

**DRAFT GUIDANCE FOR IMPLEMENTATION  
OF THE PROPOSED RULE,  
“DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS  
AND TO GENERAL LICENSEES AND REVISIONS OF GENERAL  
LICENSE AND EXEMPTIONS,”  
IN 10 CFR PARTS 30, 40, 70, 170, and 171**

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## Introduction

This document provides guidance to licensees and applicants for implementing the U.S. Nuclear Regulatory Commission’s (NRC’s) proposed rule, “Distribution of Source Material to Exempt Persons and to General Licensees and Revisions to General License and Exemptions,” in Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 40, 70, 170, and 171. The NRC proposed this rule on July 26, 2010 (75 FR 43425), and will revise this guidance as needed for consistency with the final rule. The guidance is intended for use by applicants, licensees, Agreement States, and NRC staff. It describes methods acceptable to the NRC staff for implementing the proposed regulation amendments to 10 CFR Part 40, “Domestic Licensing of Source Material.” The approaches and methods described in this guidance are provided for information only. Methods and solutions different from those described in this document are acceptable if they meet the requirements in 10 CFR Part 40. This guidance will be made consistent with the final rule for 10 CFR Part 40.

The guidance in this document is provided in the form of questions and answers pertinent to the following sections of the proposed rule:

- [General Questions](#)
- [10 CFR 40.13, “Unimportant Quantities of Source Material”](#)
- [10 CFR 40.22, “Small Quantities of Source Material”](#)
- [10 CFR 40.52, “Certain Items Containing Source Material; Requirements for License to Apply or Initially Transfer”](#)
- [10 CFR 40.54, “Requirements for License to Initially Transfer Source Material for Use Under 10 CFR 40.22”](#)

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## General Questions

### QUESTIONS AND ANSWERS:

#### **Q1. What is a specific license?**

**A1.** A specific license is a license issued to a named person upon application submitted to the NRC in accordance with the regulations. For source material, application would be made under 10 CFR Part 40.

#### **Q2. What is a general license?**

**A2.** A general license is a license provided by regulation, which is effective without the filing of an application with the NRC or the issuance of licensing documents to a particular person.

#### **Q3. What is an exemption?**

**A3.** An exemption provides relief from the regulations. In this rule, the NRC discusses exemptions from licensing requirements in 10 CFR Part 40. Normally, a person possessing a product to which an exemption applies does not have any restrictions in its use and possession as long as the person does not modify the product. However, certain exemptions do have restrictions on the extent to which the exemption applies. It should be noted that, although a person may be provided with an exemption from licensing for a certain product or material, such exemption does not make the person exempt from regulations for other radioactive products or materials not covered by the exemption.

#### **Q4. What is source material?**

**A4.** Source material is (1) uranium or thorium, or any combination thereof, in any physical or chemical form, or (2) ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination thereof.

#### **Q5. What is depleted uranium?**

**A5.** Depleted uranium is uranium with a percentage of uranium-235 (U-235) lower than the 0.7 percent (by mass) contained in natural uranium. The normal residual U-235 content in depleted uranium is 0.2 to 0.3 percent by mass, with uranium-238 (U-238) comprising most of the remaining 99.7 to 99.8 percent. Depleted uranium is produced during uranium isotope separation and is typically found in spent fuel elements or in byproduct tailings or residues.

#### **Q6. What does “initial(ly) transfer” mean?**

**A6.** Initial transfer is the transfer that first puts a product or material into use under a particular regulatory provision, such as an exemption from licensing or a general license. This transfer is usually made by a manufacturer or an importer.

**Q7. How do I obtain a specific license?**

**A7.** To obtain a specific license for source material, apply under 10 CFR 40.31, “Application for Specific Licenses.” Applicants should complete NRC Form 313, “Application for Materials License,” following the instructions contained in the form.

**10 CFR 40.13****Unimportant Quantities of Source Material****EXPLANATION:**

The proposed rule provides revisions, clarifications, and deletions of certain source material exemptions. The rule proposes to require a specific license for the initial distribution of products used under an exemption in 10 CFR 40.13(c).

**QUESTIONS AND ANSWERS:****Q1. What products are exempt from NRC regulations?**

**A1.** The list of exemptions is detailed in 10 CFR 40.13.

**Q2. Are there any restrictions placed on a person exempt from licensing?**

**A2.** Most product exemptions do not have conditions for the possession, use, and disposal of the product. The primary exceptions are for uranium counterweights exempt under 10 CFR 40.13(c)(5) (which are exempt only when they are installed in aircraft, rockets, projectiles, and missiles or stored or handled in connection with installation or removal of such counterweights—see RIS-05-003, “NRC Regulatory Issue Summary 2005-03: 10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights—Storage and Repair,” issued February 2005, for more details) and for lenses exempt under 10 CFR 40.13(c)(7) (which cannot be used as eyepieces, spectacles, or contact lenses). In addition, certain exemptions prohibit modification of the exempt product.

**Q3. If I meet the conditions for an exemption under 10 CFR 40.13, are there any requirements that I must comply with?**

**A3.** As long as one operates within any restrictions in the exemptions, there are no requirements that you must comply with.

**Q4. If I meet the requirements for an exemption under 10 CFR 40.13, do I need to contact the NRC at all?**

**A4.** No.

**Q5. May I initially transfer or distribute source material to persons exempt under 10 CFR 40.13(c)?**

**A5.** You may not initially transfer for sale or distribution a product containing source material to a person exempt from the regulations under 10 CFR 40.13(c) unless authorized by a specific license under 10 CFR 40.52 (see 10 CFR 40.13(c)(10)). However, if you are already initially distributing such source material before the effective date of the final rule without specific authorization, you may continue to do so for 1 year beyond this date. Such initial distribution may also continue until the NRC takes final action on a pending application for a license or

license amendment to specifically authorize distribution submitted not later than 1 year after the effective date of the rule.

