

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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Effective Date: August 27, 2013
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REVIEWER PLEASE NOTE: 79 FR 75735, 12/19/2014 – Organization change from FSME to NMSS

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§30.6	Communications		D	N/A			
§40.4	Definitions	44-01	B	<p>In §40.4, the definition of <i>Unrefined and unprocessed ore</i> is revised to read as follows:</p> <p><i>Unrefined and unprocessed ore</i> means ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.</p>			
§40.5	Communications		D	N/A			
§40.8	Information collection requirements:		D	N/A			

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	OMB approval						
§40.13(c)	Unimportant quantities of source material	44-09	B	<p>In §40.13(c), introductory text, is revised to read as follows:</p> <p>(c) Any person is exempt from the requirements for a license set forth in section 62 of the Act and from the regulations in this part and parts 19, 20, and 21 of this chapter to the extent that such person receives, possesses, uses, or transfers:</p>			
§40.13(c)(2)(i)	Unimportant quantities of source material	44-09	B	<p>Section 40.13(c)(2)(i) is revised to read as follows:</p> <p>(2) * * *</p> <p>(i) Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material;</p>			
§40.13(c)(2)(iii)	Unimportant quantities of source material	44-09	B	<p>Section 40.13(c)(2)(iii) is revised to read as follows:</p> <p>(2) * * *</p> <p>(iii) Glassware containing not more than 2 percent by weight source material or, for glassware</p>			

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				manufactured before August 27, 2013, 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;			
§40.13(c)(5)(i)	Unimportant quantities of source material	44-09	B	Section 40.13(c)(5)(i) is removed.			
§40.13(c)(5)(ii) –(iv)	Unimportant quantities of source material	44-09	B	In §40.13, paragraphs (c)(5)(ii) through (iv) are redesignated as paragraphs (c)(5)(i) through (iii).			
§40.13(c)(5)(v)	Unimportant quantities of source material		NRC	In §40.13, paragraphs (c)(5)(v) is redesignated as paragraphs (c)(5)(iv).			
§40.13(c)(7)	Unimportant quantities of source material	44-09	B	In §40.13, paragraph (c)(7) is revised as follows: (7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium; and that the			

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				<p>exemption contained in this paragraph does not authorize either:</p> <p>(i) The shaping, grinding or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or</p> <p>(ii) The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.</p>			
§40.13(c)(10)	Unimportant quantities of source material	44-09	B	<p>In §40.13, paragraph (c)(10) is added.</p> <p>(10) No person may initially transfer for sale or distribution a product containing source material to persons exempt under this paragraph (c), or equivalent regulations of an Agreement State, unless authorized by a license issued under § 40.52 to initially transfer such products for sale or distribution.</p> <p>(i) Persons initially distributing source material in products covered by the exemptions in this paragraph</p>			

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				<p>(c) before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.</p> <p>(ii) Persons authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under § 40.52 for distribution only and are exempt from the requirements of parts 19 and 20 of this chapter, and § 40.32(b) and (c).</p>			
§40.13(d)	Unimportant quantities of source material	44-09	B	Section 40.13(d) is removed.			
§40.13 Footnote 2	Unimportant quantities of source material	44-09	B	<p>In §40.13, Footnote 2 is revised as follows:</p> <p>²The requirements specified in paragraphs (c)(5)(i) and (ii) of this</p>			

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				<p>section need not be met by counterweights manufactured prior to Dec. 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by §40.13(c)(5)(ii) in effect on June 30, 1969.</p>			
§40.22(a)	Small quantities of source material	44-12	B	<p>Section 40.22, paragraph (a) is revised to read as follows:</p> <p>(a) A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:</p>			
§40.22(a)(1) – (4)	Small quantities of source material	44-12	B	<p>Section 40.22, paragraph (a)(1) through (a)(4) are added as follows:</p>			

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				<p>(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. 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. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Commission takes final action on a pending application submitted on or August 27, 2014, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and</p>			

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				<p>(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of paragraph (a)(1) of this section; or</p> <p>(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or</p> <p>(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this</p>			

