GUIDANCE FOR IMPLEMENTATION
OF THE FINAL RULE
"DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS"
10 CFR PARTS 30, 40, 70, 170, and 171

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U.S.NRC
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Protecting People and the Environment

GUIDANCE FOR IMPLEMENTATION OF THE FINAL RULE "DISTRIBUTION OF SOURCE MATERIAL TO EXEMPT PERSONS AND TO GENERAL LICENSEES AND REVISION OF GENERAL LICENSE AND EXEMPTIONS" 10 CFR PARTS 30, 40, 70, 170, AND 171

Introduction

This document provides guidance to licensees and applicants for implementing the U.S. Nuclear Regulatory Commission's (NRC's) final rule, "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 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 issued the final rule on May 29, 2013 (78 FR 32310). On January 7, 2011, the NRC published the draft guidance for public comment (76 FR 1100; corrected by 76 FR 8314; February 14, 2011). This guidance has been revised for consistency with the final rule and in response to comments. 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 regulatory 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.

The guidance in this document is provided in the form of questions and answers pertinent to the following sections of the final 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 source material?

A1. 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. Source material does not include special nuclear material. Although source material is found in nature, it does not fall under regulation until its removal from its place in nature. It should be noted that certain isotopes of uranium and thorium, that exist only as a product of reactions occurring in nuclear reactors or in an accelerator, are not considered to be source material and are instead regulated as byproduct material as defined in 10 CFR 30.4, "Definitions."

Q2. What is a specific license?

A2. A specific license is a license issued to a named person who has filed an application for the license with the NRC in accordance with the regulations. For source material, the application would be filed under 10 CFR Part 40.

Q3. How do I obtain a specific license?

A3. 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. This form would be used for all license applications under 10 CFR Part 40, such as for possession and use of source material or for initial distribution of source material to persons for use under an exemption or a general license.

Q4. What is a general license, and do I need to apply for one?

A4. A general license is a license that is provided by regulation and is effective without the filing of an application. As such, no licensing documents are issued to a particular person. There are a number of general licenses granted in 10 CFR Part 40, but the primary general license addressed by the rulemaking is 10 CFR 40.22, "Small quantities of source material."

Q5. What is an exemption?

A5. An exemption provides relief from the regulations. In this rule, the NRC discusses exemptions from licensing requirements that are provided in the regulations in 10 CFR 40.13, "Unimportant quantities of source material." There is no requirement to apply for a license for possession and use of materials that fall within the constraints of such an exemption. Normally, a person possessing a product to which an exemption applies does not have any restrictions on its use and possession, as long as the person does not modify the product. However, on 10 CFR Part 40, 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 that are not covered by the exemption.

Q6. When is a license required to possess source material?

A6. Source material only falls under NRC licensing authority after its removal from its place in nature. However, a license is not necessary if the source material meets any of the conditions for exemption under 10 CFR 40.13. Thus, no license is required for certain products described in 10 CFR 40.13(c) or if the material containing source material has a concentration of less the 0.5 percent by weight of the source material (10 CFR 40.13(a)). Also included is an exemption (10 CFR 40.13(b)) for any ores that are "unprocessed and unrefined" as defined in 10 CFR 40.4, "Definitions."

Q7. What is depleted uranium?

A7. Depleted uranium is uranium with a percentage of uranium-235 (U-235) less than 0.711 percent (by mass) of total uranium, which is the concentration of U-235 normally found in natural uranium. The typical 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 of the uranium. Depleted uranium is produced during uranium isotope separation (enrichment) and is typically stored or disposed of as a waste or used in other products such as shielding or aircraft counter weights.

Q8. What does "initial(ly) transfer" mean?

A8. 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.

Q9. How do I handle submittals of information requested by the NRC that I believe are proprietary? Do I need to submit the information? Will the NRC protect such information submitted from disclosure?

A9. The NRC has procedures in place for protecting proprietary information. Any information required to be submitted is considered pertinent to allow the NRC and the Agreement States to properly evaluate issues related to determining the health and safety of an activity or product. Applicants and licensees requesting information to be treated as proprietary must submit the information using the requirements in 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing your submittal.

10 CFR 40.13
Unimportant Quantities of Source Material

EXPLANATION:

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

QUESTIONS AND ANSWERS:

Q1. What products containing source material 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 NRC requirements that I must comply with?

A3. As long as you operate within any restrictions in the exemptions, there are no NRC 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 before or after I receive the source material to be possessed under the exemption?

A4. No.

Q5. What is "unrefined and unprocessed ore" under 10 CFR 40.13(b)?

A5. Unrefined and unprocessed ore is ore that has been removed from its place in nature and has not been processed (i.e., no chemical or physical changes have been made to the ore itself). Activities such as grinding, roasting, or beneficiating (i.e., preparing the ore for smelting) are considered processing. Activities directly related to prospecting are not considered to be processing. Additionally, other activities such as encapsulating ore samples or sieving (separating individual pieces of ore by size such as sand particles) are not considered to be

processing, because they don't physically or chemically change the ore itself. Similarly, mineral samples containing uranium or thorium would also be considered as unprocessed ore to the extent that the mineral samples were in the same physical condition as found in nature and not polished, ground, or otherwise physically or chemically processed.