**Q6. May I import exempted source material and receive, possess, use, or transfer it?**

**A6.** To the extent that such importation is authorized under the provisions of 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material," you may import source material for your own possession and use it under the exemption. However, if you import exempted source material for the purpose of sale or distribution, you would be required to obtain a specific license from the NRC in accordance with 10 CFR 40.13(c)(10) and 40.52 before such distributions.

**Q7. May I export the exempted source material that I have for sale or disposal?**

**A7.** To the extent such exportation is authorized under the provisions of 10 CFR Part 110, you may export source material possessed under exemption.

**Q8. If I meet the requirements for an exemption, are there any NRC requirements for getting rid of my exempted source material?**

**A8.** No.

**Q9. If I meet the requirements for an exemption, would I need to contact the NRC in any way when I am permanently ceasing operations and use of the exempted source material?**

**A9.** No.

**Q10. I bought a piece of glazed ceramic tableware over the Internet. Is the seller required to confirm the manufacture date and verify that the glaze contains less than 20 percent by weight uranium?**

**A10.** No.

**Q11. I have glazed ceramic tableware containing source material that was manufactured before the effective date of the regulation. Do I need to determine if it meets the constraints of the exemption?**

**A11.** No. If you have glazed ceramic tableware containing source material that was manufactured before the effective date of the regulation, and if the glaze contains not more than 20 percent by weight source material, you are exempt from regulation (see 10 CFR 40.13(c)(2)(i)). In this case, the product was manufactured long ago and can be assumed to meet the 20-percent limit. Glazed ceramic tableware containing source material is no longer allowed to be manufactured for use under the exemption.

**Q12. I bought a piece of uranium glass over the Internet. Is the seller required to confirm the manufacture date and the percent by weight of uranium in the glass?**

**A12.** No.

**Q13. I have glassware containing source material that was manufactured before the effective date of the regulation. Do I need to determine if it meets the constraints of the exemption?**

**A13.** No. If you have glassware containing source material that was manufactured before the effective date of the regulation, and if the glassware contains no more than 10 percent by weight source material, you are exempt from regulation (see 10 CFR 40.13(c)(2)(iii)). However, this does not apply to commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction. It is the burden of the initial distributor to ensure that its products are manufactured in accordance with the exemption.

**Q14. I have glassware containing source material that was manufactured after the effective date of the regulation. Do I need to determine if it meets the constraints of the exemption?**

**A14.** No. If you have glassware containing source material that was manufactured after the effective date of the regulation, and if the glassware contains no more than 2 percent by weight source material, you are exempt from regulation (see 10 CFR 40.13(c)(2)(iii)). However, this does not apply to commercially manufactured glass brick, pane glass, ceramic tile, or other class or ceramic used in construction. It is the burden of the initial distributor to ensure that its products are manufactured in accordance with the exemption.

**Q15. If I purchase a gun scope or other optical instrument over the Internet from a foreign manufacturer, how can I determine if it contains source-material coated lenses?**

**A15.** You would need to contact the manufacturer.

**Q16. How can I determine if an optical instrument's eyepiece is coated with source material?**

**A16.** There is no easy way for a consumer to determine if an optical instrument's eyepiece is coated with source material. However, such products cannot be legally distributed for use under exemption and, therefore, it is unlikely that a consumer would run into such a situation.

**Q17. I have finished optical lenses and mirrors with thorium or uranium in or on them that were manufactured before the effective date of the regulation. Do I need to determine if they meet the constraints of the exemption?**

**A17.** No. If you have finished optical lenses and mirrors with thorium or uranium in or on them that were manufactured before the effective date of the regulation, and if the optical lenses and mirrors contain no more than 30 percent by weight of thorium, you are exempt from regulation. However, the exemption does not authorize the shaping, grinding, or polishing of such lens or mirror, or any manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alternation of the lens or mirror, or the receipt, possession, or the transfer of uranium or thorium contained in contact lenses, spectacles, or eyepieces in binoculars (see 10 CFR 40.13(c)(7)). It is the burden of the initial distributor to ensure that its products are manufactured in accordance with the exemption

**Q18. I have finished optical lenses and mirrors with thorium or uranium in or on them that were manufactured after the effective date of the regulation. Do I need to determine if they meet the constraints of the exemption?**

**A18.** No. If you have finished optical lenses and mirrors with thorium or uranium in or on them, and if the optical lenses and mirrors contain no more than 10 percent by weight of thorium, you are exempt from regulation. For products meeting these new constraints, the date of manufacture is not limiting. However, the exemption does not authorize the shaping, grinding, or polishing of such lens or mirror; any manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alternation of the lens or mirror; or the receipt, possession, or transfer of uranium or thorium contained in contact lenses, spectacles, or eyepieces in binoculars (see 10 CFR 40.13(c)(7)). It is the burden of the initial distributor to ensure that its products are manufactured in accordance with the exemption.

**Q19. Are there any restrictions on how optical lenses with thorium or uranium in or on them might be used in my products?**

**A19.** The lenses may not be used in eyepieces (i.e., lenses in close proximity to the eye when in use) in binoculars or in other optical instruments. Also, uranium and thorium may not be used or contained in spectacles or contact lenses.

**Q20. Do I need a specific license if I find I need to smooth the outside edge of some lenses to better fit into a lens holder?**

**A20.** The exemption in 10 CFR 40.13(c)(7) does not allow for the shaping, grinding, or polishing of such lens or for manufacturing processes other than assembly into an optical instrument. If smoothing involves grinding or polishing, it is prohibited. A license would be required to conduct these activities.

**Q21. Does 10 CFR 40.13(c)(10)(ii) suggest that a person located in an Agreement State who is processing source material to produce one of the products identified in paragraph (c) is exempt from 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” and 10 CFR Part 20, “Standards for Protection Against Radiation,” or equivalent regulations in that State?**

**A21.** No. The exemption from 10 CFR Parts 19 and 20 only applies to the distribution license issued by the NRC. The person processing the source material would still be required to meet all applicable regulations of the Agreement State in which the licensee is located.

**10 CFR 40.22****Small Quantities of Source Material****EXPLANATION:**

Under the proposed revision to 10 CFR 40.22, the general license is limited to thorium and uranium in their natural isotopic concentrations and depleted uranium. The proposed rule would modify the existing possession and use requirements of the general licensee. The proposed rule would clarify disposal requirements for source material possessed under 10 CFR 40.22.

