

NUCLEAR REGULATORY COMMISSION

10 CFR Part 40

RIN 3150 - AG64

Transfers of Certain Source
Materials by Specific Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to require NRC approval for transfers from licensees of low-concentrations of source material (less than 0.05 percent by weight) to persons exempt from licensing. The object of this proposed action is to ensure that the regulations regarding transfers of materials containing low concentrations of source material are adequate to protect public health and safety.

DATES: Submit comments by (Insert date 75 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website (<http://ruleforum.llnl.gov>). This site provides the capability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher (301) 415-5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, Room O-1F23, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking website.

The NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Gary Comfort, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-8106, e-mail gcc1@nrc.gov.

SUPPLEMENTARY INFORMATION:

The NRC regulations in 10 CFR 40.13 exempt persons from the licensing requirements for certain materials containing uranium and thorium referred to as "unimportant quantities." One of these exemptions, § 40.13(a), is for "chemical mixtures, compounds, solutions, or

alloys” in which the source material is by weight less than 0.05 percent. Section 40.13(a) exempts any person from NRC licensing requirements “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 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.” This exemption stems from regulations adopted approximately 40 years ago. The 0.05 percent by weight limit appears to have been chosen on the basis of concentrations of source material that are necessary to be a useful source of fissionable material. (The 0.05-percent by weight limit is equivalent to approximately 339 picocuries uranium/gram (pCiU/gram) for natural uranium or 116 picocuries thorium/gram (pCiTh/gram) for natural thorium.)

Some NRC licensees are in possession of mixtures of material derived from their licensed processes where the source material is under 0.05 percent by weight. These licensees hold licenses because the processes which resulted in this lower concentrated material at some point used material in which the concentration of source material exceeded 0.05 percent by weight source material. Specific licensees are subject to requirements for decommissioning in Part 40 (§ 40.42) and waste disposal requirements in Part 20. The 0.05 percent standard of 10 CFR 40.13(a) is not a disposal standard. However, 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. After this material is transferred, it is no longer subject to NRC requirements because an exempt person is not subject to the requirements for decommissioning and disposal.

For some limited types and quantities of materials that fall under the exemption in § 40.13(a), transfers could potentially result in scenarios where exposure limits in 10 CFR Part 20 could be exceeded. Recent estimates of possible radiation doses from thorium and uranium suggest that quantities of source material in concentrations below the 0.05-percent limit, in certain situations, could result in individual doses of more than 1 millisievert/year (mSv/yr) (100 millirem/year (mrem/yr)). Examples of some of these estimates can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," June 2001.

This recent information on doses from less than 0.05 percent by weight source material has led the Commission to review its regulations concerning source material. This is especially important in light of decommissioning and decontamination of facilities where less than 0.05 percent by weight source material is present in significant quantities and often involves questions of disposal options for this material. Therefore, the Commission is proposing to amend § 40.51 to require NRC approval for transfers of source material derived from licensees' specifically licensed material to ensure that these transfers do not pose a health and safety concern. Until such an authorized transfer occurs, the material, regardless of its concentration of source material, remains part of the licensee's inventory of licensed material. This approval does not apply to the general license provisions in Part 40 -- the proposed approval is limited to source material derived from specifically licensed material. This is because of the more limited quantities of material handled under general license. In addition, it is not intended for this requirement to apply to uranium and thorium that is essentially at the natural background levels of the surrounding area. The primary concern for this proposed rule is to handle situations where quantities of licensed source material have been processed through licensed operations resulting in mixtures of material containing less than 0.05 percent by weight source material.

In making its determination regarding transfer of less than 0.05 percent source material, the NRC would generally evaluate the potential use and disposition scenarios on a case-by-case basis. Factors that may be considered include, but are not limited to, whether the dose arises from an occupational exposure (albeit to a worker at an unlicensed facility), whether the exposed individual is informed of and consents to the exposure, the likely duration of the exposure, the estimated number of exposed individuals, the doses the individual has received in the past from similar type actions, and whether appropriate Federal, State, and local regulations regarding possession of such material by the exempt person are met for the intended use or disposal. The Commission would expect licensees to address, as part of their approval requests for transfer of material under this rule, analyses of doses that may occur to the recipients of the material during the transfer and disposal operations, as well as, the doses that may occur as the result of the disposal consistent with the License Termination Rule, 10 CFR Part 20, Subpart E or RCRA requirements, as appropriate.