Q6. Do I need a license if I'm only analyzing the chemical content of an otherwise unprocessed ore? Otherwise, if I am analyzing ores to determine chemical content, wouldn't I be in violation of NRC requirements if I determine that the ore contains licensable concentrations of source material and I don't have a license?

A6. No, you do not need a license to analyze the chemical content of an otherwise unprocessed ore. For the purposes of the exemption in 10 CFR 40.13(b), if an unprocessed ore is analyzed to evaluate its chemical content, the NRC has made a determination that the ore sample is to continue to be considered as "unprocessed and unrefined," despite the potential for chemical and physical changes to the ore that may occur during the analytical process. This is to alleviate potential violations where a laboratory may unexpectedly identify source material in an unprocessed ore that would normally require licensing, but the laboratory does not already have a license for the unexpected source material; instead, the laboratory may continue to treat the processed sample as unprocessed ore under the exemption in 10 CFR 40.13(b). The NRC anticipates that only small quantities of source material would normally be needed for these purposes.

However, if an the ore undergoes additional processing for reasons other than analyzing the chemical content of the sample, the material would no longer fall under the exemption from licensing in 10 CFR 40.13(b), and a license would be required prior to the onset of the additional processing of the ore sample, unless the additional processing fell under another applicable exemption.

Q7. May I initially transfer or distribute source material to persons exempt under 10 CFR 40.13(c)?

A7. You may not initially transfer for sale or distribute a product containing source material to a person exempt from the regulations under 10 CFR 40.13(c) unless it is authorized by a specific license under 10 CFR 40.52, "Certain Items Containing Source Material; Requirements for License to Apply or Initially Transfer" (see 10 CFR 40.13(c)(10)). However, if you are already initially distributing such source material before August 27, 2013 without specific authorization, you may continue to do so until August 27, 2014. 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 August 27, 2014. Persons legally importing small quantities of products for possession under an exemption for personal use would not normally be required to obtain a specific license for distribution of those products to the extent they do not subsequently transfer the product for sale or distribution.

Q8. May I import exempted source material and receive, possess, use, or transfer it?

A8. 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 exemptions provided in 10 CFR 40.13.

If you import source material that is exempted under 10 CFR 40.13(c) for the purpose of sale or distribution, you are required to obtain a specific license from the NRC in accordance with

10 CFR 40.13(c)(10) and 10 CFR 40.52 before such distributions. If you are already initially distributing such imported source material before August 27, 2013 without specific authorization, you may continue to do so until August 27, 2014 without a specific license authorizing such distribution. In addition, such initial distribution may 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 August 27, 2014.

Q9. May I export the exempted source material that I have for sale or disposal?

A9. To the extent such exportation is authorized under the provisions of 10 CFR Part 110, you may export source material. A specific license issued under 10 CFR 40.52 is not required for initial distributions that are directly exported.

Q10. If I meet the requirements for an exemption, are there any NRC requirements for disposing of or transferring my exempted source material?

A10. Generally, no. However, the restrictions in 10 CFR 40.13(c)(5) may impact the disposal or transfer options for aircraft counterweights as discussed in RIS-01-013, "10 CFR Part 40 Exemptions For Uranium Contained in Aircraft Counterweights."

Q11. 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 or after I dispose of the source material?

A11. No.

Q12. I bought a piece of glazed ceramic tableware that contains source material. Do I or the seller need to determine if it meets the constraints of the exemption or confirm the manufacture date?

A12. No. Neither you nor a seller is required to determine if the product falls within the constraints of the exemption. In all likelihood, the seller of such products today would in fact be a reseller (e.g., a dealer in antiques) and not a manufacturer, because the manufacture of such products is believed to have ended long ago. A reseller would have obtained the tableware under the exemption and would be unlikely to be able to, and is not required to verify the manufacture date or uranium content of the tableware. In addition, in accordance with 10 CFR 40.13(c)(2)(i), glazed ceramic tableware is no longer allowed to be manufactured for use under the exemption or imported if manufactured after August 27, 2014.

Q13. I bought glassware containing source material. Do I or the seller need to determine if it meets the constraints of the exemption or to confirm the manufacture date?

A13. No, neither you nor the seller, unless the seller is the initial distributor (usually the manufacturer or an importer) of the product, is required to determine if the product falls within the constraints of the exemption. If you have glassware containing source material that was manufactured before August 27, 2014, it is assumed to meet the 10-percent limit that was permitted at the time of manufacture under 10 CFR 40.13(c)(2)(iii). Otherwise, the glassware is assumed to meet the 2-percent limit currently identified in 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 of these products to ensure that the products are manufactured in accordance with the exemption.

Q14. Does the exemption provided by 10 CFR 40.13(c)(2)(iii) extend to ceramics used in industries other than residential or commercial building construction, given the exclusion of ceramic in construction and the fact that other exemptions cover certain ceramics?

A14. No. The fact that there are other exemptions that cover other specific types of ceramics is evidence that the exemption in 10 CFR 40.13(c)(2)(iii) is not meant to cover all ceramics (other than building construction). The phrasing is used because some ceramics may include a glazing that could be considered to be glass and thus are not appropriate for residential or other building construction uses.

Q15. How can I determine if a gun scope or other optical instrument is coated with or contains source material?