**QUESTIONS AND ANSWERS:****Q1. What is a 10 CFR 40.22 general licensee?**

**A1.** A 10 CFR 40.22 general licensee is a commercial or industrial firm; research, educational, or medical institution; or Federal, State, or local government agency that receives, possesses, uses, or transfers small quantities of source material in the forms and quantities described in 10 CFR 40.22(a)(1)–(3) for research, development, educational, commercial, or operational purposes.

**Q2. What is a small quantity of source material under 10 CFR 40.22?**

**A2.** Under 10 CFR 40.22, a “small quantity” of source material means the following: (1) not more than 1.5 kilograms (kg) (3.3 pounds (lb)) of uranium and thorium in any form at one time and not more than 7 kg (15.4 lb) in any calendar year, (2) not more than 7 kg (15.4 lb) of uranium and thorium in a solid and nondispersible form at one time and not more than 70 kg (154 lb) in any calendar year, or (3) not more than 7 kg (15.4 lb) of uranium removed during the treatment of drinking water at any one time and not more than 70 kg (154 lb) during a calendar year.

**Q3. What are uranium and thorium in their natural isotopic concentrations?**

**A3.** Uranium and thorium in their natural isotopic concentrations have not undergone processing to separate or enrich certain radionuclides. Chemical processes alone do not change the isotopic concentration. However, some variation in the ratios of certain radionuclides exists in natural uranium or thorium depending on the time after chemical separation. Only thorium-232 (Th-232) and thorium-228 (Th-228) are normally present in significant amounts in naturally occurring thorium. These two isotopes are of equal activity abundance at the time of chemical separation, with a negligible mass abundance of Th-228. Some thorium-230 (Th-230) may be present, depending on the uranium content of the source ore. The normal content of natural uranium is 99.27 percent U-238, 0.72 percent U-235, and 0.0055 percent uranium-234 (U-234) by mass. Additional information may be found in Section 3.1 of NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,” issued June 2001.

**Q4. Are there any restrictions on processing or using source material under the 10 CFR 40.22 general license?**

**A4.** As long as you meet and continue to meet the conditions for possession of source material as stated in 10 CFR 40.22(a), there are no restrictions on how you may process or use the source material except that the source material (or radiation from it) may not be administered either externally or internally to human beings. For example, you could melt depleted uranium and pour it into various forms and shapes under the 10 CFR 40.22 general license as long as you were doing it for research, development, educational, commercial, or operational purposes and possessed less than 1.5 kg of source material at any one time and did not receive more than 7 kg of source material in any calendar year. Note that you may not isotopically separate any of the isotopes of uranium or thorium under the 10 CFR 40.22 general license because then you would possess uranium or thorium no longer is its natural isotopic concentration.

**Q5. What requirements must I comply with if I have source material generally licensed under 10 CFR 40.22?**

**A5.** The requirements (within NRC jurisdiction) applicable to the persons generally licensed for the use of source material by 10 CFR 40.22 are contained or referenced in that section of the regulations, specifically 10 CFR 40.22(b)–(e), as follows:

- Paragraph 40.22(b) requires that persons receiving, possessing, or transferring source material in accordance with a general license comply with the following: (1) they are prohibited from administering the source material or its radiations to human beings; (2) they may not abandon the source material and must dispose of it per the requirements in 10 CFR 40.22(b)(2)(i) and (ii); (3) they are subject to the provisions in 10 CFR 40.1–40.10, 40.41(a)–(e), 40.46, 40.51, 40.60–40.63, 40.71, and 40.81; (4) they must respond to written requests from the NRC for information; and (5) they may not export the source material except in accordance with 10 CFR Part 110.
- Paragraph 40.22(c) requires that activities be conducted so as to minimize contamination of the facility and the environment.
- Paragraph 40.22(d) states that the general licensee is exempt from the requirements of 10 CFR Parts 19, 20, and 21, with certain noted exceptions.
- Paragraph 40.22(e) states that no person may initially transfer or distribute source material to persons generally licensed unless authorized by a specific license issued in accordance with 10 CFR 40.54.

**Q6. What is considered “solid and nondispersible” uranium and thorium?**

**A6.** For source material to be considered as “solid and nondispersible,” it cannot be in a form that is readily ingested or inhaled (i.e., could be breathed in or swallowed by accident). Source material in the form of powders or liquids would not be considered “solid and nondispersible.” In addition, source material in solid form but small enough to accidentally ingest or inhale would not be considered “solid and nondispersible.”

**Q7. Would uranium metal filings or shavings be considered to be a “solid and nondispersible” form under the 10 CFR 40.22 general license?**

**A7.** Whether a source material is considered “solid and nondispersible” is based on whether the source material can be readily ingested or inhaled (i.e., could be breathed in or swallowed by accident). In the case of metal filings or shavings, unless there is little likelihood of accidental inhalation or ingestion (i.e., large scraps) the metal filings or shavings should not be considered “solid and nondispersible.” In most cases, the question of whether or not the metal filings or shavings of source material are considered “solid and nondispersible” is moot because they are typically possessed by the person who originated the filings or shavings through some form of processing, and the lower possession limits in 10 CFR 40.22(a)(1) would apply. The exception would be if the shavings or filings were possessed by someone other than the originator of the shavings or filings and they were of sufficient size to not be ingested or inhaled—in this case, the possession limit in 10 CFR 40.22(a)(2) would apply.

**Q8. Must I contact the NRC before my possession of source material under the 10 CFR 40.22 general license?**

**A8.** No. You do not have to notify the NRC that you want to possess or use source material under the 10 CFR 40.22 general license. However, when you cease operations under the 10 CFR 40.22 general license and have identified significant contamination, you must notify the NRC under the requirements in 10 CFR 40.22(c).

