RULEMAKING ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: **Brooke P. Clark, Secretary**

FROM: **Chairman Hanson**

SUBJECT: **SECY-22-0004: Proposed Rule: Items Containing Byproduct Material Incidental to Production**

Approved X **Disapproved** ____ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** X **Attached** X **None** ____

This proposed draft rule adds a new class exemption and distribution requirements for a group of irradiated products with similar characteristics. This rule would allow products like irradiated gemstones, silicon chips and polycarbonate track etched membranes to be licensed consistently without the need for product-specific exemptions. Otherwise, each product would require additional rulemaking or need to be reviewed on a case-by-case basis. This rule provides for an efficient pathway to regulate and license these products which have a wide variety of uses and applications.

I approve the publication of the proposed draft rule for comment subject to the attached edits.

Christopher T. Hanson

Digitally signed by Christopher T. Hanson
Date: 2022.05.06 17:00:19 -04'00'

Entered in STARS
Yes X
No ____

Signature
Christopher T. Hanson

Date **05/06/2022**

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 32

[NRC-2015-0017]

RIN 3150-AJ54

Items Containing Byproduct Material Incidental to Production

CTH edits

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and draft guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to 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. This rulemaking would resolve a petition for rulemaking submitted by GE Osmonics, Inc., that requested changes to the regulations to allow distribution of polycarbonate track etched membranes. The NRC plans to hold a public meeting to promote full understanding of the proposed rule and facilitate public comments.

DATES: Submit comments by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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 (unless this document describes a different method for submitting comments on a specific subject); however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- **Federal rulemaking website:** 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; email: Dawn.Forder@nrc.gov. For technical questions contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Email comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

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: Shirley Xu, telephone: 301-415-7640; email: Shirley.Xu@nrc.gov; and Caylee Kenny, telephone: 301-415-7150; email: Caylee.Kenny@nrc.gov. Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

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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 Website:** 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, at 301-415-4737, or by email to 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.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's Public Document Room (PDR), Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (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. Background

A. Petition for Rulemaking (PRM-30-65)

On April 18, 2011, GE Osmonics, Inc., submitted a petition for rulemaking (PRM), PRM-30-65, that requested the NRC amend its regulations to allow commercial distribution of polycarbonate track etched (PCTE) membranes. The PCTE membranes are used in a variety of research, medical, pharmaceutical, academic, scientific, and industrial applications. The membranes are irradiated (exposed to radiation in, for example, a research and test reactor), to create uniform pore size and distribution, which leaves small amounts of mixed fission products in the membranes. The incidental radioactivity of these products presents a small fraction, less than a few hundredths, of the public dose limits in NRC regulations, as based on the product safety analyses submitted by the petitioner on March 20, 2012.

The NRC docketed the petition and, on June 22, 2011, the NRC published a notice of docketing and request for public comment (76 FR 36386). The NRC received one comment and, on September 14, 2012, the NRC published a document in the *Federal Register* (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.

B. Existing Regulatory Framework for Irradiated Products Containing Byproduct Material Incidental to Production

Under part 30 of title 10 of the *Code of Federal Regulations* (10 CFR), “Rules of General Applicability to Domestic Licensing of Byproduct Material,” the NRC regulates the manufacturing, production, transfer, receipt, acquisition, ownership, possession, and use of byproduct material. Typically, the NRC regulates these processes through a specific or general license. The regulations in § 30.11, “Specific exemptions,” through

§ 30.22, “Certain industrial devices,” provide exemptions from certain licensing requirements. The regulations in § 32.11, “Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license” provide the requirements for obtaining a specific license authorizing the introduction of byproduct material into a product or material that will eventuallybe transferred to a person exempt from the licensing requirements.

Both §§ 32.11 and 30.14 provide that, for exempt distribution, the concentrations of byproduct material in a product cannot exceed the values listed in Schedule A in § 30.70. However, these regulations are not applicable to this class of products because the current regulations do not apply to items that contain byproduct material incidental to production; therefore, these items cannot be licensed for exempt transfers. For the specific case of irradiated gemstones, in the staff requirements memorandum for SECY-87-186A, the Commission approved the interim licensing of irradiated gemstones pursuant to §§ 32.11 with an exemption from requirements that prohibit application of products to a human being. Although this regulatory approach has been applied to irradiated gemstones, the existing regulatory framework is not designed to regulate the broader class of items containing byproduct material incidental to production for the reasons outlined ~~in the following explanation~~below.