A15. Packaging or labeling of the gun scope or other optical instrument may identify whether source material was used in the product. Otherwise, there is no easy way for a consumer to determine if an optical instrument's eyepiece is coated with source material other than contacting the manufacturer of the gun scope or optical instrument.

Q16. I have finished optical lenses and mirrors with thorium or uranium in or on them. Do I need to determine if they meet the constraints of the exemption?

A16. No. If you have finished optical lenses with thorium contained within the lenses that were manufactured before August 27, 2013, the assumption is that the lenses contain no more than the 30 percent by weight of thorium that was permitted at the time of manufacture in accordance with the 10 CFR 40.13(c)(7), and continue to be exempt from licensing. Otherwise, the lenses are assumed to meet the 10 percent weight limit in the current 10 CFR 40.13(c)(7). It is the burden of the initial distributor of these products to ensure that the products are manufactured in accordance with the exemption.

Please note that the exemption in 10 CFR 40.13(c)(7) 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 alteration of the lens or mirror, nor does it authorize 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)).

Q17. Are there any restrictions on how optical lenses with thorium or uranium in or on them might be used in my products that I plan to distribute?

A17. 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. As long as you did not manufacture the lenses themselves and do not modify the lenses that contain source material, you would have no additional requirements from NRC related to the lenses or the product containing the lenses. If you do alter (e.g., shape, grind, or polish) the lenses containing source material or initially apply a coating of source material to the lenses prior to or during installation in a final product, you need a license to do so. In addition, if you plan to subsequently transfer or distribute those modified products to another person for possession and use under the exemption in 10 CFR 40.13(c)(7), you need a specific license authorizing initial distribution of the product under 10 CFR 40.52 (see 10 CFR 40.13(c)(10)), because this is considered to be initial distribution of a new product.

Q18. 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?

A18. 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 and a specific license authorizing initial distribution of the product under 10 CFR 40.52 (see 10 CFR 40.13(c)(10)) would be needed if the altered products were to be subsequently transferred or distributed.

Q19. Are windows coated with or containing uranium or thorium exempt from licensing under 10 CFR 40.13(c)(7)?

A19. No. The exemption is only applicable to lenses that are defined by the Merriam-Webster Dictionary as "a piece of transparent material (as glass) that has two opposite regular surfaces either both curved or one curved and the other plane and that is used either singly or combined in an optical instrument for forming an image by focusing rays of light." As the purpose of a window is to only transmit light (not reflect or focus it), the NRC does not consider a window to be a lens or mirror falling under the exemption.

Q20. If a lens or mirror contains less than 0.05 percent by weight of uranium or thorium, may I distribute the lens or mirror under the exemption in 10 CFR 40.13(a) in order to avoid having to obtain a specific license issued under 10 CFR 40.52 for distributing products for use under exemption?

A20. When determining the applicable exemption, it would be inappropriate to use the exemption in 10 CFR 40.13(a) for a product in which the source material is intentionally applied or included, because there is a specific exemption that is more applicable to the product. As a result, in order to distribute such products, you are required to obtain a specific license authorizing distribution under 10 CFR 40.52.

Q21. Under 10 CFR 40.13(c)(10)(ii), is a person who is located in an Agreement State and processes source material to produce one of the products identified in 10 CFR 40.13(c) exempt from the Agreement State's regulations that are comparable to 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," and 10 CFR Part 20, "Standards for Protection Against Radiation"?

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 in an Agreement State would still be required to meet all applicable regulations of the Agreement State in which the licensee is located, including those comparable to NRC's 10 CFR Parts 19 and 20.

10 CFR 40.22
Small Quantities of Source Material

EXPLANATION:

Under the revision to 10 CFR 40.22, the general license is limited to thorium and uranium in their natural isotopic concentrations and depleted uranium. The final rule modifies the existing possession and use requirements of the general licensee. The final rule clarifies 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. Who is considered to be a person for the purposes of the 10 CFR 40.22 general license?

A2. Section 40.4 defines a person to be "[a]ny individual, corporation, partnership, firm, association, trust, estate, public or private institution, group…and any legal successor, representative, agent, or agency of the foregoing." Section 40.22, though, clearly lists a subset of persons for whom the 10 CFR 40.22 general license is applicable. For example, the omission of "individuals" as an authorized class in 10 CFR 40.22 means that an individual may not possess source material under a 10 CFR 40.22 general license and would instead need to apply for a specific license.

A "person" authorized under 10 CFR 40.22 is not necessarily the largest entity in a class of the listed users. A separate general license is applicable to each unit of the entity that is physically separate from other units. The purpose of the physical separation is to make it unlikely that more than the allowed amount of source material could be brought together in a single location. As such, the NRC has normally considered separate facilities operated by the same entity to be separate general licensees, even if both facilities are in different parts of the same city. Use and storage locations within the same building, complex, or campus are considered the same location.

Q3. What is a small quantity of source material under 10 CFR 40.22?

A3. 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 dispersible forms at any one time and not more than a total of 7 kg (15.4 lb) of uranium and thorium in dispersible forms in any one calendar year (any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form even after processing is completed); and (2) not more than a total of 7 kg

(15.4 lb) of uranium and thorium at one time and not more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. Although the latter possession limits include source material possessed in a dispersible form, they do not increase the amount of uranium and thorium that is allowed to be possessed in a dispersable form and instead represent the total amount of uranium and thorium in both dispersible and non-dispersible forms that you may possess at any one time and receive in total over a calendar year.

