# Regulatory Analysis of Amendment to 10 CFR Part 40

Draft Report

**U.S. Nuclear Regulatory Commission**
Office of Nuclear Material Safety and Safeguards

August 2002

# ABSTRACT

This document presents NRC's Regulatory Analysis of a proposed rulemaking that would amend 10 CFR 40.51 by requiring written NRC approval before transferring source material that is less than 0.05 percent by weight to persons exempt under section 40.13(a) or equivalent Agreement State regulations. Under the current regulations at 10 CFR 40.51 and 40.13(a), a licensee may transfer source material to persons exempt from the licensing requirements of the Atomic Energy Act, as amended, (AEA) and 10 CFR Part 40, as long as the source material content is by weight less than one-twentieth of one percent (0.05 percent) of the mixture, compound, solution, or alloy. However, as explained in this document, NRC is concerned that transfer of these concentrations of source material could pose health and safety concerns in certain circumstances.

For the two regulatory options being considered for the proposed rulemaking (i.e., the no-action option and the proposed regulatory alternative), the Regulatory Analysis evaluates the relative values (benefits) and impacts (costs) of the rulemaking.

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# 1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 10 CFR 40.51 by requiring licensees to obtain NRC approval before transferring source material that is less than 0.05 percent by weight to persons exempt under section 40.13(a) or equivalent Agreement State regulations. Under the current regulations at 10 CFR 40.51(b)(3), a licensee may transfer source material to persons exempt from the licensing requirements of the Atomic Energy Act, as amended, (AEA) and 10 CFR Part 40, as long as the source material content is by weight less than one-twentieth of one percent (0.05 percent) of the mixture, compound, solution, or alloy. 10 CFR 40.13(a) provides an exemption from NRC licensing requirements for persons receiving this material. However, as explained further below, NRC is concerned that transfer of these concentrations of source material could pose health and safety concerns in certain circumstances. This document presents a Regulatory Analysis of the regulatory options being considered by NRC.[1]

## 1.1 Statement of Problem and Objectives of Rulemaking

10 CFR 40.51(b) allows licensees to transfer source material to any person exempt from the licensing requirements of the 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 10 CFR 40.13(a) exempts persons receiving material containing less than 0.05 percent by weight of source material 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 10 CFR 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.

NRC is concerned that, in certain cases, transfer of low levels of source material to exempt persons may be inconsistent with the radionuclide concentrations and dose limits allowed for releasing decommissioned sites for unrestricted use. The 0.05 percent, by weight, source material limit translates to about 12.56 kBq U/kg (339 pCi U/g) for natural uranium or 4.30 kBq Th/kg (116 pCi Th/g) for natural thorium. NRC believes that, in some instances, exposure to unimportant quantities of 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 10 CFR 20.1301(a)(1).

NRC is further concerned that the current regulations at 10 CFR 40.51 do not provide explicit procedures for licensees to seek NRC approval in transferring the material to exempt persons. The regulations also do not provide NRC with an explicit regulatory basis for denying

[1] Discussion of the proposed rule in this document reflects changes that NRC intends to implement at the Federal level. The discussion does not account for the possibility that certain Agreement State programs may require modification to be consistent with the Federal program. In particular, any required changes could be done during the Agreement State's next revision of their equivalent to 10 CFR Part 40 to minimize the expenditure of resources.

such transfers provided that the licensee making such transfers is complying with the regulations in Part 40 as they are currently written. Currently, the NRC may stop a licensee from making such a transfer only when the transfer may result in a potentially hazardous condition that could affect public health and safety and the environment.

For these reasons, NRC is proposing to amend section 40.51 to require NRC approval before licensees may transfer less than 0.05 percent source material derived from specifically licensed material to persons exempt under section 40.13(a) or equivalent Agreement State regulations. 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).

As part of this proposed rule change to section 40.51, the Commission is also proposing to amend section 40.13(a) to include “disposes” in the list of exempt activities. This addition is merely a clarification of the existing activities covered by this exemption and is not expected to result in any additional regulatory costs or burden to licensees or the public. As such, this proposed amendment to section 40.13(a) is not discussed further.

## 1.2 Description of Current Requirements

10 CFR 40.51(b)(3) currently provides that Part 40 licensees may transfer source or byproduct material to any person exempt from the licensing requirements of the AEA and regulations in 10 CFR Part 40, to the extent permitted under such exemption. 10 CFR 40.51(b)(4) provides that Part 40 licensees may transfer source or byproduct material to any person in an Agreement State subject to the jurisdiction of that State who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemptions. Persons receiving material under 10 CFR 40.51(b)(3) or (4) include persons exempt from AEA licensing under 10 CFR 40.13(a).

Section 40.13(a) provides that any person is exempt from the licensing requirements of the AEA and Part 40 “to the extent that such person receives, possesses, uses, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which source material is by weight less than one-twentieth of one percent (0.05 percent) of the mixture, compound, solution, or alloy” (i.e., unimportant quantities of source material).

# 2. Identification of Regulatory Options

This Regulatory Analysis evaluates the proposed rule, in addition to a no-action alternative. The following paragraphs describe these two regulatory options.

## 2.1 Option 1: No Action

Under the no-action option, NRC would not modify the current regulations regarding the transfer of source material, as provided in 10 CFR 40.51.

