
**Environmental Assessment for
Final Rulemaking – 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)**

June 2012

**U.S. Nuclear Regulatory Commission
Office of Federal and State Materials
and Environmental Management Programs**



Table of Contents

1.0	INTRODUCTION	3
1.1	BACKGROUND	3
1.2	DOCUMENT ORGANIZATION	4
2.0	NEED FOR THE PREFERRED ACTION	4
3.0	APPLICABILITY OF CATEGORICAL EXCLUSION FOR CERTAIN AMENDMENTS	5
4.0	THE PREFERRED FEDERAL ACTION AND ALTERNATIVES: GENERIC DISCUSSION	6
5.0	THE PREFERRED FEDERAL ACTIONS, ALTERNATIVES, AND ENVIRONMENTAL IMPACTS: DISCUSSION OF SPECIFIC ISSUES	7
5.1	REVISE 10 CFR 40.22 IN ITS ENTIRETY	7
5.2	REVISE 10 CFR 40.13(c)(7) EXEMPTION FOR THORIUM LENSES	10
5.3	REVISE THE DEFINITION OF “UNREFINED AND UNPROCESSED ORE” IN 10 CFR 40.4	12
5.4	REVISE 10 CFR 40.13(c) AND (D)	13
5.5	NO ACTION	14
6.0	CONCLUSION	14
7.0	LIST OF AGENCIES AND PERSONS CONSULTED	15
8.0	SOURCES CITED	15

1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC or “the Commission”) is amending its regulations governing the use of source material in 10 CFR Parts 30, 40, 70, 170, and 171. These amendments add new specific licensing requirements, reporting requirements, and fees for the initial distribution of products and materials containing source material for receipt under an exemption or the general license in § 40.22, “Small quantities of source material.” In addition, the amendments modify the existing possession and use requirements for the general license in § 40.22 to better align the requirements with current health and safety standards. Finally, the amendments revise, clarify, or delete certain licensing exemptions (also known as “unimportant quantities”) in order to make the regulations for those exemptions more risk informed. These actions are intended to better ensure the protection of the public health and safety in the future; provide the NRC and the Agreement States with more complete and timely information on the types and quantities of source material distributed for use under exemption or by general licensees; modify the requirements for possession of certain products under exemptions; and remove obsolete exemptions. These changes may affect licensees who initially distribute source material to exempt persons and general licensees or use source material under general license. The NRC has prepared this environmental assessment (EA) to determine whether this rule will have any significant environmental impact.

1.1 Background

The Commission's regulations for source material are in 10 CFR Part 40, which sets out the basic requirements for domestic licensing of source material. Source material is uranium and thorium or ores containing uranium and thorium in concentrations greater than 0.05 percent by weight of the uranium or thorium. The NRC has the authority to issue both general and specific licenses for the use of source material and to exempt source material from regulatory control under Section 62 of the Atomic Energy Act of 1954, as amended. A general license, provided by regulation, grants authority to a person for particular activities involving source material as described within the general license, and is effective without the filing of an application with the Commission or the issuance of a licensing document. Requirements for general licensees appear in the regulations, such as the general license provided in § 40.22, and are designed to be commensurate with the specific circumstances covered by each general license. A specific license is issued to a named person who has filed an application with the Commission. Basic requirements for submittal of an application for a specific license are found in § 40.31 and general requirements for issuance of a specific license are found in § 40.32. Terms and conditions of specific licenses are contained in § 40.41. Exemptions, provided in situations where there is minimal risk to public health and safety, allow the end user to possess or use the source material without a license. The exemptions from the licensing requirements for source material are listed in § 40.13. With the exception of requirements for the manufacture and initial transfer of products and devices to be used under the general license in § 40.25 (contained in §§ 40.34 and 40.35), there are no specific requirements applicable to the distribution of products and materials containing source material.

Other parts are affected by this rulemaking. The regulations in 10 CFR Part 30 provide the basic requirements for possession and use of byproduct material, while 10 CFR Part 70 provides the basic requirements for possession and use of special nuclear material. Both of these parts will be amended to conform to the changes made to 10 CFR Part 40. The regulations in 10 CFR Parts 170 and 171 address fees associated with licensing and will be amended to include the new categories of 10 CFR Part 40 specific licenses for distribution.

The NRC has conducted a systematic reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40 of the NRC's regulations, which govern the use of byproduct and source material, respectively. A major part of the effort was an assessment of the potential and likely doses to workers and the public under these exemptions. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," (NRC, June 2001). In the past few years, several issues have been identified where improvements could be made to the regulations governing these products. The amendments to exemptions considered in this document largely stem from this analysis.