An exception to the limits applies for uranium removed during the treatment of drinking water and for source material used at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed. For these two activities, a person operating under the 10 CFR 40.22 general license may possess a total of up to 7 kg (15.4 lb) of uranium and thorium at one time and up to 70 kg (154 lb) during a calendar year, regardless of form or process.

Q4. What if I possess more than the limit in 10 CFR 40.22 for dispersible forms when the rule becomes effective?

A4. The rule gives you one year from the effective date of the rule to apply for a specific license for possession of the source material. As a result, you have until August 27, 2014 to apply for a specific license in order to continue to use more source material than the new general license limits. If you have applied for a specific license within that year, the general license permits you to continue operating under the previous limits until the NRC has completed action on your specific license application. If you choose not to apply for a specific license, you must reduce your possession of source material to within the new limits by December 31, 2014.

Q5. What are uranium and thorium in their natural isotopic concentrations?

A5. Uranium and thorium in their natural isotopic concentrations have not undergone processing to separate or enrich individual isotopes of 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.

Q6. May I possess separated isotopic concentrations of uranium or thorium under the 10 CFR 40.22 general license?

A6. Other than depleted uranium (primarily U-238), you may <u>not</u> possess uranium or thorium that has been separated by isotope under the 10 CFR 40.22 general license. Instead, you would need to apply for a specific license to possess those isotopes. Additionally, for isotopes of uranium or thorium that are produced only as a result of a reaction in a nuclear reactor or by an accelerator, you would need to apply for a specific license under 10 CFR Part 30 for the possession and use of byproduct material for those isotopes of uranium and thorium.

Q7. Are there any restrictions on processing or using source material under the 10 CFR 40.22 general license?

A7. 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 only a few restrictions on how you may process or use the source material: (1) you may not administer the source material (or radiation from it) either externally or internally to human beings; (2) you may not concentrate or extract uranium or thorium in ores if the primary purpose of the process is to concentrate or extract the source material because you would create waste, which is considered 11e.(2) byproduct material and would require a specific license to possess; and (3) you may not isotopically separate any of the isotopes of uranium or thorium, because then you would possess uranium or thorium no longer in its natural isotopic concentration. 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 or process more than 7 kg of source material in any calendar year.

Q8. With what requirements must I comply if I have source material generally licensed under 10 CFR 40.22?

A8. The NRC's requirements for using source material under the general license for small quantities of source material are contained or referenced in 10 CFR 40.22(b) through (e), and are summarized as follows:

- Paragraph 40.22(b) requires that persons receiving, possessing, using, 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 radiation to human beings; (2) they may not abandon the source material and must dispose of it under the requirements in 10 CFR 40.22(b)(2)(i) and (ii); (3) they are subject to the provisions in 10 CFR 40.1 through 40.10, 40.41(a) through (e), 40.46, 40.51, 40.60 through 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) exempts a general licensee 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, "Requirements for License to Initially Transfer Source Material for Use Under 10 CFR 40.22."

Q9. What is considered to be "dispersible" uranium and thorium?

A9. Source material is considered to be dispersible if it is in a form that can be readily ingested or inhaled (i.e., could be breathed in or swallowed by accident). For example, the material would be considered to be dispersible if it were in a form of a powder or liquid. For the

purposes of the general license in 10 CFR 40.22, source material in solid form, but small enough to inadvertently ingest, such as small pellets or beads, would also be considered to be dispersible.

Q10. What activities would be considered as altering the chemical or physical form of the source material?

A10. Any activity which changes the size or composition of the material containing the uranium or thorium would be considered as altering its chemical or physical form. This would include activities such as grinding or cutting the material, heating the material to the extent it results in off-gassing, melting, or making other chemical changes to the material containing the uranium or thorium (even if the uranium or thorium itself is not affected). Activities such as encapsulating the material in another material (as long as the original material is not changed) or division of already separated pieces (e.g., rocks from sand) would not be considered as changing the physical or chemical form of the source material.

Q11. Must I contact the NRC before possessing source material under the 10 CFR 40.22 general license?

A11. No. You are not required 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 if you have identified significant source material contamination, you must notify the NRC about the contamination under the requirements in 10 CFR 40.22(c).

Q12. May I initially transfer or distribute source material under my general license to other persons who are generally licensed?

A12. 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 receive source material directly from a specific licensee authorized for initial distribution or from another 10 CFR 40.22 general licensee who received the source material from a specific licensee. However, because uranium or thorium can be extracted from or concentrated in previously unlicensed materials 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 and the 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), “Transfer or source or byproduct material”).

Q13. 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?

A13. You should directly contact the recipient to determine if the recipient is authorized to receive the source material and whether it is receiving the material under a general license, a specific license, or other authorization. If you determine that the recipient will possess the source material under a general license and you plan to initially transfer the source material to the recipient for possession under the general license, you are required to obtain a specific license in accordance with 10 CFR 40.22(e) and 10 CFR 40.54. If you prefer not to obtain a license under 10 CFR 40.54, you could require the recipient to obtain a specific license authorizing the possession of the source material prior to any transfer. If the recipient obtains or already 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). In this case, you would not need to obtain a specific license issued in accordance with 10 CFR 40.22(e) and 10 CFR 40.54.