## 2.2 Option 2: Proposed Rule

Under the proposed rule, NRC would amend 10 CFR 40.51 by requiring written NRC approval before a licensee may transfer unimportant quantities of source material to persons exempt under 10 CFR 40.13(a) or equivalent Agreement State regulations. In making its determination regarding transfers of unimportant quantities to persons exempt under section 40.13(a) or equivalent Agreement State regulations, the NRC staff would expect to approve transfers under this provision, for the purpose of direct disposal in an appropriate facility, if the individual radiation dose is not expected to exceed 0.25 mSv/yr (25 mrem/yr). The Commission would be informed in cases where the individual dose is expected to exceed 0.25 mSv/yr (25 mrem/yr). For situations other than direct disposal in an appropriate facility, NRC will continue to review the request on a case-by-case basis.

# 3. Analysis of Values and Impacts

This section examines the values and impacts expected to result from NRC's proposed rule, and is presented in three subsections. Subsection 3.1 identifies attributes that are and are not expected to be affected by the proposed rule. Subsection 3.2 describes the cost model used to quantify cost impacts under the options. Finally, Subsection 3.3 summarizes the proposal's values and impacts.

## 3.1 Identification of Affected Attributes

This section identifies and describes the factors within the public and private sectors that the proposed regulatory alternative (discussed in Section 2) is expected to affect. These factors were classified as "attributes," using the list of potential attributes provided by NRC in Chapter 5 of its *Regulatory Analysis Technical Evaluation Handbook*.[2] Each attribute listed in Chapter 5 was evaluated, and the basis for selecting those attributes expected to be affected by the proposed rule is presented in the balance of this section.

### 3.1.1 Affected Attributes

The proposed regulatory alternative is expected to affect the following attributes:

- Public and Occupational Health (Accident and Routine) -- Recent assessments of potential health and safety risks suggest that in certain cases source material below the exempt concentration limit could result in radiation exposures of the public and workers exceeding 1 mSv/yr (100 mrem/yr). The report prepared by Oak Ridge National Laboratory (ORNL) for NRC entitled *Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials* indicates that the annual average effective dose equivalent to an industrial worker handling bulk zircon products could potentially range from 2.5 mSv (250 mrem) to 35 mSv

[2] *Regulatory Analysis Technical Evaluation Handbook, Final Report*, NUREG/BR-0184, Office of Nuclear Regulatory Research, January 1997.

(3,500 mrem).[3,4] The proposed rule would address public and occupational exposure concerns by requiring transfers of source material to persons exempt from the regulations under section 40.13(a) or equivalent Agreement State regulations to meet acceptable radiation dose limits.

- Offsite Property -- Under the current regulations, licensees could transfer source material to facilities ill-equipped to handle or dispose of the material. It is possible, for example, for low concentrations of source material exceeding NRC dose limits to be transferred under the current 10 CFR 40.51 to a non-licensed facility for permanent disposal. These facilities may not be equipped to monitor or otherwise protect against radiation hazards. Under the proposed rule, NRC would ensure that the radiation level of the transferred material is consistent with its intended use or permanent disposal.

- Industry Implementation -- NRC expects that the rule could affect the behavior of licensees and exempt persons involved in the transfer of low concentrations of source material. In contrast with the existing regulations, the proposed rule would make it clear that NRC approval is required prior to transfer of the material. Thus, under the proposal, a recipient of the transferred material would be more likely to require documentation of NRC's approval from the transferor prior to accepting the material.

- Industry Operation -- Relative to the no-action option, the proposed regulatory changes would result in increased industry operation costs. Under the proposed rule, licensees would incur costs for preparing and submitting a request to NRC before transferring source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations. In addition, if NRC does not approve the request, the licensee would not be able to transfer the material to exempt persons as proposed. Rather, the material would remain licensed, potentially increasing the licensee's operation costs.

- NRC Implementation -- Unlike the no-action option, the proposed regulatory changes in Option 2 might result in NRC implementation costs. Specifically, NRC might incur implementation costs to revise guidance documents and, where applicable, develop new guidance pertaining to unimportant quantities.

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[3] *Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials*, NUREG-1717, June 2001.

[4] The dose estimates in the report are based on a dose calculation methodology reflected in Part 20, but use of the more recent guidance of the International Commission on Radiological Protection, ICRP Publication 72, 1996, would lower the dose estimates for inhalation significantly. However, regardless of the question of models for the estimation of internal doses, NRC believes that external exposures may exceed 1 mSv/yr (100 mrem/yr), in certain situations, when large quantities of material are handled.

- NRC Operation -- In comparison with the no-action option, the proposed regulatory changes would result in increased NRC operation costs. Under the proposed rule, NRC would have to review and process licensee requests for the transfer of source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations. At the present time, certain licensee transferors may not notify NRC of their transfer.

- Other Government -- The proposed regulatory changes in Option 2 could increase implementation and operation costs of the government agencies licensed under Part 40 (e.g., Army installations), as described under "Industry Operation" above. The proposed regulatory option also could affect implementation and operation costs of Agreement States if they must administer parallel requirements.

- Improvements in Knowledge -- Under the current regulations, it is possible for licensees to interpret the 10 CFR 40.51 and 40.13(a) requirements as requiring no NRC approval prior to transferring low concentrations of source material. The proposed rule would clarify that licensees must obtain approval from the NRC prior to transfer. Because of this, NRC expects the proposed rule to increase the number of requests submitted to NRC, and hence, improve NRC's knowledge of where and how unimportant quantities of source material are being used or disposed.