If the approval request is for transfer for the purpose of direct disposal in an appropriate facility (e.g., a RCRA Subtitle C facility authorized for such material or other disposal facilities having in place the appropriate State or EPA permits), the request for transfer would normally be approved if the dose to a member of the general public is unlikely to exceed 0.25 mSv/yr (25 mrem/yr). If the expected dose to a member of the general public is estimated to be between 0.25 mSv/yr (25 mrem/yr) and 1 mSv/yr (100 mrem/yr), the NRC staff will inform the Commission of the request and its resolution status. These limitations, however, do not preclude a licensee from requesting approval for a transfer that could potentially result in doses to a member of the general public above 1 mSv/yr (100 mrem/yr); however, such approval would be based upon the unique circumstances of the specific case under review and would not be approved by the NRC staff without full Commission review.

The above dose limits are applicable to transfers for the purpose of direct disposal in an appropriate facility (e.g., a RCRA Subtitle C facility authorized for such material or other disposal facilities having in place the appropriate State or EPA permits). If transfers of material are sought for other purposes such as recycle or indirect disposal, such dose limits may not be appropriate. Lower dose limits may need to be considered.

Several licensees have requested NRC approval to transfer less than 0.05 percent source material to exempt persons in the past several years. The Commission has made these decisions on a case-by-case basis. Pending publication of these amendments to § 40.51 as a final rule, the Commission will continue its current policy of approving requests to transfer material to exempt persons under § 40.13(a) or equivalent Agreement State regulations on a case-by-case basis.

Additionally, NRC does not permit licensees to intentionally dilute licensed source materials without specific approval. Section 40.41(c) states that “each person licensed by the Commission pursuant to the regulations in this part shall confine his possession and use of source or byproduct material to the locations and purposes authorized in the license.” Although it is recognized that inadvertent dilution may occasionally occur (e.g., during the process of preparing contaminated material for shipment, some mixing with cleaner material may result as it is “dug up” and loaded for shipment before sampling), this natural dilution of the concentration of uranium and thorium is in contrast to the intentional dilution of contaminated material for the purpose of reducing its concentration below 0.05 percent which is not acceptable in the absence of prior authorization. Intentional dilution of licensed source material, without prior NRC authorization, would be considered a violation of § 40.41(c). The NRC is seeking public comment on whether this policy should be better clarified by adding rule language specifically prohibiting intentional dilution without prior authorization in the regulations.

As part of this proposed rule, the Commission is also proposing to amend § 40.13(a) by adding the word “disposes” to the list of exempted activities in § 40.13(a). This addition would clarify the exemption’s applicability to disposal. However, it should be noted that any on-site disposal by a licensee of mixtures of material containing under 0.05 percent by weight (that was derived from its licensed material) source material is not addressed by § 40.13(a). Any such disposal would continue to require approval under 10 CFR 20.2002 and be subject to reevaluation under the Decommissioning Timeliness Rule, 10 CFR 40.42 and the License Termination Rule, 10 CFR Part 20, Subpart E.

Agreement State Compatibility

Section 40.13 is presently a compatibility “B” item, and § 40.51 is presently a compatibility “C” item, except for § 40.51(b)(6) which deals with exports and is reserved for NRC. The compatibility status reflects the extent to which Agreement State regulations must conform to NRC regulations, as detailed in “Policy Statement on Adequacy and Compatibility of Agreement State Programs”, published September 3, 1997 (62 FR 46517). The proposed amendments, if made final, would not change the compatibility status of § 40.13 or § 40.51. Agreement States would be required to revise their regulations equivalent to § 40.13(a) and would be expected to have the same or more stringent criteria than NRC’s when making their determinations regarding transfers for direct disposal of less than 0.05 percent source material.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, "Plain Language in Government Writing" directed that the Government's writing be in plain language. In complying with this directive, editorial changes have been made in the proposed revisions to improve the organization and readability of the existing language of paragraphs being revised. These types of changes are not discussed further in this notice. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading "ADDRESSES" above.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC is presenting amendments to its regulations that allow transfers of source material that is less than 0.05 percent by weight to persons exempt under § 40.13(a) or equivalent Agreement State regulations. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this proposed rule because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. The licensees affected by the proposed changes to § 40.51 fall into two groups: those licensees who would continue to be allowed to transfer their low concentrations of source material to exempt persons and those licensees who would not be allowed to transfer their low concentrations of source materials to exempt persons. For the first group there are no environmental impacts associated with this rule because the only change brought about by this rule is the requirement to apply for such approval. There would be no change to human health or the environment as a result.

For the second group, some transfers to exempt persons may not be approved. Consequently, low concentrations of source materials at these licensed facilities would need to remain on site or could be transferred to or disposed of at other licensed facilities. As a result, this source material would continue to be managed in a regulated manner that would provide significantly greater protection to the public and the environment from exposure to radiation. Workers at licensed facilities would be expected to be exposed to lower doses of radiation than the levels to which workers at unregulated exempt facilities would be exposed, because of the routine safety precautions required at licensed facilities.