First, the concentrations in Schedule A pertain to volumetric concentrations in an item containing byproduct material. While volumetric concentrations are useful and appropriate for assessing some products, the NRC is aware of certain products (e.g., polycarbonate membranes, which are thin films) for which volumetric concentrations would not be meaningful due to the products’ shape. Consequently, the basis for using volumetric concentrations for products covered by Schedule A would not be applicable to several items that are in this class of products.

Second, the maximum concentration limits of Schedule A are based on the potential internal dose from inhalation or ingestion. Potential doses from the irradiated products under consideration, when used as intended, would likely result from external exposures, such as the wearing of a gemstone~~,~~ or the handling of a PCTE membrane~~, etc~~. Therefore, using the Schedule A concentration limits would not be appropriate for this class of products.

Third, the list of radionuclides in Schedule A is not sufficiently comprehensive to cover all potential radionuclides present in this class of products. While some of the potential radionuclides in these products would fall within the catch-all provision of Schedule A (i.e., beta- or gamma-emitting byproduct material with a half-life less than 3 years), Schedule A does not capture other radionuclides that are present in this class of products. For example, PCTE membranes are exposed to nuclear fission fragments, including strontium-90, which remain embedded in the membranes. Schedule A has never specifically included strontium-90 in the table, and strontium-90 would not fall within the catch-all provision of Schedule A because its half-life is more than 27 years. As a result, Schedule A would not cover several items in this class of products, such as PCTE membranes, because it does not capture, either specifically or in the catch-all provision, all radionuclides that may be present in these products.

These irradiated products are widely used in a variety of beneficial applications (e.g., pharmaceutical, water filtration), 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 use of these products under the exemption and distribution provisions in 10 CFR parts 30 and 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.”

C. Recent Rulemaking Actions

A regulatory basis was published in the *Federal Register* on February 2, 2021 (86 FR 7819). The NRC did not receive any public comments on the regulatory basis to inform this proposed rulemaking.

III. Discussion

A. What Action is the NRC Taking?

This proposed rule would amend 10 CFR parts 30 and 32 to 1) add a new class exemption from licensing requirements to 10 CFR part 30 and 2) add associated distribution requirements to 10 CFR part 32. These changes would apply dose criteria, rather than concentration, as the primary means of protecting health and safety. These proposed changes would fully address PRM-30-65, provide a regulatory framework for current (i.e., gemstones) and future irradiated products, and allow this class of products to be licensed without product-specific exemptions, which would otherwise require additional rulemaking in the future. This new regulatory structure would require a licensee to meet dose-based criteria, which would reduce the regulatory burden on current gemstone licensees, who currently provide both concentration and dose-based criteria. Additionally, as described below, this proposed rule would make conforming changes to include the new §§ 32.33, "Requirements for license of items containing byproduct material incidental to production and transfer of ownership or possession," and 32.34, "Items containing byproduct material incidental to production safety criteria," under § 32.303, "Criminal penalties."

In addition to providing dose measurements, the current distributors of irradiated gemstones use a variety of measurements and statistical analysis methods to demonstrate that the concentration of byproduct material at the time of sale to

consumers is unlikely to exceed the concentration limits in § 30.70 (and derived concentrations for those not specifically included). Under the new provisions, current gemstone licensees and applicants (initial distributor or transferrer) would demonstrate that their products are unlikely to result in doses exceeding the dose criteria in the new provisions.

The NRC would amend 10 CFR part 30 to add new § 30.23, “Items containing byproduct material incidental to production,” specific to products containing byproduct material that is not part of the intended end use of the product, but is instead present as a result of production. This new section would only apply to items produced in a way that unavoidably results in the incidental addition of byproduct material to the final product. The NRC would add companion paragraphs to 10 CFR part 32 that would provide the applicable licensing requirements for distribution. The new section, 10 CFR 30.23, would only apply to those products or materials that have an exempt distribution license under § 32.33.