- Regulatory Efficiency -- The proposed regulatory changes in Option 2 would clarify the procedures for transferring source material under 10 CFR 40.51 and 40.13(a). NRC expects the proposed clarifications to result in greater efficiency for licensees that currently have not pursued the transfer exemption because of uncertainty about the procedures for transferring the material. NRC also expects the rule to provide direction to Agreement States in dealing with transfer issues.

- Environmental Considerations -- The proposed rule would ensure that the radiation levels of transferred source material are consistent with its intended use or permanent disposal. Under the current regulations, licensees may transfer low concentrations of source material to an unlicensed disposal facility ill-equipped to monitor (e.g., groundwater) or control against radiation hazards. Under the proposed rule, NRC staff would generally expect to approve transfers for the purpose of direct disposal in an appropriate facility only if the estimated dose to a member of the general public is unlikely to exceed a dose limit of 0.25 mSv/yr (25 mrem/yr). Doses above 1 mSv/yr (100 mrem/yr) would only be permitted in unique circumstances after a thorough review of the specific factors presented in the request and after Commission review.

### 3.1.2 Unaffected Attributes

The proposed regulatory alternative is not expected to affect the following attributes:

- On-site Property -- The proposed regulatory option is not expected to have any effects on on-site property. That is, the 10 CFR 40.13(a) exemption applies only when the source material is transferred off of the licensee's property. While it is on the property, it is licensed material subject to the Part 40 regulations.

- General Public -- The proposed action is not expected to have any effects on the general public, except for enhanced protection against health hazards (see "Public and Occupational Health").

- Antitrust Considerations -- The proposed action is not expected to have any antitrust effects.

- Safeguards and Security Considerations -- The proposed action is not expected to have any effects on safeguards and security considerations.

## 3.2 Analysis of Cost Impacts under Options 1 and 2

This section describes the methodology, analysis, and results of NRC's analysis of the compliance costs under the no-action option (Option 1) and proposed rule option (Option 2). Note that NRC's cost analysis is based on a "worst-case" assumption that the source material would be transferred under 10 CFR 40.51 for permanent disposal. NRC acknowledges that other types of transfer (e.g., transfer for reuse) also occur; however, NRC believes that licensees transferring their waste for disposal could face relatively high compliance costs under the proposed rule.

### 3.2.1 Methodology

NRC has developed a cost model to estimate compliance costs under the no-action option and the proposed regulatory option. The cost model uses the following inputs to compute costs to industry and NRC under the no action and proposed rule options: (1) number of licensees transferring the source material; (2) costs for licensees to prepare and submit a request to transfer the source material (for proposed rule only); (3) transportation and disposal costs; and (4) costs to NRC for reviewing and processing requests (proposed rule only). The following paragraphs describe these model inputs and the methodology for computing compliance costs under both options.

**No Action Option**

Under the no-action option, NRC would not modify the current regulations regarding the transfer of less than 0.05 percent source material, as provided in 10 CFR 40.51.

*(1) Universe Assumptions*

Based on the NRC's Licensing Tracking System (LTS) database,[5] NRC estimates that there are approximately 114 licensees under the Part 40 licensing program. NRC notes that certain types of Part 40 licensees may be more likely than others to transfer low-concentrations of source material, based on their operations and types of materials. Refer to Appendix A of this document for a description of Part 40 licensees. The appendix also identifies licensees that, based on NRC's judgment, are more likely to possess source material that may be transferred to persons exempt under section 40.13(a) or equivalent Agreement State regulations.

Of the 114 licensees under the Part 40 licensing program, NRC predicts that, each year, approximately three to six licensees transfer less than 0.05 percent source material (e.g., contaminated soil, construction debris, baghouse dust, slag-like material) to persons exempt under section 40.13(a) or equivalent Agreement State regulations by using section 40.51.[6] Given the range of licensees expected to transfer material, the model computes costs for two separate scenarios, i.e., a Low Scenario and a High Scenario. The Low Scenario assumes three licensee transferees per year and the High Scenario assumes six licensee transferees per year.

Further, the model computes licensees' compliance costs based on the tonnage of material being transferred. That is, the model multiplies the total tonnage of the licensees' transferred material by the costs for transportation and disposal. Because NRC cannot predict the exact tonnage of licensees' transferred material, the model includes a range of possible tonnages.[7]

Table 1 shows the annual number of transferors and the estimated tons of transferred material under the Low and High Scenarios. The table shows that, in the Low Scenario, one licensee each is expected to transfer 100,000 $ft^3$, 500,000 $ft^3$, and 2,000,000 $ft^3$ to exempt persons for disposal (97,500 tons) annually. The table shows that, in the High Scenario, two licensees each are expected to transfer 100,000 $ft^3$, 500,000 $ft^3$, and 2,000,000 $ft^3$ to exempt persons for disposal (195,000 tons) annually.

[5] In this search, NRC obtained information based on the "040 docket" (i.e., licenses issued under 10 CFR Part 40).

[6] The estimate of three to six licensee transferors per year is based on NRC's experience in dealing with transfer issues under 10 CFR 40.51.

[7] Tonnages in the model are based on NRC's review of previous correspondence and other assessments relating to unimportant quantities of source material.

