Draft Environmental Assessment for the Proposed Rule — Allowing Exempt Distribution of Products Containing Byproduct Materials Incidental to Their Production (10 CFR Parts 30 and 32)

U.S. Nuclear Regulatory Commission
Office of Nuclear Materials Safety and Safeguards

June 2022

DRAFT FOR COMMENT

This page intentionally left blank.

Contents

This page intentionally left blank.

ABBREVIATIONS AND ACRONYMS

µSv	microSievert
CFR	*Code of Federal Regulations*
EA	environmental assessment
FR	*Federal Register*
ICBMIP	items containing byproduct material incidental to production
mrem	millirem
mSv	milliSievert
NEPA	National Environmental Policy Act of 1969, as amended
NRC	U.S. Nuclear Regulatory Commission
PCTE	polycarbonate track etched membranes
PRM	petition for rulemaking
rem	Roentgen equivalent man (a unit of radiation dose)

1 INTRODUCTION

Items containing byproduct material incidental to their production (ICBMIP) are irradiated products that serve a useful purpose (such as polycarbonate track etched (PCTE) membranes, irradiated gemstones, and certain silicon materials used in the electronics industry) and contain a minor amount of residual radiation incidental to the production process. ICBMIP are not covered under current U.S. Nuclear Regulatory Commission (NRC) regulations. The residual byproduct material is not part of the intended end use of the products and, if maintained within appropriate limits, does not present a risk to public health and safety. The NRC is proposing to amend its regulations to allow for the licensing of this class of irradiated products under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," 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. These changes are necessary because current regulations in 10 CFR Parts 30 and 32 do not cover items that contain byproduct material incidental to production; therefore, these items cannot be licensed for exempt transfers.

The NRC has prepared this draft environmental assessment (EA) in compliance with the NRC's environmental protection regulations in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," which implement the National Environmental Policy Act of 1969, as amended (NEPA).

1.1 Background

On April 18, 2011, GE Osmonics, Inc., submitted a petition for rulemaking (PRM), PRM-30-65, requesting that the NRC amend its regulations to allow commercial distribution and redistribution of PCTE membranes (76 FR 36386). PCTE membranes are used in a variety of research, medical, pharmaceutical, academic, scientific, and industrial applications. The membranes are irradiated to create uniform pore size and distribution, but the manufacturing process leaves behind small amounts of mixed fission products in the membranes. PCTE membranes are part of a larger group of materials called ICBMIP, and these items are not covered under the current regulations.

The NRC docketed the petition in November 2011. On September 14, 2012, the NRC published a notice in the *Federal Register* (FR) (77 FR 56793) stating that the petitioner raised a valid regulatory issue about the commercial distribution of PCTE membranes and that the NRC would consider the issue in the rulemaking process. On February 2, 2021, the NRC published a regulatory basis and request for comment (86 FR 7819). No substantive comments were received.

The rulemaking would amend (1) 10 CFR Part 30 by adding a new class exemption from licensing requirements for ICBMIP, and (2) 10 CFR Part 32 licensing requirements for distribution of those items. The rulemaking would make aligning changes to include the new sections in 10 CFR Part 32 under § 32.303, "Criminal penalties." The rulemaking would 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 staff recommended initiating a rulemaking related to the licensing and distribution of items containing byproduct material incidental to their production. The Commission approved proceeding with rulemaking.

1.2 Proposed Action

The proposed action is a rulemaking to amend 10 CFR Part 30 to add a new class exemption from licensing requirements for ICBMIP and to amend 10 CFR Part 32 to add new sections for distribution requirements. The current regulations in 10 CFR Parts 30 and 32 do not support the exempt licensing and distribution for the class of products containing byproduct material incidental to production.

1.3 Purpose of, and Need for, Proposed Action

The purpose of the proposed action is to create a new class of exempt materials for licensing and distribution. The rulemaking would amend 10 CFR Parts 30 and 32 to (1) add to 10 CFR Part 30 a new class exemption from licensing requirements and (2) add new sections to 10 CFR Part 32 for distribution requirements. These changes would apply dose criteria, rather than concentration, as the primary means of protecting health and safety.

The need for the proposed action is to 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. These proposed changes would fully address PRM-30-65, provide a regulatory framework for current (e.g., gemstones) and future irradiated products, and allow this class of products to be licensed without product-specific exemptions that require additional rulemakings in the future.

These irradiated products are widely used in a variety of beneficial applications, and a regulatory structure provides certainty in a pathway to licensing for this class of products. As a result, revising the regulations is appropriate to allow the potential use of these products under the exemption and distribution provisions in 10 CFR Parts 30 and 32.