In 2006, the NRC directed Pacific Northwest National Laboratory (PNNL) to review and assess regulations related to the use of source material under general license and certain exemptions. PNNL's findings were reported in PNNL-16148, Rev. 1, "Risk Assessment for Current and Projected uses of Source Material Under a U.S. NRC General License and Exemption Criteria," (PNNL, February 2007). Many of the amendments to the general license also stem from this analysis.

1.2 Document Organization

This environmental assessment presents a discussion of the basic subjects specified in 10 CFR 51.30 and fulfills the requirements of the National Environmental Policy Act of 1969, as amended. This environmental assessment is organized to best accommodate the rule's complexity. This complexity is due to the Commission's decision to aggregate multiple issues into this single rulemaking, with the purpose of minimizing the cost of the activities. The rule is therefore best understood and discussed as a collection of separate small issues. Many of the amendments meet the criteria for categorical exclusion – as detailed below – and do not require an environmental assessment to be prepared. The amendments not meeting these criteria are discussed issue-by-issue, and are the focus of the environmental assessment.

A discussion of the need for the actions is contained in Section 2.0. The applicability of categorical exclusions to certain amendments is discussed in Section 3.0. For those issues where a categorical exclusion does not apply, a discussion of the actions and their alternatives is presented generically in Section 4.0, and specifically on an issue-by-issue basis in Section 5.0 along with their environmental impacts. The conclusion is in Section 6.0. A list of agencies and persons consulted and an identification of sources used are contained in Sections 7.0 and 8.0, respectively.

2.0 Need for the Preferred Action

Currently, there are no regulatory mechanisms for the Commission to ensure that products and materials distributed for use under the general license in § 40.22 or an exemption in § 40.13 are maintained within the applicable constraints of the requirements for these uses. Because the staff cannot readily identify who possesses source material under the general license in § 40.22 or how and in what quantities the source material possessed under § 40.22 is being used, the staff cannot fully assess the resultant risks to public health and safety. In addition, some isotopically-separated source material, in particular, thorium-228, has the potential to present significantly higher potential doses. Although the NRC is not aware of large quantities of these isotopes being separated for commercial use, if the separated isotopes were readily available, the current provisions of § 40.22 could allow a person to receive quantities large enough in

terms of activity to present not only a safety concern, but also a security concern, without obtaining a specific license.

The State of Colorado and the Organization of Agreement States submitted a petition for rulemaking (PRM), PRM-40-27, in which the petitioners identified concerns regarding the use of source material under the general license granted under § 40.22. In particular, the petitioners were concerned that general licensees are specifically exempted from meeting the requirements of 10 CFR Part 19, “Notices, Instructions, and Reports to Workers: Inspection and Investigations,” and 10 CFR Part 20, “Standards for Protection Against Radiation.” Both 10 CFR Parts 19 and 20 have certain requirements and limits that apply to specific licensees. The petitioners identified certain situations where they calculated that the use of source material under the § 40.22 general license could result in exposures to workers not trained in radiation protection, that exceeded exposure limits for protection of members of the public that apply to specific licensees.

In response to PRM-40-27, the NRC attempted to collect data on general licensees in order to evaluate the impact of the use of source material under this general license. Of the information provided, one of the respondents was a specific licensee and the two other responses afforded minimal insight into the details of how persons actually operate under the § 40.22 general license. In addition, the NRC attempted to gather information from the internet, publications, and professional societies without much insight provided by the collected data. These efforts are indicative of the difficulty in identifying and obtaining information from persons operating under the § 40.22 general license using existing regulations.

The findings in the PNNL study indicated that the use of source material in products is declining. The results of the evaluation also indicated that most source material possessed under § 40.22 is likely handled in quantities, physical forms, or in uses and under conditions that would justify the continued use of the exemptions to 10 CFR Parts 19 and 20. However, as indicated by PRM-40-27, and by the bounding dose calculations evaluated in the PNNL study, situations can and do occasionally occur that exceed limitations under which 10 CFR Parts 19 and 20 usually apply.

3.0 Applicability of Categorical Exclusion for Certain Amendments

Many of these amendments being made by the final rule belong to a category of actions that the Commission has determined to be a categorical exclusion, having found that these types of actions do not individually or cumulatively have a significant effect on the human environment. Therefore, this EA is not required to evaluate these amendments.