Q14. May I export the generally licensed source material that I have for sale or disposal?

A14. Yes, but only under the provisions of 10 CFR 40.22(b)(5) and 10 CFR 40.51(b)(6) (i.e., in accordance with 10 CFR Part 110). A specific license issued under 10 CFR 40.54 is not required for initial distributions that are directly exported.

Q15. How do I determine if there is significant contamination at my facility because of my operations under the 10 CFR 40.22 general license?

A15. The NRC expects that evidence of significant contamination can be made through visual inspection (e.g., there are particulates remaining from operations on surfaces such as floors, glove boxes, vents, etc.) as well as through the review of historical information about the quantities of materials used, how they were processed, and whether spills occurred. If there is doubt as to whether remaining contamination may be considered to be significant, the licensee should consult with the NRC or a health physics consultant.

Q16. Whom 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?

A16. 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 NRC 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). NRC or Agreement State staff may be able to advise whether sampling or cleanup is necessary, or how and where to locate a health physics contractor.

Q17. Can you suggest some approaches for conducting operations at my facility so as to minimize contamination of my facility and the environment?

A17. 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. Any release of source material to the site should be avoided.

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 in some cases in order to identify contamination to clean up promptly or to improve procedures, as well as to aid in any eventual cleanup when activities involving source material are completed. 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. Contaminating inaccessible areas, such as buried piping, should be avoided. Using dispersible forms of source material in dedicated areas, separate from other processes, may be appropriate in some circumstances.

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.

Q18. When I am permanently ceasing operations at my site, may I leave any contamination behind? If so, how much residual contamination is considered allowable?

A18. The preference would be for no contamination to be left behind. 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 (see Q15 in this section), 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 resulting in exposures above the levels found in 10 CFR 20.1402 are discovered after you vacate a site, you may be liable for costs associated with the cleanup of such contamination.

Q19. 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?

A19. If you identify or are concerned that there may be significant contamination remaining at the site at the cessation of operations, you must notify the NRC before you leave the site. When you contact the NRC, you may consult with the NRC staff to determine what actions, if any, you may need to take. The NRC, at its option, may decide to inspect the facility after all decommissioning is completed to better ensure protection of public health and safety.

Q20. What must I do if I want to get rid of my generally licensed source material?

A20. 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; (2) the source material may be disposed of in accordance with 10 CFR 20.2001, "General Requirements"; or (3) the source material may be transferred to another person in accordance with 10 CFR 40.51 (e.g., given to a person authorized to receive the material under license).

Q21. 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?

A21. 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, and you should contact the NRC for further direction.

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.

Q22. Paragraph 10 CFR 40.22(b)(3) indicates that I am subject to recordkeeping requirements under 10 CFR 40.61, "Records." However, certain paragraphs in 10 CFR 40.61 require me to retain 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?**

A22. 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 a specific license and thus those requirements do not apply. For a general licensee, records retention would be tied to active possession of the source material (e.g., normally 3 years after the date of transfer or disposal of the source material per 10 CFR 40.61(a)(1)). Generally, as the NRC does not actually issue an individual license to each general licensee, the NRC would not 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 establishes the requirements for a specific license to distribute source material for use under the exemptions in 10 CFR 40.13(c) or equivalent provisions of an Agreement State. The final rule provides conditions for approval of a license under 10 CFR 40.52 and requirements for reporting and recordkeeping, quality control, and labeling in 10 CFR 40.53, "Conditions of licenses issued under § 40.52: Quality control, labeling, and records and reports."

QUESTIONS AND ANSWERS:

Q1. For what products containing source material 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. Note that if you plan to take any actions to process the ore samples, you will need a license before doing the processing.

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? What fees would I have to pay?

A4. You are responsible for obtaining a specific license authorizing initial distribution and any necessary possession licenses from the NRC. In addition to any fees applicable to a license for possession of the source material, you would be responsible for a separate license application fee and annual fee for your distribution license. The costs for these fees can be found in Category 2.C in the tables in 10 CFR 170.31, "Schedule of fees for material licenses and other regulatory services, including inspections, and import and export licenses" and 10 CFR 171.16, "Annual fees: Material licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC," respectively.

Q5. My facility is in an Agreement State, and I transfer products for use under an exemption to persons in both Agreement States and 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? What fees would I have to pay?

A5. Even if you are located in an Agreement State, 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). However, the possession and use of the products and material prior to initial distribution continue to be regulated under Agreement State regulations. Contact your Agreement State for information on additional regulatory requirements. Information on which States are Agreement States and on who to contact can be found at: http://nrc-stp.ornl.gov/ (click on your State).

In addition to any fees required by the Agreement State that are applicable for possession of the source material, you would be responsible to NRC for a license application fee and annual fees for your distribution license. The costs for these fees can be found in Category 2.C in the tables

in 10 CFR 170.31 and 10 CFR 171.16, respectively.

Q6. I am only distributing products containing source material that I imported as a finished product that falls under an exemption in 10 CFR 40.13(c). I am not changing the finished product itself, although I may install the product, as intended, into another product. What kind of license(s) would I need to distribute these products and from whom should I obtain the license(s)? What fees would I have to pay?