In the past, the NRC has established class exemptions for categories of products or devices with similar characteristics, rather than establishing individual exemptions for each product. These exemptions appear in §§ 30.19, “Self-luminous products containing tritium, krypton-85, or promethium-147”; 30.20, “Gas and aerosol detectors containing byproduct material”; and 30.22, “Certain industrial devices.” This planned rulemaking approach is similar to that for §§ 30.19, 30.20, and 30.22 in that the regulatory structure would allow new products containing byproduct material incidental to production 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 the class.

The new provision would be similar in some respects to the class exemptions in the current regulations in that it would require applicants requesting authorization to distribute a product or material to demonstrate that the product or material meets certain safety criteria. The NRC specifies these safety criteria in §§ 32.23, "Same [Self-luminous products containing tritium, krypton-85 or promethium-147~~Specific domestic licenses to manufacture or transfer certain items containing byproduct material~~]: Safety criteria"; 32.27, "Same [Gas and aerosol detectors containing byproduct material~~Specific domestic licenses to manufacture or transfer certain items containing byproduct material~~]: Safety criteria"; and 32.31, "Certain industrial devices containing byproduct material: Safety criteria." These safety criteria would form the primary means of ~~ensuring~~ providing reasonable assurance of adequate protection of public health and safety. Applicants requesting authorization to manufacture, possess, or distribute items containing byproduct material incidental to production would be required to demonstrate compliance with the safety criteria. These criteria would cover normal use, handling, storage, marketing, distribution, installation, servicing, and disposal, as well as potential accidents and misuse.

During the development of the regulatory basis for this proposed rulemaking, the NRC considered the following specific issues for this proposed rule:

1) The need for establishing standards for the exempt distribution of products that contain byproduct material that is incidental to production. These standards 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[1] to the product, including through transportation, distribution, use, and disposal; and

b) Prototype testing (if applicable) to demonstrate the degree of binding or containment that is necessary under the most severe conditions likely to be encountered in normal use of the product.

2) The need for establishing ongoing requirements for the exempt distribution of products approved for distribution under the new provision in the proposed rule:

a) Labeling requirements for the product and for final product packaging,

b) Quality control/quality assurance, and

c) Recordkeeping and annual transfer reporting.

These new provisions in the proposed rule can be applied generically and would present an appropriate regulatory framework for irradiated products of this class. ~~It~~ They 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. The safety criteria would be robust enough to cover any potential future irradiated products. In the long term, these comprehensive proposed changes would be the most cost-effective solution to the NRC and the industry because other irradiated products are expected to be brought to market in the future.

B. What Persons Would this Action Affect?

This proposed rule, if adopted, would apply to persons who submit an application for current and future products that contain byproduct material incidental to production.

[1] Individuals occupationally exposed include PCTE membrane manufacturers, truck drivers, warehouse workers, and waste disposal workers. For class exemptions, the existing criteria for such groups are 5–20 millirem (mrem)/year (50–200 microsieverts (μSv)/year) except for disposal scenarios for which the criterion is 1 mrem/year (10 μSv/year), because the same individuals could be impacted by all of the products allowed to be disposed in landfills and municipal incinerators.

Examples include PCTE membranes, irradiated gemstones, and certain silicon materials used in the electronics industry.

C. Why Do the Requirements Need to be Revised?

As noted in the “Background” section of this document, the current 10 CFR parts 30 and 32 regulations do not cover items that contain byproduct material incidental to production; therefore, these items cannot be licensed for exempt transfers. 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.

IV. Section-by-Section Analysis

The following paragraphs describe the specific changes proposed by this rulemaking.

§ 30.23 Items containing byproduct material incidental to production.

This proposed rule would add new § 30.23 to require applicants to demonstrate that the product or material for distribution would meet certain safety criteria.

§ 32.33 Requirements for license of items containing byproduct material incidental to production and transfer of ownership or possession.

This proposed rule would add new § 32.33 to provide the requirements to authorize the initial transfer of the products or materials for use.