In accordance with § 51.22(c)(1), the amendments to 10 CFR Parts 170 and 171 are categorically excluded, and do not require an environmental assessment. Additionally, under § 51.22(c)(3), amendments to 10 CFR Parts 30, 40, and 70 that relate to procedures for filing and reviewing application for licenses, recordkeeping, and reporting – paragraphs (i), (ii), and (iii), respectively – do not require an environmental assessment. The final §§ 40.13(c)(10) and 40.22(e) will require that affected persons comply with §§ 40.52 and 40.54, respectively. Sections 40.52 and 40.54 provide the requirements for approval of a specific license and are covered by this categorical exclusion. The final recordkeeping and reporting requirements for initial distributors of source material to general licensees and exempt persons in §§ 40.53 and 40.55 are also covered by this categorical exclusion. Finally, the amendments to §§ 30.6, 40.5,

and 70.5 which deal with communications, § 40.8, “Information collection requirements: OMB approval,” and § 40.82, “Criminal penalties,” are also covered by this categorical exclusion.

4.0 The Preferred Federal Action and Alternatives: Generic Discussion

Under this federal action, the NRC is amending certain Sections of 10 CFR Parts 30, 40, 70, 170, and 171 by rulemaking in accordance with the Administrative Procedure Act of 1946, as amended. The alternatives to rulemaking would be to take no action, or to take various non-rulemaking actions. Non-rulemaking alternatives include: generic letters, guidance documents, and direct one-on-one contact with licensees.

Generic letters request that addressees: (1) perform analyses or submit descriptions of proposed corrective actions regarding matters of safety, safeguards, or the environment and submit in writing that they have completed the requests with or without prior NRC approval of the action; (2) submit technical information that the NRC needs to perform its functions; or (3) submit proposed changes to technical specifications. By a generic letter, the NRC may also provide the addressees: (1) staff technical or policy positions not previously communicated or broadly understood; or (2) solicit participation in voluntary pilot programs. A generic notice could be used to clarify the NRC’s policy on certain activities by a § 40.22 general license such as disposal requirements based upon the transfer requirements in § 40.51; however, reductions to possession limits, implementation of new decommissioning or cleanup requirements, or changes to the exemptions could not be accomplished under a generic letter because there would be no regulatory basis for requiring such changes.

Guidance documents are used to provide additional direction (usually indicating actions preferred by the NRC) on how specific regulatory requirements can be met. However, guidance documents usually do not include all applicable methods of meeting requirements that may be acceptable under a regulation and cannot, by themselves, implement new requirements such as new requirements for reporting source material distributions. The NRC could issue guidance for operation under the § 40.22 general license that could suggest preferences to limit possession of certain forms of source, for properly disposing source material, or to maintain one’s site that would be consistent with the preferred alternative; however, as long as the general licensee maintains operations within the regulations, they cannot be required to meet those preferences found in the guidance. Similarly, guidance would have no impact on changes to the exemptions.

The NRC could address issues with general licensees through one-on-one contact directly with each licensee of concern. The only practicable method to require the licensee to meet the goals of the preferred action would be through issuance of orders. In such a case, the NRC would have to show there was a significant health and safety or security concern separately for each licensee that required the licensee to meet the new requirements. This process would both be inefficient if a large number of licensees needed to be addressed and does not allow for the process provided by the Administrative Procedures Act. In addition, because of the current lack of reporting requirements, the NRC and Agreement States cannot easily identify persons operating under the § 40.22 general license (or the Agreement State equivalent).

The no-action alternative is to maintain the status quo. The no-action alternative would not address the identified concerns. Specific details of the implications of the preferred action and the no-action alternative are discussed below, issue by issue. Because the non-rulemaking

alternatives discussed above do not achieve the goals of the preferred action nor result in any differences from the no-action alternative, they are not discussed further.

5.0 The Preferred Federal Actions, Alternatives, and Environmental Impacts: Discussion of Specific Issues

5.1 Revise 10 CFR 40.22 in its Entirety

Section 40.22 provides the requirements for possession and use of small quantities of source material under a general license. The current regulations in § 40.22 allow possession and use of up to 15 pounds (lb) (~7 kilograms (kg)) of source material at one time and receipt of no more than 150 lb of source material within a calendar year. These requirements have no associated reporting or registration requirements and exempt the user from the health and safety requirements in 10 CFR Part 20 and the training requirements in 10 CFR Part 19, thus effectively allowing the general license to operate similar to those exempt from licensing.