A6. Under 10 CFR 40.13(c)(10)(ii), if you are only importing finished products containing source material that fall under an exemption in 10 CFR 40.13(c), or an Agreement State equivalent, and you distribute them without modification, you would only need to apply for a specific license for initial distribution issued under 10 CFR 40.52. You would obtain this license from the NRC, regardless of whether your operations are located in an Agreement State. In this situation, you do not need to apply for a possession license, because you would continue to possess the products under the applicable exemption.

Because you are only receiving a license for distribution of source material, you would only be responsible to the NRC for a license application fee and annual fees for your distribution license. The costs for these fees can be found in Category 2.C in the tables in 10 CFR 170.31 and 10 CFR 171.16, respectively.

Q7. Where should I send my application for authorization under 10 CFR 40.52 to distribute a product identified in 10 CFR 40.13(c)?

A7. In accordance with 10 CFR 40.5, "Communications," applications for a specific license to initially transfer for sale or distribution any products containing source material to persons exempt from regulation must be submitted to:

> Director, Office of Federal and State Materials and Environmental Management Programs
> ATTN: Document Control Desk
> U.S. Nuclear Regulatory Commission
> Washington, DC 20555-0001

It would be helpful if you inserted "Division of Materials Safety and State Agreements" after the ATTN: line in order to expedite the delivery of this type of application to the responsible reviewing organization.

Q8. 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?

A8. The NRC retains the authority to issue the distribution license for exempt products nationally, but most other activities taking place within an Agreement State are regulated by the Agreement State. The Agreement State is responsible for issuing a possession and use license for applicants, and will address matters such as in-plant safety, effluents, and ultimately

decommissioning. Agreement State licensees are exempt from NRC regulation of these matters, because the Agreement State has licensing authority over these matters.

However, for any 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 must propose procedures and standards for quality control, and there may be aspects of training, experience, equipment, and facilities relevant to the applicant's ability to ensure that the activity or concentration limits are not exceeded, because this information would be considered part of its quality control program.

Q9. What details of the "physical and chemical form" of my product do I need to include in my application in response to the requirement in 10 CFR 40.52(b)(1)?

A9. 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).

Q10. Paragraph 40.52(b)(1) is also asking me to provide the maximum quantity per product as part of my application. How will NRC staff use this information?

A10. 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.

Q11. As part of my application for a specific license for initial distribution, if I am importing a finished optical system, should I provide the individual different lens weights or the weight of the finished optical product in response to the requirement in 10 CFR 40.52(b)(1)?

A11. To the extent practicable, you should provide the quantity (weight) of source material contained on or in each individual lens. You should also provide the weight of each lens in order to demonstrate compliance with 10 CFR 40.52(c), that the concentration (weight percent) does not exceed the applicable limit.

Q12. I plan to manufacture depleted uranium as shielding in shipping containers. My products are frequently custom-made, and the amount of depleted uranium used can vary greatly depending on the customer's need. What information will the NRC require me to include in my license application?

A12. If there is significant variation in the products, you should provide some general information on the ranges of sizes and weights, and/or lists of models with more specific

information to the extent practical. 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)).

Q13. What information about the "details of construction and design" of my product would the NRC find "sufficient" under 10 CFR 40.52(b)(2)?

A13. 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. If there are significant variations in similar product types planned to be initially distributed, an applicant may provide general information about the ranges of sizes and weights, and/or lists of models, but should provide more specific information, where practical. 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.

In many cases, operating manuals, descriptive sales literature, or similar documents may include relevant information and may be submitted as part of an application.

If applicable to the type of product (e.g., a finished manufactured product vs. a rare earth compound being distributed in bulk), 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.

Q14. What information would I need to provide as part of my license application 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?

A14. 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, 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. The term, "source material," should **not** be used in lieu of "uranium" or "thorium."

Q15. I sell uranium glass marbles (exempt under 10 CFR 40.13(c)(2)(iii)). Is a single marble considered to be a unit for the purposes of labeling?

A15. Although a single marble could be considered a unit, the labeling of individual marbles is not required. Instead, labeling a bag or other container of marbles would be acceptable.

Q16. 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?

A16. 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.

Q17. 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)?

A17. No. Licenses for distribution are only required for initial transfer for sale or distribution; as long as your customers operate within the constraints of the exemption, no requirements apply to them.

Q18. I am distributing imported finished optical systems. Does the product I am initially transferring for sale or distribution require labeling?

A18. Yes. The identity of the manufacturer or your company's name as the distributor and the fact that thorium or uranium is present should, at a minimum, appear on the point-of-sale packaging.

Q19. 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?

A19. This requirement only applies to the initial distribution of thorium contained in gas mantles and welding rods. 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, minimizing any intake of thorium is the primary point. The instructions should address the importance of ventilation and minimization of handling.

In the past, distributors of gas mantles have included precautions on the wrap on the individual mantles. Although this practice is preferred, brochures provided with packages containing small numbers of mantles would also be acceptable. For welding rods, information on radiation safety may be provided in material safety data sheets; however, the radiological aspect of hazards would need to be specifically addressed in the MSDS (e.g., hazards presented by the dust created from grinding tips). The intent is that the information provided on the label or in the brochure is available to the ultimate user of the product.

Q20. 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?

A20. 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.

Q21. 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?