**Q9. May I initially transfer or distribute source material under my general license to other persons who are generally licensed?**

**A9.** No. You may only initially transfer or distribute source material under a specific license issued under 10 CFR 40.54. As stated in 10 CFR 40.22(e), no person may initially transfer or distribute source material to persons generally licensed unless authorized by a specific license issued in accordance with 10 CFR 40.54 or equivalent provisions of an Agreement State.

Most persons possessing source material under the 10 CFR 40.22 general license are expected to have received the source material from a specific licensee authorized for initial distribution or for material that was already initially transferred from another 10 CFR 40.22 general licensee. However, because uranium or thorium can be extracted from or concentrated in previously unprocessed ores (initially possessed under an exemption in 10 CFR 40.13(b)) or directly from its place in nature, the processor could initially possess the source material under the 10 CFR 40.22 general license without receiving it from another licensee. Examples of such activities would include processing for other minerals from ores, extraction of uranium or thorium from ores, and extraction of uranium from drinking water. Under these situations, any initial transfer of such source material to another 10 CFR 40.22 general licensee would require a specific license authorizing distribution; however, if the transfer were to someone for possession under the exemption in 10 CFR 40.13(a) or to a specific license (e.g., a licensed disposal site), no specific license authorizing distribution would be needed (see 10 CFR 40.51(b)(1)–(7)).

**Q10. How do I know if the source material that I am transferring would be used under 10 CFR 40.22, thus requiring me to obtain a specific license before I can initially transfer the source material?**

**A10.** You should directly contact the recipient to determine that it is authorized to receive the source material and whether it is receiving the material under a specific license, a general

license, or other authorization. If the recipient states that it has a specific license authorizing the possession and use of the source material to be transferred, you are required to verify that the recipient's license authorizes receipt of the type, form, and quantity of source material to be transferred using a method indicated in 10 CFR 40.51(d). Otherwise, if you determine that the recipient would possess the source material under a general license, you are required to obtain a specific license in accordance with 10 CFR 40.22(e) and 40.54.

**Q11. May I export the generally licensed source material that I have for sale or disposal?**

**A11.** Yes, but only under the provisions of 10 CFR 40.22(b)(5) and 40.51(b)(6) (i.e., in accordance with 10 CFR Part 110).

**Q12. How might I visually tell if evidence of significant contamination may have occurred at my facility because of my operations under the 10 CFR 40.22 general license?**

**A12.** The primary basis for determining the likely presence of significant contamination and the possible need for radiation surveys would be historical information about the quantities of materials used, how they were processed, and whether spills occurred. Visual inspection may come into play if the equipment used in processes involving the source material, such as a glove box, has visible residues.

**Q13. Who at the NRC should I call to consult about the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material is not likely to result in exposures that exceed the limits in 10 CFR 20.1402, "Radiological Criteria for Unrestricted Use"? What if I am located in an Agreement State? Can I expect the NRC contact to explain how to sample and what kind of restoration might be necessary?**

**A13.** While 10 CFR 40.22 requires notifying the Director of the Office of Federal and State Materials and Environmental Management Programs (FSME), you may also wish to contact and discuss these matters with regional staff, as they may be able to provide more detailed information. Paragraph (b)(2) of 10 CFR 40.5, "Communications," indicates which States and territories are handled by the various regional offices. Those in Agreement States should contact their State regulator. Information on which States are Agreement States and their contacts can be found at <http://nrc-stp.ornl.gov> (click on your State).

**Q14. Can you suggest some approaches for conducting operations at my facility so as to minimize contamination of my facility and the environment?**

**A14.** Appropriate procedures and facility designs for minimizing contamination depend on the quantities of materials used, their chemical and physical form, and what processes are conducted with the material. Minimizing contamination can be achieved with good "housekeeping" practices, such as cleaning up spills of liquids, powders, or residues from grinding promptly before they are tracked around a facility. Procedures should be designed to reduce the likelihood of spills and to contain materials when there are spills, such as not leaving containers open unnecessarily, conducting operations on nonporous surfaces, and using absorbent covers on laboratory counter surfaces when liquids are being handled. Those general licensees using larger quantities of liquids or otherwise dispersible materials may already be using survey equipment for operational purposes; monitoring and recordkeeping may be useful for minimizing contamination in some cases. Glove boxes not only reduce intakes while processes are taking place but also contain particulates that may otherwise be spread

more widely or released to the environment. The examples discussed above are illustrative only, and are not intended to provide complete instruction on how to minimize contamination. If a general licensee is not confident in its ability to determine the best approaches to avoid significant contamination of its premises or the environment, the licensee could hire a health physics consultant.

**Q15. When I am permanently ceasing operations at my site, may I leave any contamination behind? If so, how much residual contamination is considered allowable?**

**A15.** The preference is none. In accordance with the provisions of 10 CFR 40.22(c), when activities involving generally licensed source material are permanently ceased at a site, if evidence of significant contamination is identified, the Director of FSME must be notified by one of the methods listed in 10 CFR 40.5(a). You may at that time consult with the NRC on the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material is not likely to result in exposures that exceed the limits in 10 CFR 20.1402. If significant amounts of contamination from your operation are discovered after you vacate a site, you may be liable for costs associated with the cleanup of such contamination.

**Q16. If there is residual contamination at my site, must I notify the NRC before I permanently cease operations with source material and leave the site?**

**A16.** If residual contamination is identified at the site at the cessation of operations, you must notify the NRC. This allows the NRC to determine whether it would choose to inspect the facility after all decommissioning is completed to better ensure protection of public health and safety. When you contact the NRC, you also may consult with the NRC staff to determine what actions you may need to take, if any.

**Q17. What must I do if I want to get rid of my generally licensed source material?**

**A17.** In accordance with the provisions of 10 CFR 40.22(b)(2), if you wish to get rid of generally licensed source material, you must dispose of it in one of the following ways: (1) a cumulative total of 0.5 kg of source material in solid, nondispersable form may be transferred each calendar year to persons receiving the material for permanent disposal as allowed by other Federal and State agencies; or (2) it may be disposed of in accordance with 10 CFR 20.2001, "General Requirements," or 10 CFR 40.51, "Transfer of Source or Byproduct Material" (i.e., given to a person authorized to receive the material under license or exemption).