The Commission approved the NRC staff recommendation to initiate a rulemaking related to the licensing and distribution of items containing byproduct material incidental to their production, and directed staff to ensure the rulemaking conforms to the NRC's Consumer Product Policy Statement (79 FR 2907).

2 APPLICABILITY OF CATEGORICAL EXCLUSION FOR CERTAIN AMENDMENTS

Certain amendments within the proposed rulemaking belong to a category of actions that the Commission has determined are categorically excluded from environmental assessment, having found that these types of actions do not individually or cumulatively have a significant effect on the human environment. Therefore, this draft EA is not required to evaluate these amendments further.

Under the categorical exclusions in 10 CFR 51.22(c)(3)(ii) and (iii), the amendments to 10 CFR Parts 30 and 32 that relate to requirements for recordkeeping and reporting do not require an EA. The proposed 10 CFR 32.35(b) and (c) related to recordkeeping and reporting

requirements for initial distributors of ICBMIP to exempt persons, and are therefore covered by the categorical exclusions in 10 CFR 51.22(c)(3)(ii) and (c)(3)(iii).

3 ENVIRONMENTAL IMPACTS OF THE PROPOSED ACTION

The recommended changes to 10 CFR Parts 30 and 32 to be analyzed during the rulemaking development process require the NRC to prepare an EA to address the potential associated environmental impacts, except for those covered by a categorical exclusion in Section 2.0 of this draft EA. The following sections discuss the regulatory changes and the potential environmental impacts.

3.1 Establish a new class exemption for items containing byproduct material incidental to their production

The NRC would amend 10 CFR Part 30 to add a new section, § 30.23, specific to products containing byproduct material that is not part of the intended end use of the product but instead is present as a result of production. This new § 30.23 would only apply to processes that unavoidably result in the incidental addition of byproduct material to the final product. The NRC would add new sections to 10 CFR Part 32 with the applicable licensing requirements for distribution, §§ 32.33, 32.34, and 32.35. Aligning changes would be made to include the new §§ 32.33 and 32.34 under § 32.303, "Criminal penalties." The new section in 10 CFR Part 30 would only apply to those products or materials that have an exempt distribution license under 10 CFR Part 32. This new regulatory structure would require a licensee to meet only dose-based criteria, which would reduce the burden on current gemstone licensees who are currently required to provide both concentration and dose-based criteria, as well as limit the NRC's review to only dose-based criteria in the license applications.

This new regulatory structure would allow new products to be licensed without product-specific exemptions, each of which would otherwise require additional rulemaking. Public health and safety are ensured by evaluating each specific product against safety criteria contained in the regulations that apply to all products in a class. This is similar to previous established class exemptions for categories of products or devices with similar characteristics, such as 10 CFR 30.19, "Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147"; 10 CFR 30.20, "Gas and Aerosol Detectors Containing Byproduct Material"; and 10 CFR 30.22, "Certain Industrial Devices." Establishing a class exemption increases efficiency rather than establishing individual exemptions for each product.

Creating an exemption from licensing results in products being released from any further regulatory control. This results in these products being used or disposed of without regard to radioactivity, which could cause an environmental impact. However, the safety criteria in § 32.34 establish limits for the products that the distributor must meet to obtain a license, including demonstrating that dose due to products being disposed at the distributor site and dose to individual users in regular use and during accident scenarios would be below regulatory thresholds. Maintaining dose below regulatory thresholds when using or disposing of the products would help minimize any environmental impact. This is discussed further in Section 3.2 of this draft EA. The proposed amendment to 10 CFR Part 30 would not result in significant environmental impacts.

3.2 Create requirements for initial distributors of items containing byproduct material incidental to their production

The NRC would add new sections to 10 CFR Part 32 to establish standards for the exempt distribution of ICBMIP.

These are the proposed new sections:

- § 32.33 would establish requirements for the initial distributors of ICBMIP
- § 32.34 would establish new safety criteria
- § 32.35 would establish the specific conditions of the license issued under § 32.33

Section 32.303 would be modified to include the new §§ 32.33 and 32.34, under § 32.303, "Criminal penalties."
The standards in these new sections would include requiring applicants to provide information relating to the design, manufacture, prototype testing (if applicable); quality control procedures, labeling and marking; and conditions of handling, storage, use, and disposal of the products to demonstrate that the product would meet the following specific safety criteria:

(a) dose limits to the general public and those occupationally exposed to the product, including through transportation, distribution, use, and disposal and
(b) prototype testing (if applicable) to demonstrate the degree of binding or containment under the most severe conditions likely to be encountered in normal use of the product