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				paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.			
§ 40.22(b)	Small quantities of source material	44-12	B	<p>Section 40.22, paragraph (b) is revised to read as follows:</p> <p>(b) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph (a) of this section:</p>			
§40.22(b)(1) – (3)	Small quantities of source material	44-12	B	<p>Section 40.22, paragraph (b)(1) through (b)(3) are added as follows:</p> <p>(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the NRC in a specific license.</p> <p>(2) Shall not abandon such source material. Source material may be disposed of as follows:</p> <p>(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a</p>			

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				<p>person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or</p> <p>(ii) In accordance with § 20.2001 of this chapter.</p> <p>(3) Is subject to the provisions in §§ 40.1 through 40.10, 40.41(a) through (e), 40.46, 40.51, 40.56, 40.60 through 40.63, 40.71, and 40.81.</p>			
§40.22(b)(4)	Small quantities of source material	44-12	D	N/A			
§40.22(b)(5)	Small quantities of source material	44-12	B	Section 40.22, paragraph (b)(5) is added as follows:			

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				(5) Shall not export such source material except in accordance with part 110 of this chapter.			
§40.22(c)	Small quantities of source material	44-12	C	<p>Section 40.22, paragraph (c) is added as follows:</p> <p>(c) Any person who receives, possesses, uses, or transfers source material in accordance with paragraph (a) of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 40.5(a) about such contamination and may consult with the NRC as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that</p>			

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				exceed the limits in § 20.1402 of this chapter.			
§40.22(d)	Small quantities of source material	44-12	B	<p>Section 40.22, paragraph (d) is revised to read as follows:</p> <p>(d) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in paragraph (a) of this section is exempt from the provisions of parts 19, 20, and 21 of this chapter to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of §§ 20.1402 and 20.2001 of this chapter to the extent necessary to meet the provisions of paragraphs (b)(2) and (c) of this section. However, this exemption does not apply to any person who also holds a specific license issued under this chapter.</p>			
§40.22(e)	Small quantities of source material	44-12	B	<p>Section 40.22, paragraph (e) is added as follows:</p> <p>(e) No person may initially transfer or distribute source material to persons generally licensed under paragraph</p>			

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				(a)(1) or (2) of this section, or equivalent regulations of an Agreement State, unless authorized by a specific license issued in accordance with § 40.54 or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph (a) of this section before August 27, 2013, without specific authorization may continue for 1 year beyond this date. Distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or August 27, 2014.			
§40.32(f)	General requirements for issuance of a specific license	44-15	D	N/A			
§40.52	Certain items containing source material;		NRC	Section 40.52 is added as follows:			

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	requirements for license to apply or initially transfer			<p>An application for a specific license to apply source material to, incorporate source material into, manufacture, process, or produce the products specified in § 40.13(c) or to initially transfer for sale or distribution any products containing source material for use under § 40.13(c) or equivalent provisions of an Agreement State will be approved if:</p> <p>(a) The applicant satisfies the general requirements specified in § 40.32. However, the requirements of § 40.32(b) and (c) do not apply to an application for a license to transfer products manufactured, processed, or produced in accordance with a license issued by an Agreement State or to the import of finished products or parts.</p> <p>(b) The applicant submits sufficient information regarding the product pertinent to the evaluation of the potential radiation exposures, including:</p> <p>(1) Chemical and physical form and maximum quantity of source material in each product;</p>			

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				<p>(2) Details of construction and design of each product, if applicable. For coated lenses, this must include a description of manufacturing methods that will ensure that the coatings are unlikely to be removed under the conditions expected to be encountered during handling and use;</p> <p>(3) For products with applicable quantity or concentration limits, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;</p> <p>(4) The proposed method of labeling or marking each unit, and/or its container with the identification of the manufacturer or initial transferor of the product and the source material in the product; and</p> <p>(5) The means of providing radiation safety precautions and instructions relating to handling, use, and storage of products to be used under § 40.13(c)(1)(i) and (c)(1)(iii).</p> <p>(c) Each product will contain no more than the quantity or the concentration</p>			

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				of source material specified for that product in § 40.13(c).			
§40.53	Conditions for licenses issued for initial transfer of certain items containing source material: Quality control, labeling, and records and reports		NRC	<p>Section 40.53 is added as follows:</p> <p>(a) Each person licensed under § 40.52 shall ensure that the quantities or concentrations of source material do not exceed any applicable limit in § 40.13(c).</p> <p>(b) Each person licensed under § 40.52 shall ensure that each product is labeled as provided in the specific exemption under § 40.13(c) and as required by their license. Those distributing products to be used under §§ 40.13(c)(1)(i) and (iii) or equivalent regulations of an Agreement State shall provide radiation safety precautions and instructions relating to handling, use, and storage of these products as specified in the license.</p> <p>(c)(1) Each person licensed under § 40.52 shall file a report with the Director, Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 40.5(a), including in the address: ATTN:</p>			

