

SUPPORTING STATEMENT
FOR
INFORMATION COLLECTIONS CONTAINED IN
ITEMS CONTAINING BYPRODUCT MATERIAL INCIDENTAL TO PRODUCTION

PROPOSED RULE

10 CFR PART 32

3150-0001

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32 provide requirements for the manufacture and distribution of a wide range of materials and products containing radioactive material. Part 32 also provides requirements governing holders of certificates of registration for certain products and materials. The requirements in Part 32 specify information that must be submitted in an application for a license to manufacture and distribute materials and products, records that must be kept, reports that must be submitted, labeling and marking products, and information that must be forwarded to users of these products and materials.

The NRC is proposing to amend its regulations in Part 32 to add requirements for the exempt distribution of items containing byproduct material incidental to production. The new §§ 32.33, "Requirements for license of items containing byproduct material incidental to production and transfer of ownership or possession," 32.34, "Items containing byproduct material incidental to production safety criteria," and 32.35, "Conditions of licenses issued under § 32.33: Quality control, labeling, and reports of transfer," would include specific requirements for obtaining this license. This rulemaking also makes conforming changes to § 32.303, "Criminal penalties" to account for these sections.

A. JUSTIFICATION

1. Need for the Collection of Information

This information is necessary to determine the kind of products and materials into which byproduct material will be incorporated and provides the NRC with information concerning those persons who would produce and transfer the products or materials. The information is also needed so that the NRC may determine that the product has an adequate margin of safety. The NRC determines that use of the product or materials, and performance of any operations associated with the product or materials, can be safely performed by individuals untrained in radiological protection.

The records and reports described in this information collection are necessary for products distributed to persons exempt from licensing so that the NRC will be aware of what types and quantities of byproduct materials are introduced into materials that could enter the environment and/or be used by persons not subject to any regulatory requirements. The NRC must be aware of the location of devices and products in the

possession of general licensees and distribution trends of exempt products. These reports are the only means the Commission has to keep track of the location of the generally licensed radioactive devices and perform trend analysis of exempt distribution products.

The labeling requirements are needed to inform the person exempt from the regulations that the product contains radioactive material and so consumers may then make a choice as to whether they want a radioactive or nonradioactive product in their home if a choice is available. Also, in the event of a recall or problem with the item, the public and the NRC can readily determine who the initial distributor is from all the non-licensed distributors in the marketing chain. Labeling is also necessary so that individuals who handle these packages will know they contain radioactive material and in the event of an accident will know the type of isotope involved and the amount. In addition, appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material will be available to the user.

Each recordkeeping, reporting, and third-party disclosure requirement in 10 CFR Part 32 affected by the proposed rule is described below.

10 CFR 32.33(a)(1) and (a)(2) would require the licensee to satisfy the general requirements specified in 10 CFR 30.33 and submit 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.

10 CFR 32.34 would require the licensee to demonstrate that the item is designed and will be manufactured to meet specific safety criteria.

10 CFR 32.35(b) would require labeling or marking of each point-of-sale package.

10 CFR 32.35(c) would require the licensee to maintain records of all transfers and file a report with a description or identification of the type of each item and the model number(s), and the number of units of each type of product transferred during the reporting period by model number.

2. Agency Use and Practical Utility of Information

The records that 10 CFR Part 32 requires the licensees to maintain will be reviewed during inspections to evaluate compliance with NRC radiation safety requirements for manufacture or transfer of certain items containing byproduct material incidental to production.

The records of transfer of byproduct material incidental to production will be reviewed by the NRC inspectors to determine compliance with regulatory requirements, and the reports are used by the NRC to keep track of the type and quantity of products and the amount of radioactivity that has been introduced into materials that could enter the environment and/or have been distributed to persons exempt from licensing requirements.

The records needed to generate the transfer reports must be kept long enough for the NRC to receive and process the information, identify and resolve any discrepancies, or require any needed clarifications.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them.

The NRC has issued [Guidance for Electronic Submissions to the NRC](#), which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" web page, by Optical Storage Media (e.g., CD-ROM, DVD), by facsimile or by email. It is estimated that approximately **80%** of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

Most items containing byproduct material incidental to production (ICBMIP) end users are small businesses and are exempt from any reporting, recordkeeping, or accounting and control requirements. To the best of our knowledge, approximately 10 percent of ICBMIP licensees (manufacturers and distributors) are small businesses.

6. Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

If the information is not collected, the NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the manufacture or transfer of certain items containing byproduct material incidental to production. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.5(f), Section 32.35(b) requires that the licensee commit to labeling requirements for the life of the product. This is to ensure that the labels are maintained on the product as originally stated in the application and they will be inspected periodically by NRC.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package has been published in the *Federal Register*. Any comments related

to information collection requirements in the proposed rule will be addressed at the final rule stage.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no information normally considered confidential is requested except for proprietary information. Some proprietary information may be included when necessary to provide an adequate response. An application to withhold such information from public disclosure may be made in accordance with the provisions of § 2.390.

11. Justification for Sensitive Questions

This regulation does not request sensitive information.

12. Estimated Burden and Burden Hour Cost

This supporting statement provides an estimate of the reporting, recordkeeping, and third-party disclosure burden for 10 CFR Part 32 ICBMIP licensees for the 3-year period following the effective date of the rule (assumed to be 2023-2026). The proposed rule would apply to persons who submit an application for an initial ICBMIP distribution license, if the application is submitted after the effective date of this rule.

The burden estimates are based on NRC staff knowledge of the industry to make projections for the 3-year period following the effective date of the rule. Based on that staff knowledge of the industry, the NRC anticipates approximately nine applications annually for an initial ICBMIP distribution license for the 3-year period following the effective date of the rule. The \$288 hourly rate used in the burden estimates is based on the NRC's fee for hourly rates as noted in 10 CFR 170.20, "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2021 (86 FR 32146; June 16, 2021).

The burden estimates are based on the numbers of applicants for an initial ICBMIP distribution license that are affected by applicable regulations and estimates of the time necessary to comply with these regulations. The cost to licensees and applicants is calculated at a rate of \$288 per hour for professional staff who prepare the technical information submitted in response to the additional cost for the information collection requirements.

NRC Licensees:

The total annual burden is estimated to be 630 hours per year for the nine estimated NRC licensees that applied for initial ICBMIP distribution licenses that are expected to report and keep records annually. This estimate is the amount of time an applicant would take to submit a license application to the NRC or the amount of time a licensee

would take to submit a license renewal to the NRC after an initial 15-year licensing term. The total cost for the NRC licensees would be \$181,440 (630 hours x \$288/hour).

In addition, licensees are required to complete an annual report (1 hour per year per licensee). It is estimated that there will be an average of 18 responses per year, totaling an annual average cost of \$5,184 (18 hours x \$288/hour).

The total annual third-party disclosure burden is estimated to be 75 hours per year for licensees across the industry. This burden is related to labeling point of sale products. It is estimated that there will be an average of 900 responses per year, totaling an annual average cost of \$21,600 (833 hours x \$288/hour).

Section/Form	Description	Annualized Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response (Hrs)	Total Annual Burden (Hrs)	Cost @ \$288/Hr
<u>REPORTING</u>							
10 CFR 32.33(a)(1) – (a)(2)	Application: Design Requirements	9	1	9	30	270	\$77,760
10 CFR 32.34	Application: Demonstration of Safety Criteria	9	1	9	30	270	\$77,760
10 CFR 32.35(c)	Material Transfer Reports	9	1	9	10	90	\$25,920
Section/Form	Description	Annualized Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hours per Response	Total Annual Burden (Hours)	Cost @ \$288/Hour
<u>RECORDKEEPING</u>							
10 CFR 32.35(c)	Records and material transfer reports	9	1	9	1	9	\$5,184
Section/Form	Description	Annualized Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hours per Response	Total Annual Burden (Hours)	Cost @ \$288/Hour
<u>Third-Party Disclosure</u>							
10 CFR 32.35(b)	Labelling point of sale package	9	100	900	0.083	75	\$21,600

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the recordkeeping storage

cost has been estimated to be equal to .0004 percent of the recordkeeping burden. Therefore, the additional recordkeeping storage savings for 10 CFR Part 32 is estimated to be \$2.08 (18 recordkeeping hours x \$288 x 0.0004).

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses. The NRC estimates that it will take the NRC 60 hours to review each ICBMIP distribution license application or renewal and 10 hours to review each material transfer report.

The total annual burden is estimated to be 630 hours per year for the nine estimated license applications or renewals. The total cost for the NRC would be \$181,440 (630 hours x \$288/hour).

15. Reasons for Change in Burden or Cost

This rulemaking creates a new class exemption for ICBMIP and requires initial distributors to obtain an initial exempt distribution license. Current irradiated gemstone licensees will have a 40-hour reduction in burden per license application or renewal, because each irradiated gemstone applicant or licensee will only need to submit dose-based criteria instead of both dose-based and concentration-based criteria.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The recordkeeping and reporting requirements for this information collection are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Furthermore, amending the regulatory text of the CFR to display information that, in an annual publication could become obsolete, would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.