The proposed amendment to § 40.13(a) is only for the purpose of clarifying existing rule language. As a result, there would be no impact on human health or the environment resulting from this amendment.

Because under adoption of the proposed rule, there would be either 1) no change to human health or the environment or 2) greater protection of human health and the environment (relative to the current regulation), the determination of this environmental assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation. The NRC has also committed to complying with Executive Order (EO) 12898 - Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994, in all its actions. Therefore, the NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule but somehow were not addressed. The NRC uses the following working definition of "environmental justice": the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of the Environmental Assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined at the NRC Public Document Room, O-1F23, 11555 Rockville Pike, Rockville, MD. Single copies of the environmental assessment

are available from Gary Comfort, telephone (301) 415-8106, e-mail, gcc1@nrc.gov of the Office of Nuclear Material Safety and Safeguards.

Paperwork Reduction Act Statement

This proposed rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for these information collections is estimated to average 50 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0020), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the regulatory analysis are available from Gary Comfort, telephone (301) 415-8106, e-mail, gcc1@nrc.gov of the Office of Nuclear Material Safety and Safeguards.

During development of the regulatory analysis, the NRC evaluated the possibility of a licensee disposing of its material in a mill tailings impoundment rather than a licensed burial facility, if the licensee was denied approval to transfer their source material to a person exempt under § 40.13(a) or equivalent Agreement State regulations. Although it is expected that this disposition method would reduce the costs related to the potential impact of this proposed rule, sufficient cost data were not available to include it as part of the regulatory analysis. Therefore, the NRC is seeking public comment and any available cost data regarding the inclusion of this disposal method in the Regulatory Analysis. Comments should be sent to the address listed under the heading "ADDRESSES," above.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The proposed rule would require licensees to apply to the Commission for approval to transfer source material to persons exempt under § 40.13(a) or equivalent Agreement State regulations. In total, the NRC estimates that, of the approximately 114 licensees under Part 40, approximately three to six licensees per year would apply to the Commission, i.e., about three to five percent of all Part 40 licensees. The NRC further estimates that the vast majority of licensees would need only submit an application to the NRC at an estimated one-time cost of about \$3,600 to \$5,300 per licensee. The NRC further estimates that, in rare circumstances, a licensee may be denied permission to transfer the material and, as a result, incur significant costs above the current (i.e., baseline) regulatory program. However, the NRC estimates that this would happen to about one licensee per year, i.e., less than one percent of all Part 40 licensees.

In sum, because the annual number of licensees submitting an application to NRC is expected to be very small (3-6 licensees annually), the NRC believes that the proposed rule would not impact a substantial number of entities, large or small.

Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this proposed rule because this amendment would not involve any provisions that

would impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.

List of Subjects in 10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Part 40.

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

1. The authority citation for Part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95-604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended, (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97-415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104-134, 110 Stat. 1321, 1321-349 (42 U.S.C. 2243).

Sec. 40.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).
Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. Section 40.13(a) is amended to read as follows:

§ 40.13(a) Unimportant quantities of source material.

(a) Any person is exempt from the regulations in this part and from the requirements for a license set forth in section 62 of the Act to the extent that such person receives, possesses, uses, disposes, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy. The exemption contained in this paragraph does not include byproduct material as defined in this part.

3. Section 40.51 is amended to read as follows:

§ 40.51 Transfer of source or byproduct material.

(a) No licensee shall transfer source or byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in its license and subject to the provisions of paragraphs (c), (d), and (e) of this section, any licensee may transfer source or byproduct material:

(1) To the Department of Energy;

(2) To the agency in any Agreement State that regulates radioactive materials pursuant to an agreement with the Commission or the Atomic Energy Commission under section 274 of the Act;

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) 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;

(5) To any person authorized to receive such source or byproduct material under terms of a specific license or a general license or their equivalents issued by the Commission or an Agreement State;

(6) To any person abroad pursuant to an export license issued under part 110 of this chapter; or

(7) As otherwise authorized by the Commission in writing.

(c) Before transferring source or byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the source or byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes receipt of the type, form, and quantity of source or byproduct material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in its possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may have in its possession a written certification by the transferee that it is authorized by license or registration certificate to receive the type, form, and quantity of source or byproduct material to be transferred, specifying the license or registration certification number, issuing agency, and expiration date;

(3) For emergency shipments, the transferor may accept oral certification by the transferee that it is authorized by license or registration certificate to receive the type, form, and quantity of source or byproduct material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations;
or

(5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of these methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the source or byproduct material.

(e) A licensee shall 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