**Q18. I plan to sell my business, and I possess and use source material as a 10 CFR 40.22 general licensee as part of my business. As paragraph 10 CFR 40.22(b)(3) indicates that I am subject to 10 CFR 40.46, "Inalienability of Licenses," do I need to get NRC approval before I sell the business?**

**A18.** If the business of using the source material is continuing, the new owner would need to individually qualify for the general license in 10 CFR 40.22 (i.e., meet the constraints of the general license—in particular, be a commercial or industrial firm, research, educational, or medical institution or Federal, State, or local government agency) or would need to be a specific licensee authorized to possess the source material. There is no transfer of your authority under the general license. If the new owner fits either of these cases, no NRC permission or notification is required. Otherwise, 10 CFR 40.46 would not allow you to transfer the business to someone not covered by 10 CFR 40.22 or an appropriate specific license without NRC

consent. If no use of the source material by the new business is anticipated, 10 CFR 40.22(b)(2) and (c) would apply, and the source material should be disposed of and any contamination dealt with before transfer of the business.

**Q19. I'm confused. Paragraph 10 CFR 40.22(b)(3) indicates that I am subject to recordkeeping requirements under 10 CFR 40.61, "Records," until the Commission terminates the license. Does the Commission normally terminate 10 CFR 40.22 general licenses? Will the NRC notify me that I am no longer considered to be a general licensee?**

**A19.** In the case of a general license, no termination of license procedure takes place. Some of the records retention periods in 10 CFR 40.61 are tied to the termination of the license and thus do not apply. For a general licensee, records retention would be tied to active possession of the source material (i.e., normally 3 years after the date of transfer or disposal of the source material). As the NRC does not actually issue an individual license to each general licensee, the NRC would not normally notify you that you no longer are a general licensee.

**10 CFR 40.52**  
**Certain Items Containing Source Material;**  
**Requirements for License to Apply or Initially Transfer**

**EXPLANATION:**

This section would establish the requirements for a specific license to distribute source material for use under the exemptions in 10 CFR 40.13(c). The proposed rule provides conditions for approval and requirements for reporting and recordkeeping, quality control, and labeling.

**QUESTIONS AND ANSWERS:**

**Q1. For what products containing source material I must I obtain a specific license to initially transfer for sale or distribution?**

**A1.** You must obtain a specific license under 10 CFR 40.52 to apply source material to, incorporate source material into, manufacture, process, produce, or initially transfer for sale or distribution the following products in the United States:

- thorium contained in incandescent gas mantles, vacuum tubes, welding rods, and electric lamps for illuminating purposes
- rare earth metals and compounds, mixtures, and products
- personnel neutron dosimeters
- piezoelectric ceramics
- glassware containing not more than 2 percent by weight source material (note that this exemption does not include commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction)
- photographic film, negatives, and prints containing uranium or thorium
- any finished product or part fabricated of or containing tungsten or magnesium-thorium alloys
- uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights
- natural or depleted uranium metal used as shielding constituting part of any shipping container
- thorium or uranium contained in or on finished optical lenses and mirrors

- thorium contained in any finished aircraft engine part containing nickel-thoria alloy

**Q2. I own a small mineral collection that contains several pieces of uranium ore. Do I need a license to sell my collection?**

**A2.** No. Unprocessed ore is exempt from any licensing requirements under 10 CFR 40.13(b). There are no requirements associated with the distribution of unprocessed ore.

**Q3. My antique store has some glazed ceramic Fiesta tableware that may contain source material. Do I need to obtain an NRC license?**

**A3.** No. Although Fiestaware is still being manufactured, all tableware that had uranium glazes added were manufactured and initially transferred long ago. This rule does not change any regulations for previously manufactured items.

**Q4. My facility is in an NRC State and I initially transfer products for use under an exemption to persons in both Agreement States and in NRC States. Am I responsible to the Agreement State or to the NRC for obtaining a specific license and for the conduct of my operations?**

**A4.** You are responsible to the NRC.

**Q5. My facility is in an Agreement State, and I transfer products for use under an exemption to persons in both Agreement States and in NRC States. Am I responsible to the Agreement State or to the NRC for obtaining a specific license and for the conduct of my operations?**

**A5.** You are responsible for obtaining an NRC specific license for the initial distribution of products containing source material specified in 10 CFR 40.13(c). Possession of the products and material comes under Agreement State regulations. Contact your Agreement State for information on additional regulatory requirements. Information on which States are Agreement States and on their contacts can be found at: <http://nrc-stp.ornl.gov/> (click on your State).

**Q6. Where would I send my application for authorization under 10 CFR 40.52 to distribute a product identified in 10 CFR 40.13(c)?**

**A6.** In accordance with 10 CFR 40.5, applications for a specific license to distribute products containing source material to persons exempt from regulation are submitted to the following NRC Headquarters Office:

Office of Federal and State Materials and Environmental Management Programs  
Division of Materials Safety and State Agreements  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Q7. In 10 CFR 40.52(a), the NRC requires an applicant for a license under that section to satisfy the general requirements specified in 10 CFR 40.32, "General Requirements for Issuance of Specific Licenses," but states that 10 CFR 40.32(b) and (c) (requirements for training and experience and for facilities and equipment to ensure radiation protection) do not apply to an application for a license to transfer products manufactured, produced, or processed in accordance with a license issued by an Agreement State. Why?**

**A7.** The NRC retains the authority to issue the distribution license for exempt products nationally, but other activities taking place within an Agreement State are regulated by the State. The Agreement State would issue a possession license for applicants to apply source material to, incorporate source material into, manufacture, process, or produce such products. Agreement State licensees are exempt from NRC regulation of these matters, because the Agreement State has licensing authority over these matters.

However, for the products identified in 10 CFR 40.13(c), where the regulation specifies a product limit on activity or concentration, an applicant for a license under 10 CFR 40.52 should be able to demonstrate and describe adequate training, experience, equipment, and facilities necessary to ensure that the activity or concentration limits are not exceeded as part of its quality assurance procedures.