A21. 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 subsequently 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 because you would be the first person transferring the lenses domestically. 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 under the exemption, and instead, a specific NRC or Agreement State license would be required to conduct these activities.

Q22. Do I have to supply information about disposal of my product to my customers?

A22. No. Products that fall under an exemption are allowed to be disposed of without constraint by the NRC; however, there may be other federal or local requirements that the person disposing of the product will need to meet.

Q23. If I have the required distribution license issued under 10 CFR 40.52 and transfer my product for use under an exemption, and a recipient uses or modifies the product in ways that make the product no longer eligible for possession under an exemption, do I have any associated liability?

A23. An initial distributor for source material is required to transfer the product in accordance with the requirements in 10 CFR 40.51. If you transferred a product that meets the conditions of the applicable exemption to a recipient that is authorized to receive the source material under an exemption from licensing, then you have met your obligations. If the recipient subsequently uses or modifies the product in a way that is inconsistent with the exemption or contrary to other regulations, the recipient would be solely responsible. In some cases, such use by the recipient may be covered by the general license in 10 CFR 40.22; however, the recipient should realize that if they further distribute a modified product (and its final form once again meets the requirements for possession under the original or another exemption), the recipient would need to obtain a specific license under 10 CFR 40.52 for initial distribution of the modified product.

Q24. May I export my product for sale or disposal?

A24. Yes. You may export your product as long as you meet any applicable requirements in 10 CFR Part 110.

Q25. For the reports required to be submitted under 10 CFR 40.53(c), what level of precision is expected for the information required by 10 CFR 40.53(c)(3)? Does each item identified in 10 CFR 40.53(c)(3)(ii) have to be assessed individually or can one provide alternative verifications and indicate that the amount of source material was below the percentage or quantity limit? Should the reporting units be weight percent (i.e., ppm) or activity (i.e., Ci or Bq)?

A25. Simply providing information that the source material was below a concentration or quantity limit would not be acceptable. The better the characterization that can be provided by the distributor, the better the NRC will be able to refine its estimates of impacts to the public from exempt products in the future. However, the intent is not to require additional sampling or any significant analysis that is not already performed. The form of the information that is appropriate will vary for the type of product. Nominal values for specific products and total quantity of source material distributed in those products may be adequate. If products can be categorized by type, one approach would be to give the range of source material content for each type and provide the total quantity for each type distributed. While information on weight percent may be provided, total weight would also be needed to meet the requirement of reporting the total quantity of source material in each type of product. The reporting requirement does not specify the units, so distributors may report in whatever units they are currently keeping records.

Q26. What must I do if I want to get rid of my products containing source material that I have not sold under my specific license?

A26. A person who possesses a specific license under 10 CFR 40.52 must comply with the regulations in 10 CFR Part 40 (or comparable Agreement State regulations if located in an Agreement State) 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 (or applicable Agreement State equivalents). 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 to another specific licensee, that person would be required to obtain a license under 10 CFR 40.52 before subsequently distributing the products for use under exemption because the recipient specific licensee would be considered the initial transferor.

Q27. As an NRC licensee, what are the procedures that I must follow to terminate my specific license issued under 10 CFR 40.52? Will the NRC notify me that I am no longer considered a specific licensee?

A27. Termination of the NRC distribution license issued under 10 CFR 40.52 can be requested at any time after distribution activities are permanently ceased. This request may occur prior to decommissioning and termination of any associated possession licenses. Under 10 CFR 40.53(c)(4), you are required to submit a final transfer report within 30 days of ceasing distribution. The NRC will issue a termination notice upon request after receiving the final

transfer report. However, after the license is terminated, the former distribution licensee may no longer initially transfer for sale or distribution any remaining or new products.

Termination of the distribution license does not relieve the licensee from any obligations or requirements related to terminating any associated possession license issued by the NRC or an Agreement State. This would include requirements related to residual contamination at the site.

10 CFR 40.54

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

EXPLANATION:

This section establishes the requirements for a specific license to distribute source material for use under the general license in 10 CFR 40.22 or equivalent provisions of an Agreement State. The final rule provides conditions for approval of a license under 10 CFR 40.54 for initial distribution and requirements for reporting and recordkeeping, notifications, quality control, and labeling in 10 CFR 40.55, "Conditions of licenses issued under § 40.54: Quality control, labeling, safety instructions, and records and reports."

QUESTIONS AND ANSWERS:

Q1. 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? Where would I send my application for such license?

A1. If your business is located in an NRC State, your licenses for possession of source material and to initially transfer source material for use under 10 CFR 40.22 (or its Agreement State equivalent) would be issued by the NRC, and you would be responsible to the NRC.

You should send your license application(s) to the appropriate NRC regional office as indicated in 10 CFR 40.5(b)(2). These addresses can also be obtained from the NRC Web site at http://www.nrc.gov/about-nrc/locations.html.

Q2. 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? Where would I send my application for such license?

A2. If your business is in an Agreement State, you are subject to that State's regulatory requirements and your license for possession and to initially transfer source material for use under 10 CFR 40.22 (or its Agreement State equivalent) would be issued by the Agreement State. You would need to contact your State regulatory agency for more information, including on where to send any necessary applications. Information can be obtained from the NRC Web site at http://nrc-stp.ornl.gov/asdirectory.html

Q3. If I initially distribute products or materials containing source material, some of which are used under an exemption and others used under a general license, what licenses do I need? What fee categories would I have to pay as listed in the tables in 10 CFR 170.31 and 10 CFR 171.16?

