



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July XX, 2020

ALL AGREEMENT STATE RADIATION CONTROL PROGRAM DIRECTORS

OPPORTUNITY TO COMMENT ON THE U.S. NUCLEAR REGULATORY COMMISSION'S REGULATORY BASIS: ITEMS CONTAINING BYPRODUCT MATERIAL INCIDENTAL TO PRODUCTION (RCPD-20-XXX)

Purpose: To provide Agreement States an advanced opportunity to comment on the U.S. Nuclear Regulatory Commission (NRC) regulatory basis for the rule titled "Items Containing Byproduct Material Incidental to Production."

Background: The NRC is proposing to amend its regulations to allow for the licensing of items that contain byproduct material due to the production process under Part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Rules of General Applicability to Domestic Licensing of Byproduct Material," and Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." Items containing byproduct material incidental to production are irradiated products that serve a useful purpose and contain a minor amount of residual radiation incidental to the production process. The residual byproduct material is not part of their intended end use and does not present a risk to public health and safety. Polycarbonate track etched (PCTE) membranes, silica chips, and irradiated gemstones are examples of widely used irradiated products in this class.

This rulemaking would address issues raised in the petition for rulemaking (PRM), PRM-30-65, from GE Osmonics (Agencywide Documents Access and Management System [ADAMS] Accession No. ML120250133) to: (1) add a new class exemption from licensing requirements to 10 CFR Part 30 and (2) add associated distribution requirements to 10 CFR 32.11.

These proposed changes would create a regulatory framework for current and future irradiated products and allow this class of products to be licensed without product-specific exemptions. This rulemaking would affect both NRC and Agreement State licensees. Details and rationale for the proposed changes are discussed in the enclosed regulatory basis document.

Discussion: Enclosed for review and comment is the regulatory basis document. Consistent with NMSS procedure SA-801A, "Agreement State Participation in Rulemaking Working Groups," the Agreement States have the opportunity to provide comments before publication of the Regulatory Basis in the *Federal Register*, at which time the general public would have an opportunity to comment.

OFFICIAL USE ONLY – SENSITIVE INTERNAL INFORMATION

Please provide any comments to the point of contact listed below. We would appreciate receiving your comments no later than 30 days from the date of this letter.² This comment period was coordinated with the Organization of Agreement States. If you have any questions regarding this correspondence, please contact me at 301-415-2486, or the individual named below:

POINT OF CONTACT: Alexa Sieracki E-MAIL: Alexa.Sieracki@nrc.gov

TELEPHONE: 301-415-7509

John Tappert, Director
Division of Rulemaking, Environmental,
and Financial Support
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Regulatory Basis for the rulemaking
“Items Containing Byproduct Material
Incidental to Production”

²This information request has been approved by OMB 3150-0029 expiration 7/31/2023. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comment regarding the burden estimate to the FOIA, Library and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.