

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Parts 30 and 32**

**[Docket No. NRC-2015-0017]**

**RIN 3150-AJ54**

**Items Containing Byproduct Material Incidental to Production**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Regulatory basis; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is requesting comment on a regulatory basis to support developing a rulemaking that would amend its regulations by adding a new class exemption from licensing and associated distribution requirements. This new class exemption would create a path for licensing current and future products that contain byproduct material incidental to their production. The rulemaking would resolve a petition for rulemaking (PRM), PRM-30-65, submitted by GE Osmonics, Inc. on April 18, 2011, requesting changes to the regulations to allow commercial distribution and redistribution of polycarbonate track etched membranes.

**DATES:** Submit comments by April 5, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date.

**ADDRESSES:** You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the **Federal Rulemaking Web Site**:

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2015-0017**. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; e-mail: [Dawn.Forder@nrc.gov](mailto:Dawn.Forder@nrc.gov). For technical questions, contact the individual(s) listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **E-mail comments to:** [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov). If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** Alexa Sieracki, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-7509; e-mail: [Alexa.Sieracki@nrc.gov](mailto:Alexa.Sieracki@nrc.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Obtaining Information and Submitting Comments**

#### **A. Obtaining Information**

Please refer to Docket ID NRC-2015-0017 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2015-0017.

- **NRC's Agencywide Documents Access and Management System**

**(ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, 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). For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **Attention:** The [Public Document Room \(PDR\)](#), where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via e-mail at [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov) or call 1-800-397-4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

#### B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking Web Site (<https://www.regulations.gov>). Please include Docket ID NRC-2015-0017 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment

submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## **II. Discussion**

To facilitate early stakeholder engagement on the rulemaking process, the NRC is requesting comment on a regulatory basis to support a rulemaking that would amend 1) part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR), “Rules of General Applicability to Domestic Licensing of Byproduct Material,” by adding a new class exemption from licensing requirements for items containing byproduct material incidental to their production, and 2) 10 CFR part 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material,” licensing requirements for distribution of those items.

The regulatory basis is developed as a precursor to a proposed rule and describes the NRC’s preferred approach for resolving PRM-30-65. The rulemaking would close the regulatory gap for these irradiated products, create appropriate criteria for evaluating public health and safety impacts of these products, reduce burden on existing licensees, and provide consistency for regulating products within this class.

The NRC will consider any comments received on the regulatory basis in the development of the proposed and final rule and will provide responses to comments on the regulatory basis in the associated *Federal Register* notice publishing the proposed rule for public comment.

## **III. Plain Writing**

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

#### **IV. Availability of Documents**

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

<b>DOCUMENT</b>	<b>ADAMS ACCESSION NO. / WEB LINK / <i>FEDERAL REGISTER</i> CITATION</b>
Regulatory Basis for Items Containing Byproduct Material Incidental to Production, January 12, 2020	ML20339A400
Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics (Consideration in the Rulemaking Process), September 14, 2012	77 FR 56793
GE Osmonics, Inc., Polymer Track Etch Membrane 10 CFR 32.14—Manufacturer and Distribution Product Safety Information, March 20, 2012	ML120800277
GE Osmonics, Inc., Environmental Report—Polymer Track Etch Membrane—10 CFR 30.15, March 20, 2012	ML120800264
NRC Consumer Product Policy Statement, January 16, 2014	79 FR 2907
Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics, April 18, 2011	ML120250133
SECY-87-186A, Distribution of Radioactive Gems Irradiated in Reactors to Unlicensed Persons (Follow-up to SECY-87-186), October 5, 1987	ML092400170
Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics (Receipt and Request for Comment), June 22, 2011	76 FR 36386

Comment (1) of Benjamin Kerensa Opposing Petition for Rulemaking (PRM-30-65) Regarding the NRC Amend Its Regulations Regarding the Commercial Distribution of Byproduct Material, June 24, 2011	ML11178A021
Agreement State Program Policy Statement; Correction, October 18, 2017	82 FR 48535
Management Directive 5.3, Agreement State Participation in NRC Working Groups, June 22, 2016	ML18073A142
NUREG-1556, Volume 8, Revision 1, Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses, June 2018	ML18158A165
Strategic Plan: Fiscal Years 2018–2022, NUREG-1614, Volume 7, February 2018	ML18032A561
International Atomic Energy Agency, OECD Nuclear Energy Agency, Radiation Safety for Consumer Products, IAEA Safety Standards Series No. SSG-36, January 2016	<a href="https://www.iaea.org/publications/10716/radiation-safety-for-consumer-products">https://www.iaea.org/publications/10716/radiation-safety-for-consumer-products</a>
International Atomic Energy Agency, IAEA Safety Standards Series, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards—General Safety Requirements Part 3 No. GSR Part 3, July 2014	<a href="https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards">https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards</a>

The NRC may post documents related to this rulemaking activity to the Federal rulemaking Web site at <https://www.regulations.gov> under Docket ID NRC-2015-0017.

The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2015-0017); 2) click the “Sign up for E-mail Alerts” link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

Dated January 15, 2021.

For the Nuclear Regulatory Commission.

**/RA/**

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