**Table 1**
**Cost Model Inputs on Number of Affected Licensees per Year**

| Volume (and Tonnage) of Waste Transferred for Permanent Disposal Per Licensee [a] | Number of Licensees Disposing of Unimportant Quantities Each Year | |
|---|---|---|
| | Low Scenario | High Scenario |
| 100,000 $ft^3$ (3,750 tons) | 1 | 2 |
| 500,000 $ft^3$ (18,750 tons) | 1 | 2 |
| 2,000,000 $ft^3$ (75,000 tons) | 1 | 2 |
| Total Number of Licensees/yr | 3 | 6 |

[a] Assumes a waste density of 1,281.33 $kg/m^3$ (0.04 $tons/ft^3$ or 75 $lbs/ft^3$).

*(2) Transportation and Disposal Costs*

NRC recognizes that licensed material may be subject to a myriad of Federal and State transportation and disposal requirements, depending on its constituents and properties. Certain types of licensed material are subject solely to the NRC or Agreement State regulatory program, i.e., radioactive-only wastes. If transferred out of NRC or Agreement State jurisdiction, the material could qualify as a solid waste subject to the RCRA Subtitle D program. Other licensed material may be regulated by EPA or Authorized States under the RCRA Subtitle C program if it exhibits a hazardous characteristic identified at 40 CFR Part 261, Subpart C, and/or contains a hazardous waste listed at 40 CFR Part 261, Subpart D. Such wastes would be considered “mixed waste,” since they contain a radioactive waste component and a hazardous waste component; if transferred out of NRC or Agreement State jurisdiction, the material would be regulated as a strictly hazardous waste.

For purposes of this analysis, NRC’s cost model assumes that licensees transfer their source material for disposal to either (i) an industrial solid waste disposal facility, if the material being transferred is radioactive-only or (ii) a hazardous waste disposal facility, if the material being transferred is a mixed waste.

Table 2 shows that transportation and disposal of the material as an industrial solid waste is estimated to cost $0.08/kg ($75/ton). In estimating this unit cost, the model applies a

transportation cost of $0.04/kg ($32/ton) [8] and a disposal cost of $43/ton.[9] The cost model assumes a 200-mile travel distance between the licensed facility and the disposal facility.[10]

Table 2 also shows that the cost for transportation and disposal of the material as a hazardous waste is estimated to be $0.66/kg ($600/ton). In estimating these unit costs, the cost model applies a transportation cost of $0.38/kg ($350/ton) [11] and a disposal cost of $0.28/kg ($250/ton).[12] The cost model assumes a 200-mile distance between the licensed facility and the disposal facility.

Based on these cost assumptions, the model derives a weighted-average cost of transportation and disposal ($337/ton), assuming that 50 percent of licensees would transport/dispose their source material as industrial solid waste and the remaining 50 percent would transport/dispose their source material as hazardous waste. The model then applies the weighted-average cost in Table 2 ($337/ton) to the tons of material being transferred by licensees, as shown in Table 1, in order to derive transportation and disposal costs in the Low and High Scenarios.

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[8] EPA, *Technical Background Document, Economic Impact Analysis for the Proposed Rule for the Management of Spent-Mercury-Containing Lamps*, 1994. NRC updated these 1994 costs to 2000 levels using an annual cost increase of three percent.

[9] EPA, *Technical Background Document, Economic Impact Analysis for the Proposed Rule for the Management of Spent-Mercury-Containing Lamps*, 1994. NRC updated these 1994 costs to 2000 levels using an annual cost increase of three percent.

[10] Travel distance is based on NRC's judgment. Other travel distances are possible.

[11] Based on transportation cost model function for hazardous waste: $150 + $200/ton. This cost model function may be found in Exhibit 3: Transportation Cost Model Functions of ICF's memorandum to Allen Maples, EPA*: Baseline Costs and Cost Comparisons Between Hazardous Waste, Hazardous Material, and Non-hazardous shipments, Work Assignment No. B-31, Contract No. 68-W6-0061*, August 31, 1998.

[12] Based on information obtained through personal communication on June 28, 2000 with Mr. Bill Dornsife, Vice President of Nuclear Affairs, Waste Control Specialists.

**Table 2**
**Summary of Cost Model Inputs for Transportation and Disposal Unit Costs under the No-Action Option**

| Type of Transportation and Disposal | Transportation and Disposal Cost | Weighted-Average Transportation and Disposal Cost |
|---|---|---|
| Industrial Solid Waste | $0.08/kg ($75/ton) | Weighted-average: $0.37/kg ($337/ton) |
| Hazardous Waste | $0.66/kg ($600/ton) | |

**Proposed Action**

Under the proposed rule, NRC would amend 10 CFR 40.51 by requiring written NRC approval before transfers of source material derived from specifically licensed material to persons exempt under 10 CFR 40.13(a) or equivalent Agreement State regulations.

*(1) Universe Assumptions*

For the proposed rule, the cost model assumes that the same three to six licensees modeled in the no-action option would seek to transfer their source material under the proposed rule. Refer to Table 1 for these universe assumptions.

*(2) Costs to Licensees for Preparing and Submitting a Request to NRC*

Following is a description of the unit costs for licensees to prepare and submit requests to NRC under the proposed rule. Refer to Table 3 for a summary of the unit cost assumptions.

*Initial Request*

NRC estimates that, on average, a licensee will take approximately 50 hours to prepare and submit a request demonstrating that the proposed transfer meets NRC's dose limit criteria and is otherwise protective of public health and the environment.