**Q8. What details of the “physical and chemical form” of my product do you want to know under 10 CFR 40.52(b)(1)?**

**A8.** A “physical form” description might include such information as whether the product is made of metal, a metal alloy, a ceramic mixture, or other material. Physical form may be best described as the properties of materials and how those properties are determined by the material’s composition and structure, both macroscopic and microscopic.

The “chemical form” of the source material would be the actual chemical or molecular formula that identifies each constituent element by its chemical symbol and indicates the number of atoms of each element found in each discrete molecule of that compound. Examples might include uranium dioxide ( $UO_2$ ) or triuranium octaoxide ( $U_3O_8$ ) (the most stable form of uranium and the one most commonly found in nature).

**Q9. Paragraph 40.52(b)(1) is also asking me to provide the maximum quantity per product. How will NRC staff use this information?**

**A9.** The quantity provided to the NRC should be the total mass/weight of source material in each product. In limited cases, there are weight limits in the exemptions; thus, the NRC would be able to use this information to ensure that the products will remain within the constraints of the exemption. In addition, for any of the exemptions, the maximum weight/mass would help the NRC to evaluate the health and safety impacts of the products being distributed.

**Q10. If I am importing a finished optical system, should I provide the individual different lens weights or the weight of the finished optical product?**

**A10.** You should provide the mass of source material for each individual lens.

**Q11. I plan to manufacture depleted uranium as shielding in shipping containers, products that are frequently custom-made and where the amount of depleted uranium used can vary greatly depending on its application. What information will the NRC require me to include in my license application?**

**A11.** If there is significant variation in the products, you should provide some general information on the ranges of sizes and weights, or lists of models with more specific information. The most important information for this product would be about the labeling and encasement, to show that they will meet the constraints in the exemption (10 CFR 40.13(c)(6)).

**Q12. What information about the “details of construction and design” of my product would the NRC find “sufficient” under 10 CFR 40.52(b)(2)?**

**A12.** Because of the variety of product types identified in 10 CFR 40.13(c), the extent of information about the details of construction and design will vary depending on the product. For some products, such as welding rods; rare earth metals, compounds, and mixtures; glassware; and photographic film, negatives, and prints, sufficient information may be a description of the product and variations planned to be initially distributed. For other products, such as incandescent gas mantles, electric lamps, and tungsten parts, drawings and other details of the products may be necessary in addition to a description because such additional information may be important in evaluating the safety of the product.

Operating manuals, descriptive sales literature, or similar documents may be submitted as part of an application.

If applicable to the type of product, the applicant should describe construction aspects of the product, including components of the product, materials of construction, dimensions, and assembly methods. An overall drawing of the product identifying primary components and indicating overall dimensions is useful as a complement to the written description of the product.

**Q13. What information would I need to provide about the proposed method of labeling or marking to meet the requirement specified in 10 CFR 40.52(b)(4) for a product that’s not easily labeled, such as lenses or glassware?**

**A13.** Only two of the exemptions currently have specific labeling requirements: 10 CFR 40.13(c)(5) for counterweights, and 10 CFR 40.13(c)(6) for shipping containers. Paragraph (b) of 10 CFR 40.53, “Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports,” requires that products are labeled to meet the constraints of the exemptions. In 10 CFR 40.52(b)(4), the NRC requires all applicants to submit information on labeling to identify the manufacturer or distributor and the source material. Applicants typically provide samples or copies of labels or packaging, although descriptions could be acceptable. The NRC does not intend to make significant changes to industry practice with this requirement. Many of the products covered by the exemptions are not practical to label; and it is possible that in some cases only the packaging would be labeled. Glassware is typically labeled either with impressions or small stickers to identify the manufacturer. For some products, the initial recipient would need some information about the identity and quantity or concentration of source material. In such cases, packaging or accompanying paperwork would provide the information. In most cases, the identification of the manufacturer or distributor and the fact that thorium or uranium is present should appear on point-of-sale packaging.

**Q14. I sell uranium glass marbles (exempt under 10 CFR 40.13(c)(2)(iii)). Is a single marble a unit? What does the NRC consider to be an acceptable label for glassware containing uranium?**

**A14.** A marble might be considered a unit, but labeling of individual marbles is not expected; labeling a bag or other container of marbles would be appropriate. In the particular case of glassware, labeling that identifies the manufacturer, which is a common industry practice, would be acceptable.

**Q15. If I sell bulk quantities of coated lenses, do I need to propose labeling or marking for each item or would it be acceptable to just propose a single marking on a package that contains multiple lenses?**

**A15.** Labels on packaging of multiple lenses should be adequate as long as the information applies to all of the lenses in the package, and as long as this package is what the person installing them into a product will be receiving. It would not be appropriate to only provide it on an outer package that would be expected to be removed by someone other than the person installing the lenses.

**Q16. I will be selling bulk quantities of coated lenses. Do my customers who will be assembling the lenses into finished optical systems need to include labeling or marking information as specified in 10 CFR 40.52(b)(4)?**

**A16.** No.

**Q17. I am distributing imported finished optical systems. Does the product I am distributing require labeling?**

**A17.** Yes. The product and/or packaging should provide some information on the identity and quantity or concentration of source material. The identity of the manufacturer or distributor and the fact that thorium or uranium is present should appear on point-of-sale packaging.

**Q18. What information about radiation safety precautions and instructions relating to handling, use, and storage of my products will the NRC find acceptable under 10 CFR 40.52(b)(5)? Also, to whom do I supply these precautions and instructions?**

**A18.** In most cases, either a label or an accompanying product brochure should contain instructions for the proper handling, use, storage, and disposal of the radioactive material. The label or brochure should include basic radiation safety practices applicable to the particular product. For example, in the case of either welding rods or gas mantles, minimization of intakes is the primary point. The instructions should address the importance of ventilation and minimization of handling. Distributors of gas mantles have included such precautions on the wrap on the individual mantles. This is a good practice, although brochures provided with packages of small numbers of mantles would also be acceptable. For welding rods, information on radiation safety may be provided in material safety data sheets. Hazards presented by the dust created from grinding tips should be addressed. The intent is that the information provided on the label or in the brochure be made available to the ultimate user of the product.