§ 32.34 Items containing byproduct material incidental to production safety criteria.

This proposed rule would add new § 32.34 to provide the safety criteria for license applicants.

§ 32.35 Conditions of licenses issued under § 32.33: Quality control, labeling, and reports of transfer.

This proposed rule would add a new § 32.35 to require adequate control procedures, labeling, and recordkeeping.

§ 32.303 Criminal penalties.

This proposed rule would amend paragraph (b) to include new §§ 32.33 and 32.34 as conforming changes.

V. Regulatory Flexibility Certification

The NRC has prepared a draft regulatory analysis of the impact of this proposed rule. This proposed rule would affect approximately 27 current and expected licensees that manufacture and/or distribute items containing byproduct material incidental to production, some of which may qualify as small business entities as defined by § 2.810, "NRC size standards." On the basis of the draft regulatory analysis conducted for this action, the estimated averted cost of this proposed rule for affected licensees is $40,000 (calculated using a 7 percent discount rate). Based upon historical data, the NRC estimates that approximately 2 out of the 27 estimated licensees subject to this rulemaking may qualify as small business entities as defined by § 2.810. These two small business entities are anticipated to be gemstone licensees. It is expected that all businesses will incur the same savings resulting from the licensing process. These savings are a small percentage of the gross sales; therefore the NRC concludes that there would be no significant economic impact to small business entities. The NRC believes that the selected alternative reflected in this proposed rule is the least

burdensome, most flexible alternative that would accomplish the NRC's regulatory objective.

The NRC is seeking public comment on the potential impact of this proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how this proposed regulation would affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities, while still adequately protecting the public health and safety and common defense and security. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss:

1) The size of the business and how the proposed regulation would result in a significant economic ~~burden~~ cost as compared to a larger organization in the same business community;

2) How the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

3) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

4) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations as opposed to providing special advantages to any individuals or groups; and

5) How the proposed regulation, as modified, would still adequately protect the public health and safety and common defense and security.

Comments should be submitted as indicated under the "Obtaining Information and Submitting Comments" section of this document.

VI. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The regulatory analysis is available as indicated in the "Availability of Documents" section of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the "Obtaining Information and Submitting Comments" section of this document.

VII. Backfitting and Issue Finality

The NRC has determined that the backfitting provisions in §§ 50.109, 70.76, 72.62, and 76.76, and the issue finality provisions in 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," do not apply to this proposed rule. The class of licensees subject to this rulemaking are applicants for a new exempt distribution license for items containing byproduct material incidental to production or current irradiated gemstone licensees that submit an application for a license amendment for a new irradiated gemstone exempt distribution license, the application for which is submitted after the effective date of this rule. This class of licensees would be regulated in accordance with 10 CFR parts 30 and 32. As 10 CFR parts 30 and 32 contain no backfitting provisions, and these licensees are not within the scope of an NRC regulation that contains a backfitting or issue finality provision, this proposed rule is not within the scope of the NRC's backfitting and issue finality provisions.

VIII. Cumulative Effects of Regulation

The NRC is following its Cumulative Effects of Regulation (CER) process by engaging with external stakeholders throughout this proposed rule and related regulatory activities. Opportunity for public comment is provided to the public at this proposed rule stage. The NRC is issuing the draft guidance for comment along with this proposed rule to support more informed external stakeholder feedback. Further, the NRC may hold public meetings throughout the rulemaking process. Section XV, "Availability of Guidance," of this document describes how the public can access the draft guidance for which the NRC seeks external stakeholder feedback. The NRC is requesting CER feedback on the following questions:

1. In light of any current or projected CER challenges, does the proposed rule's effective date provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility?

2. If CER challenges currently exist or are expected, what should be done to address them? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?

3. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) influence the implementation of the proposed rule's requirements?

4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

5. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports the proposed rule.