*Additional Demonstrations (if necessary)*

NRC expects that, infrequently, licensees may be requested to submit additional information to NRC in making an adequate demonstration. The cost model assumes that, on average, 33 percent of licensees would have to submit an additional demonstration, i.e., one licensee under the Low Scenario and two licensees under the High Scenario. A licensee is expected to take, on average, 25 hours to prepare the additional demonstration.

*(3) Transportation and Disposal Costs*

Under the proposal, NRC expects that most licensees will receive NRC approval for transfer. However, NRC expects that a small percentage of requests may be denied. For purposes of this analysis, the cost model assumes that, under the Low Scenario, all three requests would be approved and that, under the High Scenario, five requests would be approved and one request would be denied. The licensees whose requests are approved would incur the same average transportation and disposal costs as under the no-action option, i.e., $337/ton.

The single licensee whose request is denied in the High Scenario must dispose its waste in accordance with NRC's disposal requirements, i.e., the licensee must send its waste to a disposal facility licensed by NRC or an Agreement State. The model computes a weighted-average cost for the licensee to send its waste to either a radioactive waste disposal facility or to a mixed waste disposal facility, i.e., assuming a 50 percent probability the waste is radioactive-only and a 50 percent probability the waste is a mixed waste. The model assumes a cost of $4,000/ton[13] for transportation and disposal of radioactive-only wastes and a cost of $6,933/ton[14] for transportation and disposal of mixed waste. The licensee's weighted-average cost for transportation and disposal is $5,467/ton.

In summary, the model assumes under the High Scenario that five licensees will transport/dispose their waste as a solid or hazardous waste at a weighted-average cost of $337/ton and that one licensee will transport/dispose its waste as a radioactive-only or mixed waste at a weighted-average cost of $5,467/ton. Based on these assumptions, the model uses the following formula to compute total waste transportation and disposal costs for the six licensees under the High Scenario:

195,000 tons x [5/6 x $337/ton + 1/6 x $5,467/ton] = $232,440,000, where:

- 195,000 tons is the quantity of waste material that is transported/disposed of by the six licensees;
- 5/6$^{th}$ of the material is transported/disposed of as a solid or hazardous waste at $337/ton; and
- 1/6$^{th}$ of the material is transported/disposed of as a radioactive-only or mixed waste at $5,467/ton.

Refer to Table 3 for a summary of the unit cost assumptions.

[13] Based on price lists and personal communications with US Ecology and Chem-Nuclear Systems representatives. The $4.41/kg ($4,000/ton) estimate includes transportation and disposal services through a broker.

[14] Based on price lists and personal communications with US Ecology and Chem-Nuclear Systems representatives. The $7.64/kg ($6,933/ton) estimate includes transportation and disposal services through a broker.

**Table 3**
**Summary of Cost Model Inputs for Estimating Transportation and Disposal Unit Costs under the Proposed Rule**

| | | | |
|---|---|---|---|
| **Costs for Preparing Initial Request** | 50 hours @ $71/hour for technical staff[a] | | |
| **Costs for Preparing Additional Demonstrations (if necessary)** | 25 hours @ $71/hour for technical staff[a] | | |
| **Transportation and Disposal** | Industrial Solid Waste Disposal Facility | $0.08/kg ($75/ton) | Weighted-average: $0.37/kg ($337/ton) |
| | Hazardous Waste Disposal Facility | $0.66/kg ($600/ton) | |
| | Low-level Waste Disposal Facility | $4.41/kg ($4,000/ton) | Weighted-average: $6.03/kg ($5,467/ton) |
| | Mixed Low-level Waste Disposal Facility | $7.64/kg ($6,933/ton) | |

[a] Source: NRC staff, August 2000.

*(4) Costs to NRC For Reviewing and Processing Requests*

Under the proposed rule, NRC would have to review and approve/deny requests for the transfer of source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations. As shown in Table 4, the cost model assumes that, on average, NRC staff would spend about ten hours reviewing and processing each request. In addition, NRC estimates that NRC staff would spend on average five hours reviewing and processing any additional demonstration submitted by licensees.

**Table 4**
**Summary of Cost Model Inputs for Estimating NRC Costs under the Proposed Rule**

| | |
|---|---|
| **Reviewing and Processing Transfer Requests - Initial Request** | 10 hours @ $71/hour for technical staff[a] |
| **Reviewing and Processing Transfer Requests - Additional Demonstrations** | 5 hours @ $71/hour for technical staff[a] |

[a] Source: NRC staff, August 2000.

### 3.2.2 Analysis and Results

Based on the inputs described in Subsection 3.2.1, the cost model computed the total costs to licensees and the NRC under the no-action option and proposed rule. The results of the model's computations are shown in Tables 5 and 6 for licensee costs and NRC costs, respectively.

**Estimated Costs to Licensees**

Table 5 shows that total baseline costs under the no-action option range from $32.9 million (Low Scenario) to $65.7 million (High Scenario) per year. The table also shows that total costs under the proposed option range from $32.9 million (Low Scenario) to $232.5 million (High Scenario) per year.