The final rule will revise § 40.22 to:

- limit the general license to natural isotopic concentrations of thorium and uranium and to depleted uranium;
- limit possession to less than 1.5 kg (3.3 lb) of source material at any one time and 7 kg (15.4 lb) per calendar year for dispersible or processed forms, while continuing to allow up to 7 kg (15.4 lb) total of source material at any one time and receipt of no more than 70 kg (154 lb) per calendar year including source material in solid, non-dispersible forms for persons removing uranium from drinking water, or for laboratories handling samples for the purpose of determining the concentration of the uranium and thorium;
- clarify disposal requirements and the applicability of other 10 CFR Part 40 regulations; and
- require the general licensee to minimize contamination at the site and ensure that the site is cleaned up after the use of source material is ended.

The revised § 40.22 will also require a general licensee to respond to NRC written requests and prohibit the initial transfer of source material to a general license without a specific license. The requirement to respond to NRC written requests is considered to be a reporting requirement and the prohibition on the initial transfer of source material is considered to be a procedure related to the filing of an application; both of which fall under the categorical exclusion in § 51.22(c)(3) (see Section 3.0, above). The remaining requirements in § 40.22 are restated from the current requirements in § 40.22.

5.1.1 Revision of 10 CFR 40.22 Possession Limits

Although source material, in particular thorium, has an external radiation impact, the primary concern when dealing with source material is limiting internal uptake. The 2006 PNNL report concluded that certain activities allowed under the current possession limits in § 40.22 could expose workers to almost 5 rem (50 millisieverts (mSv)) per year (both internal and external doses) using conservative assumptions. More realistic scenarios indicated worker exposures could still exceed 800 millirem (mrem) (8 mSv) per year. In both cases, the majority of the exposures were related to inhalation and ingestion which would only result from material that was dispersible in air or processed to create dust. By reducing the possession limit for such material to 1.5 kg (3.3 lb) of source material at any one time and receipt of up to 7 kg (15.4 lb) of source material in dispersible or processed forms in a calendar year, the NRC expects worker exposures to generally be below 100 mrem (1 mSv) per year, which is the limit in § 20.1301 that applies to most NRC licensees for protection of members of the public. Because § 40.22 general licensees are not required to meet the training requirements in 10 CFR Part 19, it is more appropriate to treat their workers similar to members of the general public. Implementation of normal industrial hygiene requirements would further reduce these potential exposures. In addition, by limiting the types of source material to only natural isotopic concentrations of thorium and uranium and depleted uranium, the new possession limits reduces the possibility that a person will accumulate large quantities of isotopes with high specific activities. Possession of large quantities of certain isotopes of source material (in particular thorium-228) could significantly increase the possibility of high exposures.

The use of quantities of source material above the revised limits will require specific licensing and thereby entail much greater controls on use of the source material. Reduction of the possession limits for dispersible or processed source material will better align the general license with the health and safety requirements required for most other radioactive material. This final amendment to possession limits will likely reduce the potential impact to environmental resources compared to not changing the possession limits.

The NRC is retaining the possession limits and annual receipt limits for: (1) solid, unprocessed source material (e.g., ore or uranium metal samples that are used for display); (2) removal of uranium from drinking water; and (3) laboratories handling samples for the purpose of determining the concentration of the uranium and thorium. Because solid, unprocessed source materials will likely not contribute significantly to internal uptakes of source material or significantly result in additional contamination, the NRC has determined that the current limit is sufficient. In the case of water treatment, the primary treatment method that is expected to accumulate concentrations of source material that would fall under the general license would be from ion exchange. In this case, the uranium would be expected to be selectively isolated from its progeny. As a result, exposures from the uranium itself, because the uranium would be imbedded on resin and not readily available for internal uptake, are expected to be minimal. The third exception from the change to possession limits was added in the final rule to avoid potential unintended and inappropriate impacts to these laboratories and to the mining industry. Because there is no change being made to the possession limits for non-dispersible source material, for water treatment activities, or for sample measurement laboratories from the current general license, there will be no significant impact to any environmental resources.