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				<p>Document Control Desk/Exempt Distribution.</p> <p>(2) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee and indicate that the products are transferred for use under § 40.13(c), giving the specific paragraph designation, or equivalent regulations of an Agreement State.</p> <p>(3) The report must include the following information on products transferred to other persons for use under § 40.13(c) or equivalent regulations of an Agreement State:</p> <p>(i) A description or identification of the type of each product and the model number(s), if applicable;</p> <p>(ii) For each type of source material in each type of product and each model number, if applicable, the total quantity of the source material; and</p> <p>(iii) The number of units of each type of product transferred during the reporting period by model number, if applicable.</p> <p>(4) The licensee shall file the report, covering the preceding calendar year,</p>			

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				<p>on or before January 31 of each year. Licensees who permanently discontinue activities authorized by the license issued under § 40.52 shall file a report for the current calendar year within 30 days after ceasing distribution.</p> <p>(5) If no transfers of source material have been made to persons exempt under § 40.13(c) or the equivalent regulations of an Agreement State, during the reporting period, the report must so indicate.</p> <p>(6) The licensee shall maintain all information concerning transfers that support the reports required by this section for 1 year after each transfer is included in a report to the Commission.</p>			
§40.54	Requirements for license to initially transfer source material for use under the 'small quantities of source material' general license	44-26	B	<p>Section 40.54 is added as follows:</p> <p>An application for a specific license to initially transfer source material for use under § 40.22, or equivalent regulations of an Agreement State, will be approved if:</p>			

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				<p>(a) The applicant satisfies the general requirements specified in § 40.32; and</p> <p>(b) The applicant submits adequate information on, and the Commission approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.</p>			
§40.55(a)	Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports	44-27	B	<p>Section 40.55(a) is added as follows:</p> <p>(a) Each person licensed under § 40.54 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."</p>			
§40.55(b)	Conditions of licenses to initially transfer source material for use under the 'small quantities	44-27	B	<p>Section 40.55(b) is added as follows:</p> <p>(b) Each person licensed under § 40.54 shall ensure that the quantities and concentrations of source material</p>			

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	of source material' general license: Quality control, labeling, safety instructions, and records and reports			are as labeled and indicated in any transfer records.			
§40.55(c)	Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports	44-27	B	<p>Section 40.55(c) is added as follows:</p> <p>(c) Each person licensed under § 40.54 shall provide the information specified in this paragraph to each person to whom source material is transferred for use under § 40.22 or equivalent provisions in Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:</p> <p>(1) A copy of §§ 40.22 and 40.51, or relevant equivalent regulations of the Agreement State.</p> <p>(2) Appropriate radiation safety precautions and instructions relating</p>			

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				to handling, use, storage, and disposal of the material.			
§40.55(d)	Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports	44-27	B	<p>Section 40.55(d) is added as follows:</p> <p>(d) Each person licensed under § 40.54 shall report transfers as follows:</p> <p>(1) File a report with the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:</p> <p>(i) The name, address, and license number of the person who transferred the source material;</p> <p>(ii) For each general licensee under § 40.22 or equivalent Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to</p>			

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				<p>whom the material was sent; and the type, physical form, and quantity of source material transferred; and</p> <p>(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.</p> <p>(2) File a report with each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to § 40.22, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State being reported to:</p> <p>(i) The name, address, and license number of the person who transferred the source material; and</p> <p>(ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.</p>			

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				<p>(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State.</p> <p>(3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under § 40.22 or equivalent Agreement State provisions during the current period, a report shall be submitted to the Commission indicating so. If no transfers have been made to general licensees in a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.</p>			
§40.55(e)	Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality	44-27	C	<p>Section 40.55(e) is added as follows:</p> <p>(e) Each person licensed under § 40.54 shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a</p>			

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	control, labeling, safety instructions, and records and reports			report to the Commission or to an Agreement State agency.			
§40.82	Criminal penalties		D	N/A			
§70.5	Communications		D	N/A			