**Table 5**
**Total Annual Costs to Licensees under the**
**No-action Option and the Proposed Rule Option (in thousands)[a]**

| | Low[b] | | | High[c] | | |
|---|---|---|---|---|---|---|
| | **Total Cost under No-action Option** | **Total Cost under Proposed Rule** | **Incremental Cost** | **Total Cost under No-action Option** | **Total Cost under Proposed Rule** | **Incremental Cost** |
| **Costs for Preparing Initial Request** | $0 | $11 | $11 | $0 | $21 | $21 |
| **Costs for Preparing Additional Demonstrations if necessary)** | $0 | $2 | $2 | $0 | $4 | $4 |
| **Transportation and Disposal** | $32,858 | $32,858 | $0 | $65,715 | $232,440 | $166,725 |
| **Total** | $32,858 | $32,871 | $13 | $65,715 | $232,465 | $166,750 |

[a] Costs are rounded to the nearest thousand dollars.
[b] Assumes three licensee transferors per year.
[c] Assumes six licensee transferors per year.

The table further shows that the total incremental cost under the proposed rule ranges from approximately $13,000 (Low Scenario) to $166.8 million (High Scenario) per year. Incremental costs in the Low Scenario result from the costs to the three licensees for preparing and submitting requests to NRC for permission to transfer their material. Incremental costs in the High Scenario result, to a small extent, from costs to the six licensees for preparing their requests. However, the majority of incremental costs (approximately 99%) result from the incremental transportation and disposal costs of the one licensee whose request is denied. Rather than sending its waste to an industrial solid waste or hazardous waste disposal facility (weighted-average cost of $337/ton), the licensee must send the waste to a radioactive waste or mixed waste disposal facility at substantially higher costs (weighted-average cost of $5,467/ton).

Despite the incremental costs in the High Scenario, however, NRC believes that incremental costs to most licensees submitting a request would be substantially lower than estimated. First, the model includes a worst-case assumption that the denied licensee would transfer its material for disposal as a radioactive-only or mixed waste. NRC notes that many other transfer scenarios are possible, which could result in lower incremental costs (e.g., transfer to exempt persons for recycling). The model also includes a worst-case assumption that one request would be denied each year. NRC firmly believes that the overwhelming majority of licensees desiring to transfer their material would take the steps necessary to demonstrate that their material meets NRC's dose limit criteria.

**Estimated Costs to NRC**

Under the proposed rule, NRC would have to review and process requests for the transfer of source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations. As shown in Table 6, NRC costs would range from $2,500 (Low Scenario) to $5,000 (High Scenario).

**Table 6**
**Total Annual Incremental Costs to NRC**
**under the Proposed Rule (in thousands)[a]**

| | Low[b] | High[c] |
|---|---|---|
| **Reviewing and Processing Transfer Requests - Initial Request** | $2.1 | $4.3 |
| **Reviewing and Processing Transfer Requests - Additional Demonstrations** | $0.4 | $0.7 |
| **Total Costs** | $2.5 | $5.0 |

[a] Costs are rounded to the nearest hundred dollars.
[b] Assumes three licensee transferors per year.
[c] Assumes six licensee transferors per year.

## 3.3 Summary of Values and Impacts

A summary of the values and impacts associated with the no-action option (Option 1) and the proposed regulatory alternative (Option 2) follows.

### 3.3.1 Values and Impacts of Option 1

Under the no-action option, NRC would maintain the current regulations regarding the transfer of source material, as provided in 10 CFR 40.51. By definition, the no-action alternative has no values or impacts.

### 3.3.2 Values and Impacts of Option 2

Under the proposed rule, NRC would amend 10 CFR 40.51 by requiring written NRC approval before transfers of source material to persons exempt under 10 CFR 40.13(a) or equivalent Agreement State regulations. A summary of the values and impacts under the proposed regulatory alternative is presented in Table 7.

## 4. Decision Rationale

In this section of the Regulatory Analysis, NRC explains why the proposed regulatory option is recommended over the no-action option.

1. Option 2, the proposed option, would establish explicit procedures for licensees to obtain NRC approval before transferring source material to persons exempt under 10 CFR 40.13(a) or equivalent Agreement State regulations. NRC expects these proposed changes to eliminate uncertainty and potential noncompliance among licensees and provide direction to Agreement States in dealing with transfer issues. NRC believes that, under the current regulations, certain licensees may not be notifying NRC or Agreement States prior to transfer of their material to exempt persons.

2. Under Option 2, licensees would incur costs for preparing and submitting a request to NRC for permission to transfer source material. If the request is denied, they must handle the material in accordance with NRC requirements. Because the potential incremental costs to licensees may be high if the request is denied, NRC fully expects that licensees will take the steps necessary to make a successful demonstration to NRC and that denial of a request would be infrequent.

   NRC believes the incremental costs to licensees under Option 2 are justified because the rule would increase public safety. 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. In making its determination regarding transfers of source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations for the purpose of direct disposal in an appropriate facility, the NRC staff would expect to approve transfers under this provision if the individual radiation dose is not expected to exceed 0.25 mSv/yr (25 mrem/yr). The Commission would be informed in cases where the individual dose is expected to exceed 0.25 mSv/yr (25 mrem/yr). For situations other than direct disposal in an appropriate facility, the NRC would continue to review the request on a case-by-case basis.

3. For the reasons stated in (1) and (2) above, Option 2 is superior to Option 1 (the no-action alternative).

## 5. Implementation

The action would be enacted through a Proposed Rule Notice, public comments, and a Final Rule, with promulgation of the Final Rule in early 2003. Implementation can begin immediately following the enactment of the final rulemaking. No impediments to implementation of the recommended alternatives have been identified. Regulatory Guidance

may need to be revised to clarify the modified requirements and procedures for transferring source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations.

