

**OMB SUPPORTING STATEMENT  
FOR PROPOSED RULE  
10 CFR PART 40  
(3150-0020)**

**AMENDMENT TO 10 CFR PART 40**

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations in 10 CFR Part 40 to require that licensees obtain NRC approval before transferring less than 0.05 percent source material to persons exempt under § 40.13(a). The current regulations, §§ 40.51(b)(3) and (b)(4), do not specifically require an NRC licensee (either general or specific) to obtain NRC approval before transferring source material to persons exempt from licensing requirements under § 40.13(a) or equivalent Agreement State regulations. However, NRC is concerned that transfer of this material could pose health and safety concerns in certain circumstances.

Section 40.51(b) allows licensees to transfer source material to any person exempt under §40.13(a) from the licensing requirements of the Atomic Energy Act of 1954, as amended, (AEA) and Part 40, as long as the source material content is by weight less than 0.05 percent of the material as a whole. Because § 40.13(a) exempts persons receiving unimportant quantities from AEA licensing, these persons cannot be held to any of the requirements for licensing in Part 40, or the requirements for radiological protection, waste disposal, or license termination and decommissioning in Part 20. Once the material is transferred out of the licensee's control, NRC can no longer place restrictions on the use of the material to reduce potential doses, absent an NRC order based on health and safety.

Under the proposed rule, NRC would amend § 40.51 by requiring licensees to obtain written NRC approval before transferring less than 0.05 percent source material derived from specifically licensed material to persons exempt under § 40.13(a). Although these evaluations would generally be done on a case-by-case basis, NRC staff would expect to approve transfers for direct disposal in an appropriate facility if the individual radiation dose is not expected to exceed 0.25 mSv/yr (25 mrem/yr) and would inform the Commission in cases where the individual dose is expected to exceed 0.25 mSv/yr (25 mrem/yr).

However, NRC is concerned that, in some instances, exposure to large quantities of less than 0.05 percent source material could result in annual doses to the public in excess of NRC's public dose limit from licensed activities of 1 mSv/yr (100 mrem/yr), as contained in §20.1301(a)(1). NRC is also concerned that the current regulations at §40.51 do not provide explicit requirements for licensees to seek NRC approval in transferring the material to exempt persons. The regulations do not provide NRC with an explicit regulatory basis for denying such transfers provided that the licensee making such transfers is complying with the regulations in Part 40 as they are currently written. NRC believes that, under the current regulations, certain licensees may not be notifying NRC prior to transfer of their material to exempt persons.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

Section 40.51(e) would require licensees to obtain written approval from the NRC before transferring any source material derived from its specifically licensed material to persons exempt under § 40.13(a) or equivalent Agreement State regulations. A licensee seeking NRC approval to transfer such material must submit a dose assessment with information containing the estimated annual total effective dose equivalent to a member of the public that would result from the transfer, and the parameters and assumptions used in the assessment.

The proposed rule would establish explicit procedures for licensees to obtain NRC approval before transferring less than 0.05 percent source material to persons exempt under §40.13(a) with the addition of Section 40.51(e). NRC believes that, through review/approval of the requests, NRC would ensure that the radiation level of the transferred material is compatible with its intended use or permanent disposal.

2. Agency Use of the Information

Through review/approval of requests to transfer source material to persons exempt under §40.13(a), NRC would ensure that the radiation level of the transferred material is compatible with its intended use or permanent disposal. In making its determination regarding transfers of source material to persons exempt under §40.13(a), these evaluations would generally be done on a case-by-case basis. However, NRC staff would expect to approve transfers for direct disposal in an appropriate facility if the individual radiation dose is not expected to exceed 0.25 mSv/yr (25 mrem/yr) and would inform the Commission in cases where the individual dose is expected to exceed 0.25 mSv/yr (25 mrem/yr).

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. Indeed, use of automated information technology is encouraged and, for certain nuclear material transaction data, automated submission is required. Licensees may use electronic information systems to prepare and submit their requests, as appropriate.

4. Effort to Identify Duplication and Use Similar Information

The proposed requirements at §40.51 for licensees to submit a request for transfer of source material to persons exempt under §40.13(a) would not duplicate information currently collected by the NRC. The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found. There is no similar information available to the NRC.

5. Effort to Reduce Small Business Burden

Some of the licensees who use source and byproduct material are small businesses. However, since the health and safety consequences of improper handling or use of radioactive source and byproduct material are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

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

If the NRC does not require licensees to formally request approval to transfer less than 0.05 percent source material derived from specifically licensed material to persons exempt under §40.13(a), NRC will have no way to evaluate whether such transfers pose unacceptable risks to public health or the environment. It is possible under the existing regulations, for example, for NRC licensees to transfer source material to facilities that do not have an NRC license and that are ill-equipped to handle or dispose of the material in a safe manner. NRC believes it is necessary to amend the Federal program to ensure that transfers of source material to persons exempt under §40.13(a) are compatible with their intended use or permanent disposal.