**Q19. In 10 CFR 40.13(c)(6)(ii), the NRC specifies that the uranium shipping container must be encased in mild steel or equally fire-resistant metal. What is "mild steel"? What other metal is acceptable?**

**A19.** Mild steel is an iron-carbon alloy typically with a maximum of 0.25 percent carbon. It is the most common form of steel because it provides material properties that are acceptable for many applications. Its noncombustible property makes it effective as an encasement for the uranium in shipping containers. Other noncombustible metal alternatives, including stainless steel, are also commonly used in shipping containers.

**Q20. I was planning to import finished lenses that have a thorium coating and to assemble the lenses into gun scopes, binoculars, telescopes, and similar items. Do I need a specific license to assemble the coated lenses into my products?**

**A20.** No. As a result of the exemption granted in 10 CFR 40.13(c)(7), you would not need a specific license to possess the lenses and assemble them into gun scopes, binoculars, telescopes, and similar items. However, if you plan to initially transfer the products containing the lenses for sale or distribution to others, you will need to obtain a license from the NRC under 10 CFR 40.52. The lenses may not be used in eyepieces (i.e., lenses in close proximity to the eye when in use) in binoculars or in other optical instruments. Also, uranium and thorium may not be used or contained in spectacles or in contact lenses. .

The exemption in 10 CFR 40.13(c)(7) does not allow for the shaping, grinding, or polishing of such lenses or for manufacturing processes other than assembly into an optical instrument. If smoothing involves grinding or polishing, it is prohibited. A specific NRC or Agreement State license would be required to conduct these activities.

**Q21. Do I have to supply information about disposal of my product to my customers?**

**A21.** No.

**Q22. May I export my product for sale or disposal?**

**A22.** Yes. You may export your product as long as you meet any applicable requirements in 10 CFR Part 110.

**Q23. What must I do if I want to get rid of any product that I have not sold under my specific license?**

**A23.** A person who possesses a specific license under 10 CFR 40.52 must comply with the regulations in 10 CFR Part 40 for specific licensees, including the requirements for disposal or transfer of material and for decommissioning and license termination of the facility and site. The licensee could dispose of the unsold products in conjunction with the constraints of 10 CFR 20.2001, or through transfer under 10 CFR 40.51. However, any transfers for use under exemption would be required to be within the scope of the transferor's initial distribution license. If the materials were transferred otherwise to another specific licensee, that person would be required to obtain a license under 10 CFR 40.52 before distributing the products for use under exemption.

**Q24. When I am permanently ceasing operations at my site, what are the procedures that I must follow to terminate my specific license? Also, if there is residual contamination at my site, must I notify the NRC before I permanently cease operations with source material and leave the site? Will the NRC notify me that I am no longer considered to be a specific licensee?**

**A24.** The requirements for terminating a specific license for source material are in 10 CFR 40.42, "Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas." You are not required to notify the NRC before permanently ceasing operations, but you must provide notice within 60 days afterwards and under other circumstances. Under 10 CFR 40.42(k), the NRC terminates the specific license by notifying the licensee when certain conditions are met. The licensee cannot abandon the site

until this has happened. If the licensee is in an Agreement State and only has a license from the NRC for distribution of products for use under an exemption, the Agreement State would be authorizing possession under either a general or specific license and would be the one to determine if contamination has been adequately cleaned up.

An importer of finished products for use under an exemption who does not have other licensed material would be exempt from 10 CFR Part 20, including 10 CFR 20.1402. However, 10 CFR 40.42 would still apply. In this case, many aspects of 10 CFR 40.42 are not relevant, but the NRC would require certification of disposition of materials and would terminate the license (see 10 CFR 40.42(j)(1) and (k)(1)).

**10 CFR 40.54**  
**Requirements for License to Initially Transfer Source Material for Use**  
**Under 10 CFR 40.22**

**EXPLANATION:**

This section would establish the requirements for a specific license to distribute source material for use under the general license in 10 CFR 40.22. The proposed rule provides conditions for approval for the initial distribution and requirements for reporting and recordkeeping, notifications, and labeling.

**QUESTIONS AND ANSWERS:**

**Q1. I am located in an NRC State. Where would I send my application for a specific license to receive authorization under 10 CFR 40.54 to distribute source material to 10 CFR 40.22 general licensees?**

**A1.** Applications to distribute source material pursuant to a 10 CFR 40.22 general license should be sent to the NRC regional office. Addresses can be obtained from the NRC Web site at <http://www.nrc.gov/about-nrc/locations.html>.

**Q2. I am located in an Agreement State. Where would I send my application for a specific license to receive authorization to distribute source material to 10 CFR 40.22 general licensees?**

**A2.** You would need to contact your State regulatory agency for more information. Information can be obtained from the NRC Web site at <http://nrc-stp.ornl.gov/asdirectory.html>.

**Q3. I am located in an NRC State and supply materials containing source material to persons in both Agreement States and NRC States for initial use under a 10 CFR 40.22 general license (or its Agreement State equivalent). Am I responsible to the Agreement State or to the NRC for obtaining a specific license and for conduct of my operations?**

**A3.** If your business is located in an NRC State, your license to initially transfer source material for use under 10 CFR 40.22 would be issued by the NRC, and you would be responsible to the NRC.

**Q4. My facility is located in an Agreement State, and I supply materials containing source material to persons in both Agreement States and NRC States for initial use under the general license in 10 CFR 40.22 (or its Agreement State equivalent). Am I responsible to the Agreement State or to the NRC for obtaining a specific license and for conduct of my operations?**

**A4.** If your business is located in an Agreement State, you are subject to your State's regulatory requirements for the distribution of small quantities of source material.

**Q5. Can I import and possess source material under the 10 CFR 40.22 general license even though it was not transferred to me by a person licensed under 10 CFR 40.54?**

**A5.** Yes, as long as the source material was imported under the appropriate requirements in 10 CFR Part 110. However, should you wish to transfer such source material to other general licensees, you would be required to obtain a specific license in accordance with 10 CFR 40.54.

