

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

PROPOSED RULE

10 CFR PART 30

3150-0017

Description of the Information Collection

The regulatory requirements in Title 10 of the *Code of Federal Regulations* (CFR) Part 30 identify the information required by the U.S. Nuclear Regulatory Commission (NRC) for an individual or other entity to be licensed to possess, use, or distribute byproduct material. These requirements specify that the individual or other entity must submit an application that contains the information that will permit the NRC to determine whether the applicant has training, experience, equipment, facilities, and procedures for the use and distribution of byproduct material that are adequate to protect public health and safety. There is no required template for applying for a license; however, the NRC published a series of technical reports (NUREG-1556 series, "Consolidated Guidance About Materials Licenses")¹, that may assist applicants in developing their submissions. An applicant may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in 10 CFR 30.6, "Communications."² The information collections related to NRC Form 313 are captured under OMB No. 3150-0120.

The NRC is proposing to amend its regulations in 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 instead is present as a result of production. This new section would only apply to processes that unavoidably result in the incidental addition of byproduct material to the final product. 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 32.33.

A. JUSTIFICATION

1. Need for the Collection of Information

The commitments made by the applicant in the application, as well as the information provided as part of the application package, are reviewed by the NRC staff to determine if the applicant has training, experience, equipment, facilities, and procedures for the use and distribution of byproduct material that are adequate to protect public health and

¹ NUREG-1556 is available on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>.

² NRC Form 313 is available on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf> and is approved by OMB under clearance number 3150-0120.

safety. In addition, the information is needed by NRC staff to prepare the license. The license will include the quantity and type of byproduct material that will be used, the form of the byproduct material, and will identify the types of activities that the licensee will be authorized to perform. When issued, the licenses for possession, use, and distribution will include conditions in the license or "license conditions." License conditions are specific to the licensee as dictated by that licensee's particular facilities, equipment, or type of use of material. Some license conditions are applied to most licensees, and some to certain types of licensees based on the category of use of byproduct material (e.g., radiography, medical use for humans, etc.). These are known as "established standard license conditions." Established standard license conditions are utilized by NRC and the Agreement States to ensure that provisions for protection of public health and safety are imposed consistently among licensees. They are used in conjunction with the requirements in Chapter I of Title 10 of the *Code of Federal Regulations* (10 CFR) that the licensee commits to when applying for a license. A selection of commonly used standard license conditions that contain reporting or recordkeeping requirements is described in detail under the description of 10 CFR 30.34(e)(4).

The new technology/uses standard license conditions are imposed on individual licensees and groups of licensees engaged in new materials uses or the use of new technologies in established materials uses. New technology/uses standard license conditions will be utilized by the NRC to ensure that provisions for protection of public health and safety are imposed consistently among licensees. New technology/uses standard license conditions, which contain reporting or recordkeeping requirements similar to those in the regulations and established license conditions, are described in greater detail in 10 CFR 30.34(e)(4).

After the NRC issues a license, the NRC will ensure that licensees are performing health and safety inspections. Inspections include review of the licensee records related to distribution of byproduct material. These records are needed to ensure that the licensee is using the byproduct material safely and in accordance with applicable NRC regulations. It is the licensee's responsibility to ensure it continues to maintain the commitments it made in its application to ensure it fulfills the regulatory requirements in 10 CFR Part 30.

2. Agency Use and Practical Utility of Information

The records that 10 CFR Part 30 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for possession and use of byproduct material.

The records of receipt, transfer, and disposal of byproduct material are reviewed by the NRC inspectors to determine that licensees have confined their possession and use of byproduct material to the locations, purposes, receipt, and quantities authorized in their licenses. Reports of significant safety events and theft of radioactive material are used by the agency in evaluating the protective actions required to avoid exposures to radiation or releases of radioactive materials that could exceed regulatory limits and, therefore, impact public health and safety, the common defense and security, and the environment.

Bankruptcy reports, decommissioning plans, decommissioning funding plans, and certifications of financial assurance for decommissioning are reviewed by the NRC to

ensure that a licensee has adequate procedures and funds for any necessary cleanup efforts before a licensee's responsibility for byproduct materials is terminated and the site is released for unrestricted use.

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 percent** 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 the 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 possession, use, or transfer of byproduct material.

The required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and each individual license amendment is submitted only once. Applications for renewal of licenses are usually submitted every 15 years. Information submitted in previous applications may be referenced without being resubmitted. 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

There are no circumstances which vary from OMB guidelines.

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 and recordkeeping burden for 10 CFR Part 30 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 ICBMIP possession 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 ICBMIP possession license for the 3-year period following the effective date of the rule.

The burden estimates are based on the numbers of applicants for an ICBMIP possession 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.

Agreement State Licensees:

Under this rulemaking, the NRC will be issuing all exempt distribution licenses; however, for those licensees located in an Agreement State, the Agreement State would issue the

associated 10 CFR Part 30 possession license. The NRC estimates that all licensees will be located in Agreement States.

The total annual reporting burden is estimated to be 540 hours per year for approximately nine Agreement State licensees that applied for possession licenses. The total cost for the Agreement State licensees is expected to be \$155,520 (540 hours x \$288/hour).

The total annual recordkeeping burden is estimated to be 45 hours per year for approximately nine Agreement State licensees for a total cost of \$12,960 (45 hours x \$288/hour).

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).

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>REPORTING</u>							
10 CFR 30.33	Possession licenses	9	1	9	60	540	\$155,520

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 30.33	Possession licenses	9	1	9	5	45	\$12,960

13. Estimate of Other Additional Costs

The 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 0.0004 percent of the recordkeeping burden. Therefore, the additional recordkeeping storage savings for 10 CFR Part 30 is estimated to be \$5.18 (45 recordkeeping hours x \$288 x 0.0004).

14. Estimated Annualized Cost to the Federal Government

There are no estimated annualized cost to the Federal Government, because the burden for reviewing possession licensees will be experienced by the Agreement States, not the Federal Government.

15. Reasons for Change in Burden or Cost

There is no change in burden or cost.

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.