The proposed requirements to approve a license for initial distributors for use under the proposed exemption include criteria related to routine handling and accident scenarios. These criteria limit the potential for significant risks from use, handling, storage, and disposal, including marketing, distribution, installation, or servicing. Important environmental considerations are (1) the requirement that it is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the item will exceed 50 μSv (5 mrem); (2) the requirement that it is unlikely that the dose to a suitable sample of the group of individuals expected to be most highly exposed from disposal of the quantities of products likely to accumulate in the same disposal site will exceed 10 μSv (1 mrem) in any one year; (3) the requirement that in use, handling, storage, and disposal of the quantities of exempt products likely to accumulate in one location, including during marketing, distribution, installation, and/or servicing of the item, the probability is low that the safety features of the item would fail under such circumstances that a person would receive an external radiation dose or committed dose in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or committed dose of 100 mSv (10 rem) or greater; and (4) the requirement that certain doses would not be exceeded in specified misuse scenarios involving the unshielded source.

The requirement in item (1) is set to limit exposure to occupational workers. With respect to item (2), the total quantity expected to be distributed annually must be provided, and this would be considered in the projection of the total number of devices likely to accumulate in a single landfill, municipal incinerator, or, if applicable, recycling center. This limit is very low because persons exposed to radioactive material through disposal scenarios are exposed to all materials which end up in ordinary trash. The intent is that the combined effect of the disposal of all materials exempt from regulatory control will not result in exposures to persons, such as waste collectors and waste workers at municipal incinerators, of more than 1 mSv (100 mrem)/year. It

is also intended to control exposures to others such as people who may live at the site of a closed landfill in the future; however, waste collectors or waste workers are typically the most exposed population as a result of uncontrolled disposal.

The requirement in item (3) is set to protect the public even if the safety features of a device do not perform properly.

The misuse scenario in item (4) above is intended to essentially limit the quantity of any radionuclide which could be in any device, regardless of any shielding and containment designed to limit the exposures from the source in the device. This has a number of intended benefits, including minimizing impacts to the environment.

In addition to the specific provisions being proposed with this new exemption, the Commission has a consumer product policy statement which calls for the Commission to monitor the overall impact of its exemptions from licensing (79 FR 2907). The Commission has reporting requirements for the distribution of byproduct material nationally, through which it can monitor the amount of byproduct material distributed under the exemptions from licensing, which will ultimately be disposed as ordinary trash.

Concurrent with the final rule, the staff would issue interim guidance for these new provisions. Additionally, the NRC staff would revise, during the next comprehensive review, NUREG 1556, "Consolidated Guidance about Materials Licenses," Volume 8, Revision 1, "Program Specific Guidance About Exempt Distribution Licenses" (NRC 2018), which contains guidance for the issuance of licenses authorizing distribution to exempt persons.

These provisions would allow for new products and materials to be developed, evaluated, and licensed under a framework that would adequately protect health and safety without the need for additional rulemaking, and the safety criteria would be robust enough to cover any potential future irradiated products.

The establishment of safety criteria to limit occupational and general public dose and issuance of guidance for the new provisions will minimize waste impacts and human health impacts. These changes to 10 CFR Part 32 would not result in significant environmental impacts.

4 ENVIRONMENTAL IMPACTS OF THE ALTERNATIVES TO THE PROPOSED ACTION

The NRC staff identified alternatives to the proposed action of conducting a rulemaking. The alternatives to rulemaking would be to take no action or to develop non-rulemaking guidance documents.

4.1 No-Action Alternative (status quo)

Under this alternative, the NRC would continue to rely on existing regulations, orders, and guidance, and no resources would be necessary to perform rulemaking activities. The ICBMIP may be widely used, and this alternative would require each manufacturer, distributor, and user of an irradiated item in this class, except gemstones, to possess a specific license. There would be expenses related to this effort. Preparing and evaluating each specific license request would also require NRC resources. Further, recognizing the National Materials Program, each Agreement State would need to issue a specific license for these materials, which may cause transboundary issues. Gemstone licensees would continue to be licensed under the current

framework and would continue to provide concentration and dose-based criteria in their applications. The no-action alternative would result in additional resources expended for manufacturers, distributors, and users of ICBMIP to obtain a specific license and for the NRC and Agreement States to evaluate each specific license request and issue the specific licenses. There would not be significant impacts on the environment from the no-action alternative. However, this alternative would not address concerns identified in PRM-30-65 and would not meet the purpose and need for the proposed action.

4.2 Develop Guidance Without Rulemaking

Under this alternative, the NRC would continue to rely on existing regulations and would develop guidance for manufacturers, distributors, and users of ICBMIP, except for gemstones. Gemstone licensees would continue to be licensed under the current framework and would continue to provide concentration and dose-based criteria in their applications. These non-rulemaking guidance documents could include generic letters, information notices, and guidance documents, such as regulatory guides. There would be additional resource impacts to the NRC to produce such guidance but no significant impacts on the environment from this alternative.