IX. 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 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

X. Environmental Assessment and Proposed Finding of No Significant Environmental Impact

The NRC has determined that the proposed § 32.35(b) and (c) in this proposed rule are the types of actions described in § 51.22(c)(3)(ii) and (iii), and neither an environmental impact statement nor an environmental assessment has been prepared for the proposed amendments because they relate to recordkeeping and reporting requirements for initial distributors of items containing byproduct material incidental to production to exempt persons.

An environmental assessment has been prepared for proposed changes not covered by the categorical exclusions listed in § 51.22(c)(3)(ii) and (iii). The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule, if adopted, 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 basis of this determination is as follows: The amendments 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 to amend

10 CFR part 32 to add new sections for distribution requirements. The environmental impacts arising from the changes have been evaluated and would not involve any significant environmental impact or significant effect on the quality of the human environment. The environmental assessment is available as indicated in the "Availability of Documents" section of this document. Comments on the environmental assessment may be submitted to the NRC as indicated under the "Obtaining Information and Submitting Comments" section of this document. The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and has requested comments.

XI. Paperwork Reduction Act

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collections.

Type of submission, new or revision: New.

The title of the information collection: Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material.

Part 32 - Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.

How often the collection is required or requested: Every 15 years.

Who will be required or asked to respond: Applicant applying for an initial or renewed distribution and possession license for items containing byproduct material incidental to production.

An estimate of the number of annual responses:

Part 30: 18 (9 reporting + 9 recordkeepers).

Part 32: 918 (9 reporting + 9 recordkeepers + 900 third-party disclosure).

The estimated number of annual respondents:

Part 30: 9.

Part 32: 9.

An estimate of the total number of hours needed annually to comply with the information collection requirement or request:

Part 30: 585 (540 reporting hours + 45 recordkeeping hours).

Part 32: 714 (630 reporting hours + 9 recordkeeping hours + 75 third-party disclosure hours).

Abstract: In part 30 of title 10 of the *Code of Federal Regulations* (10 CFR) the NRC regulates the manufacturing, production, transfer, receipt, acquisition, ownership, possession, and use of byproduct material. Part 32 of 10 CFR provides requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution. This proposed rule 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 add new sections for distribution requirements.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection(s) contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of the burden of the proposed information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the Office of Management and Budget (OMB) clearance package and proposed rule is available in ADAMS or can be obtained free of charge by contacting the NRC's Public Document Room reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.resource@nrc.gov. You may obtain information and comment submissions related to the OMB clearance package by searching on https://www.regulations.gov under Docket ID NRC-2015-0017.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following methods:

- **Federal rulemaking website:** Go to https://www.regulations.gov and search for Docket ID NRC-2015-0017.

- **Mail comments to:** FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0017 and 3150-0001), ATTN: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW, Washington, DC 20503; email: oira_submission@omb.eop.gov.

Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. 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 on or before this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this proposed rule that would amend 10 CFR parts 30 and 32 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of this rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR parts 30 and 32 are discussed in §§ 30.64 and 32.303, respectively.

XIII. Coordination with Agreement States

The working group involved in the preparation of this proposed rule included two representatives from the Organization of Agreement States. Early drafts of this proposed rule were provided to Agreement States for review. Comments from Agreement States were taken into consideration during the development of this proposed rule.

XIV. Compatibility of Agreement State Regulations

Under the "Agreement State Program Policy Statement" approved by the Commission on October 2, 2017, and published in the *Federal Register* on October 18, 2017 (82 FR 48535), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC, or adequacy category Health and Safety (H&S). Compatibility Category A are those program elements that include basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B pertains to a limited number of program elements that cross jurisdictional boundaries and should be addressed to ensure uniformity of regulation on a nationwide basis. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C above, and thus, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended (AEA), or provisions of title 10 of the *Code of Federal Regulations*. These program elements should not be adopted by the Agreement States. Category H&S program elements are

not required for purposes of compatibility; however, they do have particular health and safety significance. The Agreement State should adopt the essential objectives of such program elements to maintain an adequate program.

The proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The compatibility categories are designated in the following table:

Compatibility Table

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
30.23	New	Items containing byproduct material incidental to production	---	B
Part 32				
32.33	New	Requirements for license of items containing byproduct material incidental to production and transfer of ownership or possession	---	NRC
32.34	New	Items containing byproduct material incidental to production safety criteria	---	NRC
32.35	New	Conditions of licenses issued under § 32.33: Quality control, labeling, and reports of transfer	---	NRC
32.303	Amend	Criminal penalties	D	D

XV. Availability of Guidance

The NRC is issuing draft guidance in conjunction with this proposed rule. The draft guidance is intended for use by applicants, licensees, Agreement States, and the NRC when preparing and evaluating an exempt distribution licensing action for items containing byproduct material incidental to production. These exempt distribution licenses will authorize the initial distribution of byproduct material incidental to production to persons exempt from the regulatory requirements (exempt distribution) for an NRC

license under 10 CFR part 30 and exempt from licensing requirements under the equivalent provisions in Agreement State regulations.

The draft guidance document reflects the provisions in this proposed rule. Comments on the draft guidance may be submitted by the methods provided in Section I, "Obtaining Information and Submitting Comments," of this document. The draft guidance is available as indicated under the "Availability of Documents" section of this document. The NRC plans to incorporate the final guidance into the next comprehensive revision of NUREG-1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses."

XVI. Public Meeting

The NRC will publish a notice of the location, time, and agenda of the meeting on https://www.regulations.gov, and on the NRC's public meeting website within at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: https://www.nrc.gov/public-involve/public-meetings/index.cfm.

XVII. 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.

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / *FEDERAL REGISTER* CITATION

Draft Guidance Document to NUREG-1556, Volume 8, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," dated [Month XX, 2021]	ML21256A291
Federal Register notification for the Regulatory Basis for this Proposed Rule, published February 2, 2021	86 FR 7819
Draft Regulatory Analysis	ML21256A281
Draft Environmental Assessment	ML21256A282
Federal Register notification for PRM-30-65 Docket Closure [NRC-2011-0134], published September 14, 2012	77 FR 56793
Federal Register notification for PRM-30-65 Receipt and Request for Comment [NRC-2011-0134], published June 22, 2011	76 FR 36386
NRC Agreement State Program Policy Statement, published October 18, 2017	82 FR 48535
Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998	63 FR 31885
GE Osomics - Polymer Track Etch Membrane 10 CFR 32.1 – Manufacture and Distribution Product Safety Information, March 20, 2012	ML120800277
SECY-87-186A, "Distribution of Radioactive Gems Irradiated in Reactors to Unlicensed Persons (Follow-up to SECY-87-186)," October 5, 1987	ML092400170
Regulatory Basis for Items Containing Byproduct Material Incidental to Production	ML20339A312 (package)
OMB Clearance Package [Month XX, 2021]	ML21256A288

Throughout the development of this rule, the NRC may post documents related to this rule, including public comments, on the Federal rulemaking website at https://www.regulations.gov under Docket ID NRC-2015-0017.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear energy, Nuclear materials, Penalties, Radiation protection, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the AEA; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC proposes the following amendments to 10 CFR parts 30 and 32:

PART 30 – RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

2. Add § 30.23 to read as follows:

§ 30.23 Items containing byproduct material incidental to production.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution items containing byproduct material that is incidental to production and except as provided in paragraphs (e) and (f) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act.

(b) For persons exempt under paragraph (a) of this section, they are also exempt from parts 20, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires items containing byproduct material incidental to production.

(c) A specific license issued under 10 CFR 32.33, which authorizes the initial transfer of the products or materials for use under this section, is needed to manufacture, process, produce, or initially transfer items containing byproduct material incidental to production.

(d) This section may not be deemed to authorize the import of byproduct items containing byproduct material incidental to production.

(e) This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product that is designed to be ~~for being~~, or could reasonably be expected to be, ingested, inhaled, or absorbed by, or applied to ~~intaken by~~ a human being~~, such as food, beverage, cosmetic, or drug~~.

(f) No person may introduce byproduct material incidental to production into a product or material knowing, or having reason to believe, that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under 10 CFR 32.33.

PART 32 – SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

3. The authority citation for part 32 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

4. In Subpart B, add §§ 32.33, 32.34, and 32.35 to read as follows:

§ 32.33 Requirements for license of items containing byproduct material incidental to production and transfer of ownership or possession.