As proposed, licensees seeking to transfer source material to persons exempt under §40.13(a) must submit a *one-time* request to the NRC. These proposed procedures reflect the minimum frequency deemed necessary by NRC to assure that licensees inform NRC of their intended transfers and conduct these transfers in a manner that is protective of public health and the environment.

7. Circumstances Which Justify Variation from OMB Guidelines

The regulations being proposed at §40.51 are consistent with OMB guidelines.

8. Consultations Outside the NRC

The opportunity for public comment has been published in the Federal Register.

9. Payment or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

To the extent information submitted by licensees is business confidential, procedures are in place to protect the information from improper disclosure.

11. Justification for Sensitive Questions

None.

12. Estimated Burden and Burden Hour Cost

Under the proposed rule, NRC would amend §40.51 by requiring written NRC approval before a licensee may transfer less than 0.05 percent source material derived from specifically licensed material to persons exempt under §40.13(a). Based on the NRC’s Licensing Tracking System (LTS) database, NRC estimates that there are approximately 114 Part 40 licensees, of which about 75 possess source material that may be transferred to exempt persons. Based on past experiences, annually about 5 licensees submit requests to transfer source material to persons exempt under §40.13(a). In addition, NRC estimates that about 2 licensees will be required to submit additional information to NRC for its use in reviewing the transfer request. Below is a description of the burden hours and cost that these licensee transferors would incur in preparing and submitting requests to NRC under the proposed rule.

**Table 1**  
**Total Annual Burden Hours and Cost to Licensees for Preparing and Submitting Requests to NRC under Proposed Rule for Part 40**

Section	No. of Respondents	Annual Responses per Respondent	Total Annual Responses	Burden Hours per Response	Total Annual Burden Hours
§ 40.51(e) original submittal	5	1	5	50	250
§ 40.51(e) follow up responses, as necessary	2	1	2	25	50
Total:	5		7		300

**TOTAL LICENSEE COST\* from this request**

**\$45,600**

**(\$38,000 for original responses + \$7,600 for follow up responses)**

\*Cost to licensees is calculated at a rate of \$152 per hour.

NRC estimates that a licensee will take approximately 50 hours to prepare and submit a request to NRC demonstrating that the proposed transfer meets NRC’s dose limit criteria and otherwise protective of public health and the environment. In addition, NRC expects that licensees who may be requested to submit additional (i.e., supplementary) information to NRC in making an adequate demonstration is expected to take approximately 25 hours to prepare and submit the additional demonstration. These estimates are based on the number of actions received in the past 3 years and the review provided by the NRC technical contractor’s technical knowledge and experience in handling various types of transfers.

In total, NRC estimates that the annual burden to licensees for preparing and submitting requests to the NRC would be 300 hours per year. The total annual cost to the licensees would be \$45,600 per year.

13. Estimate of Other Additional Costs

Licensees would not incur any other costs (i.e., capital or operation and maintenance costs) under the proposed rule.

14. Estimated Annualized Cost to the Federal Government

Under the proposed rule, NRC would review and approve or deny (i.e., process) requests from licensees to transfer less than 0.05 percent source material derived from specifically licensed material to persons exempt under § 40.13(a). Below is a description of the burden hours and cost to NRC in processing requests under the proposed rule. The details are shown in Table 2.

NRC estimates that the burden for NRC staff to review 5 requests from licensees to transfer source material to persons exempt under § 40.13(a), is about 10 hours to process each request. In addition, NRC expects that approximately 2 licensees may be requested to submit additional information to NRC staff and require about 5 hours for the staff to process each submittal. These estimates are based on the number of actions received in the past 3 years and the review provided by the NRC technical contractor’s technical knowledge and experience in handling various types of transfers.

In total, NRC estimates that the annual burden to NRC for processing requests would be 60 hours per year. The total annual cost to the NRC to process requests would be \$9,120 per year.

**Table 2  
Total Annual Burden Hours and Cost to NRC for Processing  
Licensees’ Requests under Proposed Rule**

<b>Proposed Activities (\$40.51)</b>	<b>Annual Number of Licensee Responses</b>	<b>NRC Staff Hours Per Response</b>	<b>Total NRC Burden Hours</b>	<b>Total Costs at \$152/hr</b>
Process request	5	10	50	\$7,600
Process additional demonstration, if requested by NRC	2	5	10	\$1,520
<b>Total</b>	<b>7</b>	<b>15</b>	<b>60</b>	<b>\$9,120</b>

15. Reasons for Change in Burden

Under the current regulations, certain licensees may not be notifying NRC prior to transfer of their source material to persons exempt under § 40.13(a). The proposed rule would establish explicit procedures for licensees to obtain NRC

approval before transferring less than 0.05 percent source material derived from specifically licensed material to persons exempt under § 40.13(a). Thus, under the proposed rule, licensees' burden would increase by the number of hours needed to prepare and submit their requests (300 hours per year). NRC believes this incremental burden is justified because the requested information would assist the NRC in ensuring that the radiation level of the transferred material is compatible with the established level for the intended use or permanent disposal.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The proposed rule would be inserted in the regulations at § 40.51. Amending the Code of Federal Regulations to display information that could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

Not applicable.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The collection of information will not employ statistical methods.