A3. If you are located in an NRC State, you would need: 1) a license authorizing initial distribution of source material for use under exemption issued under 10 CFR 40.52 by NRC headquarters, 2) a license authorizing the initial distribution of source material for use under general license issued under 10 CFR 40.54 by the appropriate NRC region, and 3) a license authorizing possession of the source material issued by the NRC. The above licenses would be subject to fees under Categories 2.C, 2.D, and 2.E in the tables in 10 CFR 170.31 and 10 CFR 171.16.

If you are located in an Agreement State, you would need: 1) a license authorizing initial distribution of source material for use under an exemption issued under 10 CFR 40.52 by NRC headquarters, 2) a license issued by the Agreement State for initial distribution of source material for use under a general license, and 3) a license authorizing possession of the source material issued by the Agreement State. In addition to any fees required by the Agreement State applicable to the license to distribute source material for use under a general license and the possession license, you would also be responsible to the NRC for a separate license application fee and annual fee for your license issued under 10 CFR 40.52. The costs for these fees can be found in Category 2.C in the tables in 10 CFR 170.31 and 10 CFR 171.16, respectively.

Q4. 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?

A4. 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, because you would be considered the initial domestic transferor of source material for use under the 10 CFR 40.22 license (and equivalent Agreement State provisions).

Q5. I am a general licensee and received my source material from someone who already initially transferred it to me under their specific license issued under 10 CFR 40.54 (or an Agreement State license). Do I need to get a license to transfer my source material to another general licensee who will possess the source material under 10 CFR 40.22?

A5. No. Subsequent transfers from general licensee to general licensee do not require a specific license issued under 10 CFR 40.54. The transfer, however, would have to meet the requirements in 10 CFR 40.51.

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

A6. You may export source material to the extent that such exportation is authorized under the provisions of 10 CFR Part 110.

Q7. I am a source material licensee located in an Agreement State. Can I initially transfer for sale or distribution my 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 specific license for the initial distribution of source material from 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 will be provided to the recipient 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), 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 that those licensed under 10 CFR 40.54 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 the Agreement State requirements equivalent to 10 CFR 40.55(d)?

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

Director, 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

The report is only required to include those transfers that were made to persons falling under NRC jurisdiction, although you may include a complete copy of all transfers that was submitted to your Agreement State if that is easier. If you do send the same report that you provided to your Agreement State, you should indicate the total quantity of transferred source material includes totals to all jurisdictions and not just those transfers to the NRC, if applicable.

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 or stating that no transfers occurred during the period, as appropriate. 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 are required to provide reports to an Agreement State only about general licensees in that Agreement State to whom you transferred *more* than 50 grams of source material, in any quarter(s) within the reporting period. However, even if you made no transfers to a specific Agreement State in the reporting period, you are required to report that to the Agreement State if they request you to file such a report.

Q13. If I am licensed under 10 CFR 40.54, what must I do if I want to stop distributing to general licensees and get rid of source material currently in my possession that I have not initially distributed to general licensees under my specific license?

A13. Persons specifically licensed under 10 CFR Part 40 must comply with the applicable regulations in 10 CFR Part 40 for specific licensees, including the requirements for disposal or transfer of material, decommissioning of the facility and site, and termination of the license. Under these regulations, if the licensee no longer distributes source material to general licensees, the specific licensee can instead dispose of material according to 10 CFR 20.2001 or through transfers authorized under 10 CFR 40.51 (e.g., to another person specifically licensed to receive and possess such source material).

Similar to the process used for initial distribution of byproduct material for use under a general license, the NRC will generally issue separate licenses for distribution under 10 CFR 40.54 and for possession of source material. The licensee's responsibilities for final disposition of the source material and for decommissioning the site would be handled under the possession license. As such, the distribution license may be terminated separately from, and prior to, termination of the possession license. However, any transfers for subsequent use under general license would be required to be within the scope of the distribution license prior to its termination.

Although not due until January 31 of the following year, you should submit final reports to the NRC and the Agreement States under 10 CFR 40.55(d) as soon as possible after you cease all distribution to expedite termination of your distribution license.

Q14. I consider certain information about my general licensee customers that is required in the annual reports under 10 CFR 40.55(d) to be proprietary. How do I handle submittals of this information? Will the NRC and the Agreement States protect such information submitted from disclosure?

A14. The NRC has procedures in place for protecting proprietary information. Generally, the Agreement States have procedures in place that are designed to protect proprietary information to the extent permissible under state law. The NRC recognizes that customer information may be considered proprietary under 10 CFR 2.390 and would treat it as such in accordance with the NRC's regulations and procedures. Among other things, distributors would need to mark the information as proprietary to ensure that it is treated accordingly. For reports related to the distribution of byproduct material, after the first report and associated affidavit is submitted under 10 CFR 2.390(b), the NRC typically waives the affidavit requirements under 10 CFR 2.390(b)(ii), for subsequent reports if the reports are appropriately marked as proprietary and reference the appropriate affidavit. The NRC anticipates that the annual reports provided for under 10 CFR 40.55(d) and submitted to the NRC will be handled in a similar manner.