(a) An application for a specific license to manufacture, process, or produce items containing byproduct material that is incidental to production, or to initially transfer for sale or distribution such items under 10 CFR 30.23 or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33, provided that an application for a license to transfer items containing byproduct material that is incidental to production does not need to meet the requirements of 10 CFR 30.33(a)(2) and (3) for items manufactured, processed, or produced under a license issued by an Agreement State.

(2) The applicant submits sufficient information relating to the design; manufacture; prototype testing; quality control procedures; labeling or marking; and conditions of handling, storage, use, and disposal of the item containing byproduct material that is incidental to production to demonstrate that the product will meet the safety criteria set forth in § 32.34. The information must include:

(i) A description of the item and its intended use or uses.

(ii) The type and quantity of byproduct material in each unit.

(iii) Chemical and physical form of the byproduct material in the item and changes in chemical and physical form that may occur during the useful life of the product.

(iv) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2)(iii) and (xii) of this section.

(v) Details of construction and design of the item as related to safety features under normal and severe conditions of handling, storage, use, and disposal of the item.

(vi) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(vii) Degree of access of human beings to the item during normal handling and use.

(viii) Total quantity of byproduct material expected to be distributed in the items annually.

(ix) The expected useful life of the item.

(x) The proposed method of labeling or marking each point of sale package and, if feasible, each unit. Each mark or label must contain the statement “CONTAINS RADIOACTIVE MATERIAL” and must identify the initial transferor of the item.

(xi) Procedures for prototype testing of the item to demonstrate the effectiveness of the safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(xii) Results of the prototype testing of the item, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and committed dose resulting from the intake of radioactive material in any one year relevant to the safety criteria in § 32.34 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in § 32.34 meet the criteria of that paragraph.

(xv) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(xvi) Any additional information, including experimental studies and tests, requested by the Commission.

(3) The Commission determines that the product meets the safety criteria in § 32.34.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

§ 32.34 Items containing byproduct material incidental to production safety criteria.

(a) An applicant for a license under § 32.33 must demonstrate that the item is designed and will be manufactured so that:

(1) In normal use, normal handling, and normal storage of the quantities of exempt items likely to accumulate in one location, including during marketing, distribution, installation, and/or servicing of the item, it is unlikely that:

(i) 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); and

(ii) There will be a significant reduction in the effectiveness of the safety features of the item from wear and abuse.

(2) In disposal of quantities of exempt items likely to accumulate in the same disposal site, 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, will exceed 10 μSv (1 mrem).

(3) 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.[1]

(b) An applicant for a license under § 32.33 must demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the item for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of 10^{-4} of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if item is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the item in a pocket for 80 hours will not exceed 2 Sv (200 rem).

[1] This paragraph assumes that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The following values may be used as guides in estimating compliance with the criteria: Low— not more than one such failure/incident per year for each 10,000 exempt units distributed. Negligible— not more than one such failure/incident per year for each one million exempt units distributed.

§ 32.35 Conditions of licenses issued under § 32.33: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.33 must:

(a) Carry out adequate control procedures in the manufacture of the item to assure that each item meets the quality control standards approved by the Commission;

(b) Label or mark each point of sale package and, if feasible, each unit. Each mark or label must contain the statement "CONTAINS RADIOACTIVE MATERIAL" and must identify the initial transferor of the item; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in 10 CFR 30.6(a), including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the items are transferred for use under 10 CFR 30.16 or equivalent regulations of an Agreement State; and

(3) The report must include the following information on items transferred to other persons for use under 10 CFR 30.16 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each item and the model number(s); and

(ii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The report, covering the preceding calendar year, must be filed on or before January 31 of each year. The licensee must separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.33 must file a report for the current calendar year within 30 calendar days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.33 during the reporting period, the report must so indicate.

(6) The licensee must maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

§ 32.303 [Amended]

5. In § 32.303, amend paragraph (b) by adding the references “32.33, 32.34,” in sequential order.

Dated Month XX, 20XX.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.