## Table 7
## Summary of Primary Values and Impacts Associated with the Proposed Rule

| Attribute | Proposed Action | |
|---|---|---|
| | **Values/Impacts** | **Brief Description of Values/Impacts** |
| Public and Occupational Health (Accident and Routine) | V (X) | Recent assessments of potential health and safety risks suggest that in certain cases source material below the exempt concentration limit could result in radiation exposures of the public and workers exceeding 1 mSv/yr (100 mrem/yr). The proposed rule would address these exposure concerns by requiring transfers of source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations to meet acceptable radiation dose limits and receive prior NRC approval. |
| Off-Site Property | V (X) | Transferred materials exceeding NRC's prescribed dose limits could jeopardize the safety of offsite property receiving the transferred material. It is possible, for example, for licensees to transfer source material exceeding these dose limits to be transferred under the current 10 CFR 40.51 to a non-licensed facility for permanent disposal, e.g., at an industrial solid waste disposal facility. These facilities may not be equipped for monitoring or controlling against radiation hazards. The purpose of the proposed rule is to ensure that source material transferred under 10 CFR 40.51 meets accepted dose limits, as prescribed by NRC. |
| Industry Operation | I (C, R) | The proposed regulatory changes in Option 2 would result in increased industry operation costs. Under the proposed rule, licensees would be required to prepare and submit a request to NRC and receive NRC approval before transferring source material to persons exempt under section 40.13(a) or equivalent Agreement State regulations. In addition, if NRC does not approve the request, the licensee would not be able to transfer the source material to exempt persons as unlicensed material. Rather, the material would remain licensed, which could increase the licensee's operation costs. Incremental costs under the proposal range from $13,000 to $166.8 million. |
| NRC Operation | I (D) | NRC would have to review and process licensee requests, as well as any additional information deemed necessary by NRC. The cost to NRC for reviewing and processing licensee requests ranges from $2,500 to $5,000. |
| Other Government | I (C, R) | The proposed regulatory changes could increase implementation and operation costs to government agencies (e.g, the Army) licensed under Part 40. The proposed regulatory option also would affect implementation and operation costs of Agreement States to implement changes; however, these costs could be minimized if implemented during next revision of their equivalent to 10 CFR Part 40. |

## Table 7
## Summary of Primary Values and Impacts Associated with the Proposed Rule (continued)

| Attribute | Proposed Action | |
|---|---|---|
| | **Values/Impacts** | **Brief Description of Values/Impacts** |
| Improvements in Knowledge | V (D, R, X) | The proposed rule would clarify that licensees must submit a request to the NRC for prior approval of transfers. Because of this, NRC expects the proposed rule to increase NRC's knowledge and documentation of transfers of source material from licensees to person exempt under 10 CFR 40.13(a) or equivalent Agreement State regulations. |
| Regulatory Efficiency | V (D) / I (C) | NRC expects that proposed clarifications to 10 CFR 40.51 would result in greater efficiency for licensees that currently have not pursued transferring material to persons exempt under 10 CFR 40.13(a) or equivalent Agreement State regulations because of uncertainty about the appropriate procedures or the status of transferred material. The proposed changes also would give direction to Agreement States on how to deal effectively with proposed transfers. |
| Environmental Considerations | V (X) | Licensed materials containing source material that exceed NRC's prescribed dose limits would not be released to unlicensed facilities. As a result, environmental risks at the transferee's facility would remain within acceptable levels. |

KEY:

**Values/Impacts:**
I = Impact
V = Value

**Factors influencing attributes:**
C = Cost of transportation and disposal
D = Regulatory determinations
G = Cost of regulatory guidance development, publication, and distribution
R = Recordkeeping/reporting
X = Radiological exposure

# Appendix A
# Description of Licensee Universe under 10 CFR Part 40

# Table A-1
# Characterization of Licensees that May be Transferring Unimportant Quantities of Source Material to Persons Exempt under 10 CFR 40.13(a)

| Program Code | Program Code Description[1] | Number of Active Licensees[3] |
|---|---|---|
| **Universe of Licensees Likely To Transfer Unimportant Quantities of Source Material to Persons Exempt under Section 40.13(a)** | | |
| 11200 | ***Source material other less than 150 kilograms***: Source material other licenses are issued for the possession and use of source material for fabrication, research, or manufacture of consumer products. These licenses do not allow the possession of more than 150 kilograms of material. | 3 |
| 11210 | ***Source material shielding***: Source material shielding licenses are issued for the possession and use of source material in shielding for protection against radiation. | 22 |
| 11221 | ***Source material military munition - outdoor testing***: Source material military munition outdoor testing licenses are issued for the possession, use, and testing of depleted uranium products designed for the military. | 2 |
| 11230 | ***Source material, general license distribution, section 40.34***: Source material general license distribution licenses are issued to authorize the initial transfer of industrial products and devices containing depleted uranium, or to initially transfer such products or devices to persons who have been issued a general license under section 40.25. (A general license under section 40.25 authorizes the receipt, acquisition, possession, use, or transfer of depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.) | 0 |
| 11300 | ***Source material other greater than 150 kilograms***: Source material other licenses are issued for the possession and use of source material for fabrication, research, or manufacture of consumer products. These licenses authorize the possession of more than 150 kilograms of material. | 37 |
| 11400 | ***Uranium hexafluoride ($UF_6$) production plants***: Uranium hexafluoride production plant licenses are issued for the possession and use of uranium to allow the conversion of yellowcake and/or ore concentrates to uranium hexafluoride ($UF_6$). There is only one commercial production facility operating in the United States: Allied Chemical in Illinois | 2 |
| 11700 | ***Rare earth extraction and processing***: Rare extraction and processing licenses are issued for the possession and use of source material for processing activities not directly related to the nuclear fuel cycle. This category includes licenses for extraction of metals, heavy metals, and rare earths. The extraction may be accomplished by a number of different methods, with the source material generally considered to be a waste product. This program code category is not used for milling operations (program code 11100), licenses for uranium hexafluoride production (program code 11400), and licenses for processing and recovery of source material in in-situ (program code 11500) or heap leaching operations (program code 11600). | 4 |

