commenter's observation that the regulations do not place an unfair burden on the petitioner is consistent with the current regulations, which provide for an amendment process to add or subtract exempt materials or products such as those in 10 CFR 30.15. However, the NRC believes that the petitioner raised a valid concern that may warrant a regulatory solution that has not been specifically identified but could be accomplished through an amendment of the regulations.

### **Reasons for Consideration**

The NRC will consider the issue raised in the PRM in its rulemaking process because, based on the information GE has provided to date, the NRC believes that the issue may be resolved through the rulemaking process. However, due to current resource constraints, the NRC will not be able to give the future rulemaking a high priority but will strive to complete it as resources are available.

Although the petitioner requests the NRC to amend 10 CFR 30.18, the proposed amendment to the exempt quantities regulation may not be the best solution to resolve the issue raised in the petition. In the rulemaking process, the NRC will attempt to develop a technical basis to support an appropriate proposed rulemaking that would address the issue raised in the petition. If a technical basis to support a rulemaking cannot be developed, the issue will not be further considered by the NRC.

The NRC tracks all rulemaking actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/> and on the Federal rulemaking Web site, <http://www.regulations.gov>. The Regulations.gov Web site allows users to receive notifications when documents are added to a docket. To monitor further NRC action on the issue raised in PRM-30-65, register for notification under docket ID NRC-2011-0134. In addition, the NRC publishes a Unified Agenda, which is a semiannual compilation of all rules on which the NRC has recently completed action, has proposed action, or is considering action. The Unified Agenda may be found on the NRC's rulemaking website at <http://www.nrc.gov/about-nrc/regulatory/rulemaking.html>. As in all rulemakings, the NRC will solicit and consider public comments during the proposed rule phase of the rulemaking before determining the approach that will be the basis for the final rule.

For the reasons cited in this document, the NRC will consider this petition as part of its rulemaking process.

Dated at Rockville, Maryland, this 23<sup>rd</sup> day of August, 2012.

For the Nuclear Regulatory Commission,

*/RA/*

R. W. Borchardt  
Executive Director for Operations

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Dated at Rockville, Maryland, this 23<sup>rd</sup> day of August, 2012.

For the Nuclear Regulatory Commission,

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R. W. Borchardt  
Executive Director for Operations

**ML12167A158/EDATS: FSME-2012-0015**

<b>OFC</b>	RBB/DILR	RBB/DILR	FSME/DILR	FSME/DILR	OGC
<b>NAME</b>	ELohr	KO'Sullivan	DJackson	JPiccone (DJackson for)	NLO
<b>DATE</b>	6/7/12	6/11/12	6/13/12	6/13/12	6/1/12
<b>OFC</b>	DMSSA	ADM	Tech Ed	D:FSME	EDO
<b>NAME</b>	BMcDermott	CBladey	PTressler	MSatorius	RWBorchardt
<b>DATE</b>	5/29/12	5/25/12	8/14/12	8/21/12	8/23/12

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