Guidance cannot impose new requirements on licensees, and NRC cannot enforce compliance with guidance documents. Therefore, guidance alone is not a viable approach to provide for the use of a product under exemption from licensing. Developing guidance would not address concerns identified in PRM-30-65 and would not meet the purpose and need for the proposed action.

5 AGENCIES AND PERSONS CONSULTED

The NRC is requesting public comment on this draft EA. The NRC intends to hold a public meeting during the proposed rule comment period to allow stakeholders to ask questions about the proposed rule and this draft EA. The NRC will consider comments received on the docket as it develops the final rule and the final EA. The NRC will issue the final EA when it publishes the final rule. The working group involved in the preparation of the proposed rule included two representatives from the Organization of Agreement States in accordance with Management Directive 5.3, “Agreement State Participation in Working Groups” (NRC 2016). Early drafts of this proposed rule were provided to Agreement States for review, and comments from Agreement States were taken into consideration during the development of the proposed rule. The NRC also is requesting the views of the Agreement States on this draft EA.

The proposed rulemaking changes are administrative in nature or would not result in significant impact on the environment. As such, the rulemaking would not result in impacts to federally listed, threatened, or endangered species or their critical habitat; the NRC has determined that Section 7 consultation under the Endangered Species Act is not necessary. Likewise, the NRC determined that the proposed rulemaking would not have the potential to cause effects on or to historic properties. Therefore, the NRC has determined that no further consultation is required under Section 106 of the National Historic Preservation Act.

6 PRELIMINARY CONCLUSION AND FINDING OF NO SIGNIFICANT IMPACT

Rulemaking is the NRC's preferred alternative because it best resolves the need for action for these issues based on the agency's objectives of effectiveness and openness in the regulatory process, while continuing to meet its goals of ensuring adequate protection of public health and safety and the environment and adequate protection in the secure use and management of radioactive materials. In general, for these issues, rulemaking establishes regulations which can be made enforceable; affords opportunity for public involvement; and are readily available to regulators, licensees, and the general public. No non-rulemaking alternatives can realistically address these issues identified for ICBMIP. Conducting rulemaking meets the purpose and need for the proposed action.

The Commission has preliminarily determined under NEPA and the Commission's regulations in Subpart A of 10 CFR Part 51 that the proposed amendments would not be a major Federal action significantly affecting the quality of the human environment, and therefore, an environmental impact statement is not required. The rulemaking would amend 10 CFR Part 30 to add a new class exemption from licensing requirements for items containing byproduct material incidental to their production and amend 10 CFR Part 32 to create requirements for initial distributors of ICBMIP. The environmental impacts arising from the changes have been evaluated and would not involve any significant environmental impact.

The NRC preliminarily determines, through this draft EA, that there would be no significant impact to the environment from this action.

7 REFERENCES

10 CFR Part 30. *Code of Federal Regulations*, Title 10, *Energy*, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

10 CFR Part 32. *Code of Federal Regulations*, Title 10, *Energy*, Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," Subpart A, "Exempt Concentrations and Items."

10 CFR Part 51. *Code of Federal Regulations*, Title 10, *Energy*, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

77 FR 56793. September 14, 2012. "Petition for Rulemaking Submitted by Annette User on Behalf of GE Osmonics, Inc." *Federal Register* U.S. Nuclear Regulatory Commission, Washington, DC.

79 FR 2907. January 16, 2014. "Consumer Product Policy Statement." *Federal Register* U.S. Nuclear Regulatory Commission, Washington, DC.

86 FR 7819. February 2, 2021. "Regulatory Basis: Items Containing Byproduct Material Incidental to Production." *Federal Register* U.S. Nuclear Regulatory Commission, Washington, DC.

Endangered Species Act of 1973, as amended. 16 USC 1531 *et seq*.

National Environmental Policy Act of 1969, as amended. 42 U.S.C. 4321 *et seq*.

National Historic Preservation Act of 1966, as amended. 16 U.S.C. 470 *et seq*.

NRC 2016. Management Directive 5.3. "Agreement State Participation in Working Groups," June 22, 2016. ADAMS Accession No. ML18073A142.

NRC 2018. NUREG-1556, "Consolidated Guidance about Materials Licenses," Volume 8, Revision 1, "Program-Specific Guidance About Exempt Distribution Licenses." ADAMS Accession No. ML18158A165.

PRM-30-65, "Petition for Rulemaking Pursuant to 10 CFR 2.802 on Behalf of GE Osmonics Inc.," April 18, 2011. ADAMS Accession No. ML120250133.