## Table A-1 (continued)
## Characterization of Licensees that May be Transferring
## Unimportant Quantities of Source Material to Persons Exempt under 10 CFR 40.13(a)

| Program Code | Program Code Description[1] | Number of Active Licensees[3] |
|---|---|---|
| 11900 | ***Decommissioning of source material facilities*** [2] : Decommissioning of source material facility licenses are issued to facilities that have notified the Commission of their intent to terminate all or part of their activities related to source materials. The licenses authorize decommissioning the facilities where the activities were performed. A plan may have been submitted for decontaminating a property and equipment so that it may be released for unrestricted use. Includes licenses which authorize performing decontamination, decommissioning, reclamation, or site restoration in order to release a facility. | 5 |
| | **Subtotal** | **75** |
| **Universe of Licensees Less Likely To Transfer Unimportant Quantities of Source Material to Persons Exempt under Section 40.13(a)** | | |
| 11100 | ***Licenses for Conventional Mills***: Mill licenses are issued for the extraction of uranium from uranium ore. In milling operations, the ore is crushed, ground to a fine mesh, and chemically treated to extract the uranium and convert it to a form called yellowcake. | 18 |
| 11220 | ***Source material military munition - indoor testing***: Source material military munition indoor testing licenses are issued for the possession, use, and testing of depleted uranium products designed for the military. The testing is done within an enclosure—the testing usually results in fragmentation of munition. | 4 |
| 11500 | ***Solution mining (R&D and commercial facilities)***: Solution mining licenses are issued for the extraction of uranium from uranium ores. The only mining operation licensed by the NRC is solution mining, which is leaching of ore by injection of liquid chemicals into the geologic formation. | 6 |
| 11600 | ***Heap leach, ore buying stations, and byproduct recovery***: Heap leach, ore buying station, and byproduct recovery licenses are issued for the recovery of source material from low grade uranium ores, from old tailings piles, or from a small ore body at a location distant from the mill complex. The heap leach process consists of spraying or trickling an acid solution over sections of the heap pile. Pipes or covered drains, in the base of the pile, collect uranium-enriched solution after it percolates through the heap. | 2 |
| 11800 | ***Source material possession only - permanent shutdown***: Source material licenses are issued for the possession and use of source material for miscellaneous activities not covered by program codes 11100-11700. This category includes licenses for sites where source material was processed and that are now being decommissioned. Some sites include disposal areas, such as tailings or slag piles. Licenses for these sites are issued for possession and storage only. | 9 |
| | **Subtotal** | **39** |
| | **Total** | **114** |

[1] Unless otherwise noted, program code descriptions were obtained from Table 5, "Program Codes Used in Materials and Fuel Cycle Licensing and Inspection Programs," *An Examination of Source Material Requirements Contained in 10 CFR Part 40, Options Paper: Discussion of Major Issues for Revision* (NUREG/CR-5881), August 1992.

[2] Program code description obtained from *Program Code Descriptions Used on NRC Licensing and Inspection Programs, Revision 2*, Office of Field and Safety Section and Office of Policy and Procedure Section, NMSS, October 1992.

[3] Number of active licensees, as of June 26, 2000.

# Appendix B
# Regulatory Flexibility Act Analysis

# Regulatory Flexibility Act Analysis

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), whenever an agency publishes a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant adverse economic impact on a substantial number of small entities. SBREFA further requires Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

NRC is certifying that there will not be a significant adverse impact on a substantial number of small entities as a result of today's rule proposal, and therefore, no regulatory flexibility analysis or other SBREFA requirements are necessitated. NRC's proposal would require licensees to prepare and submit a request to NRC for approval to transfer less than 0.05 percent source material derived from specifically licensed material to persons exempt under 10 CFR 40.13(a) or equivalent Agreement State regulations. In total, NRC estimates that, of the approximately 114 licensees under 10 CFR Part 40, approximately three to six licensees per year would submit a request to NRC. NRC estimates that costs to prepare a request average about $3,600 to $5,300 per licensee. NRC further estimates that, only in rare circumstances, a licensee may be denied permission to transfer the material and, as a result, potentially incur significant costs above the current (i.e., baseline) regulatory program. NRC estimates that this would happen to about one licensee per year.

In sum, NRC believes the proposed rule would not significantly impact a substantial number of entities, large or small, because (i) only a small number of licensees are expected to submit requests to NRC each year (three to six licensees); (ii) the average cost of preparing and submitting a request is not significant; and (iii) only in infrequent cases could a licensee incur significant incremental costs under the rule.