**Q6. May I export my product for sale or disposal?**

**A6.** To the extent that such exportation is authorized under the provisions of 10 CFR Part 110, you may export source material possessed under exemption.

**Q7. I am a source material licensee located in an Agreement State. Can I transfer source material to a 10 CFR 40.22 general licensee located in an NRC State even though my State has not modified its regulations to require that I obtain a license similar to 10 CFR 40.54?**

**A7.** The requirement in 10 CFR 40.22(e) only applies to initial distributors in NRC States. If you are the initial distributor and are located in an Agreement State that has yet to incorporate such requirements, you do not need to obtain a license from the NRC or the Agreement State until such time that the Agreement State conforms its regulations or otherwise indicates that such a requirement is applicable.

**Q8. What is the adequate information about appropriate radiation safety precautions and instructions related to the handling, use, storage, and disposal of the source material in my product that the NRC will find acceptable? Also, to whom do I supply these instructions and by what method do I supply them?**

**A8.** What is adequate and appropriate safety instruction depends on the amount and type of material the user is obtaining. Instructions should include such statements as “The basic radiation principles of time, distance, and shielding should be practiced as effective methods for minimizing exposure”; “Eating, drinking, smoking, and the application of cosmetics should be prohibited in areas of use”; “Gloves and laboratory coats should be worn when working with liquid radioactive material”; and “All radioactive materials should be securely stored when not in use.” Reference to or a summary of 10 CFR 40.22(b)(2) would be useful, even though copies of 10 CFR 40.22 in its entirety must also be provided (see 10 CFR 40.55(c)(1)). The application under 10 CFR 40.54 should also indicate how the applicant will ensure that the information is provided before transfer of the source material, particularly as purchases are now typically made over the Internet.

**Q9. What information for labeling my product would the NRC find acceptable?**

**A9.** In 10 CFR 40.54(b), the NRC requires the applicant for a license to distribute source material to 10 CFR 40.22 general licensees to submit information on how it would label its products. Applicants typically provide samples or copies of labels or packaging, although descriptions could be acceptable. Information on how the labels would be adhered and how they would remain legible during normal conditions of use should be addressed. In 10 CFR 40.55(a), “Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports,” the NRC requires those licensed under 10 CFR 40.54 to label the immediate container of each quantity of source material with the type of source material, the quantity of material, and the words “radioactive material.” The applicant must

commit to labeling in accordance with that requirement. The submission of generic labels or a statement indicating that the required information will be contained on the label may be acceptable, provided that the required information remains as submitted and meets the necessary requirements. This allows licensees to change other information on the labels, such as brand names or telephone numbers, without having to amend their license.

**Q10. How do I ensure to the NRC's satisfaction that the quantities and concentrations of source material in my product are as labeled and indicated in my transfer records?**

**A10.** In 10 CFR 40.54(b), the NRC requires the applicant to submit information on how it would conduct quality control. Paragraph (b) of 10 CFR 40.55 requires those licensed under 10 CFR 40.54 to ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records. Therefore, quality control procedures should address the determination of quantity and concentration and how these determinations are made and used for labeling and recording transactions. It is important to ensure that the user obtains the correct material in the correct quantity or concentration that was ordered, and that it is labeled accordingly. At a minimum, the applicant should provide assurance, with a reasonable tolerance, that users would not be exposed to larger quantities or concentrations than they are expecting. Applicants may submit a quality assurance program instead of or in conjunction with a quality control program. Typically, applicants commit to adhering to a particular standard for quality assurance, such as an International Organization of Standardization or an American National Standards Institute quality assurance program standard.

**Q11. I am a 10 CFR 40.54-type licensee located in an Agreement State. With whom at the NRC should I be filing a report as specified in 10 CFR 40.55(d)?**

**A11.** When your State implements equivalent regulations, you would submit such a report to:

Director, Office of Federal and State Materials and Environmental Management  
Programs  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

**Q12. If I transfer less than 50 grams of source material to a general licensee, am I relieved of the reporting requirements of 10 CFR 40.55(d)?**

**A12.** No. Under 10 CFR 40.55(d)(1), you must still file a report with the Director of FSME indicating the name, address, and license number of the person who transferred the source material (i.e., you) and the total quantity of each type and physical form of source material transferred in the reporting period to all generally licensed recipients. Even if you did not transfer any source material during the reporting period, you must indicate such in your report. You must file the report by January 31 of each year, covering all transfers for the previous calendar year. In addition, you must maintain all information that supports the required reports for a period of 1 year after the event is included in a report. Under 10 CFR 40.55(d)(2), you would have to provide reports to an Agreement State only if you transferred more than 50 grams of source material, during each quarter within the reporting period, to a general licensee in that Agreement State.

**Q13. What must I do if I want to get rid of any material in my possession that I have not initially distributed to general licensees under my specific license?**

**A13.** A person who possesses a specific license under 10 CFR 40.54 must comply with the regulations in 10 CFR Part 40 for specific licensees, including the requirements for disposal or transfer of material and for decommissioning and license termination of the facility and site. Under these regulations, a specific licensee could dispose of the material within the constraints of 10 CFR 20.2001 or through transfer under 10 CFR 40.51. However, any transfers for use under general license would be required to be within the scope of the licensee's initial distribution license.

**A13.** A person who possesses a specific license under 10 CFR 40.54 must comply with the regulations in 10 CFR Part 40 for specific licensees, including the requirements for disposal or transfer of material and for decommissioning and license termination of the facility and site. Under these regulations, a specific licensee could dispose of the material within the constraints of 10 CFR 20.2001 or through transfer under 10 CFR 40.51. However, any transfers for use under general license would be required to be within the scope of the licensee’s initial distribution license.

OFFICE	MSSA	MSSA	MSSA	OGC (NLO)	FSME	MSSA
NAME	LCD LDimmick	JFoster	With comments JLuehman	CStokes via e- mail	CPoland	RLewis
DATE	11/ 12 /10	11/ /10	11/ 12/10	12/ 02 /10	11/ /10	11/ /10

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