5.1.2 Clarification of Disposal Requirements for 10 CFR 40.22

Under the existing § 40.22 requirements, the general licensee is exempt from the requirements in 10 CFR Part 20 unless the person is also in possession of a specific license. Because the NRC's disposal requirements are found in 10 CFR Part 20, this has often led to the conclusion that there are no restrictions on the disposal of source material possessed under the general license. However, restrictions in § 40.51, which allows the general licensee to transfer source material only to a person authorized to receive it, may make transfer for disposal more problematic. If a disposal facility not specifically licensed for possession of source material receives the material, they would either be limited to the restrictions in the current § 40.22 general license (15 lb (~7 kg) total at one time) or need to ensure that the source material received could be possessed under the exemption in § 40.13(a). Paragraph 40.13(a) provides an exemption from the licensing requirements for persons possessing or using materials containing source material in concentrations of less than 0.05 percent by weight source material. Absent discussion with the recipient, the general licensee cannot be certain that the recipient is authorized to receive the source material, nor is it proper for the general licensee to place the disposal facility in a position that is in violation of the NRC's regulations. Because of the lack of clarity in the current regulations associated with the § 40.22 general license with regard to disposal and the difficulty in identifying licensees, this environmental assessment assumes that much of the source material possessed by general licensees is currently disposed of at unlicensed landfills.

The revision of § 40.22 will clarify the disposal requirements by explicitly authorizing up to 0.5 kg (1.1 lb) of source material to be disposed of per calendar year as long as it was in a solid, non-dispersible form (e.g., in the form of a metal bar or encapsulated in cement, etc.) to limit the possibility of internal uptake. The recipient of the material will not require licensing as long as the source material was permanently disposed. All other permanent disposals of source material will be required to be consistent with the requirements in § 20.2001, "General requirements," for waste disposal.

By clearly delineating the amount and form of source material allowed to be disposed of without further NRC licensing, the final action will reduce the potential for much greater quantities of source material (conceivably up to 150 lb (~70 kg) per general licensee per year) to be disposed of at an unlicensed facility. The purpose of allowing smaller quantities of source material to continue to be disposed of without further NRC licensing is to allow an economical disposal route for persons (e.g., educational institutions) possessing very small quantities of source material. Continuing to allow these small quantities of source material to be disposed of in landfills is not expected to significantly impact the environment or members of the public because the material is required to be in a solid, non-dispersible form, which would be unlikely to spread to the environment and would not be readily inhaled or ingested. Requiring the disposal of larger quantities of source material in a manner consistent with § 20.2001 will reduce the impact to workers, the public, and the environment resulting from larger disposals at unlicensed facilities that could be construed to be acceptable under the current regulations.

Because of the limited availability of licensed disposal sites, the final action could result in longer transportation routes than disposal at the local landfill. Longer transportation routes have a potential to increase the opportunity for higher exposures to drivers, accidents, exhaust emissions, and use of non-renewable resources (gasoline or diesel). Because the possession limits in § 40.22 will limit disposal of at most 7 kg (15.4 lb) of source material at one time, it is

likely that the general licensee would use either a waste consolidator, or, if Department of Transportation regulations allow, common shippers, in order to limit transportation costs and packaging costs. Waste consolidators and common shippers would likely already be transporting other materials to or near the locales of the licensed disposal site thus limiting these potential adverse effects.

Because the final action is generally more restrictive than potential current practices, the final amendment to clarify the current disposal requirements will have no significant impact on environmental resources compared to taking no action.

5.1.3 Requirements to Minimize Contamination and Adequately Decommission the Site

Under the existing § 40.22 requirements, general licensees are exempt from the contamination control and decommissioning requirements in 10 CFR Part 20 unless they also possess a specific license. As a result, the NRC and Agreement State regulators have identified situations where sites possessing source material under the § 40.22 general license were operated and abandoned with significant quantities of source material in the form of contamination. It is expected, although not confirmed, that many general licensees do not account for such contamination toward their overall possession limit.

Revised § 40.22 will require a licensee to conduct activities so as to minimize contamination of the facility and the environment. This requirement will minimize the potential exposure to workers who are not required to have radiation training. In addition, minimizing contamination will help ensure that the general licensee does not unexpectedly exceed total possession limits. If the NRC identifies substantial contamination from source material, the final action will allow the NRC to require the general licensee to restore the site to levels protective of public health and safety.

Revised § 40.22 will also require that when activities involving source material are permanently ceased at any site, the general licensee does not abandon the site with quantities of source material that could result in exposures exceeding the limits in § 20.1402. Section 20.1402 requires a licensee to restore a site for unrestricted use such that residual radiation that is distinguishable from background will not result in exposures above 25 mrem (0.25 mSv)/year. Because of the current 10 CFR Part 20 exemption, a § 40.22 general licensee is not required to decommission the site. The final action will require the licensee to notify the NRC if significant source material contamination (i.e., there is a potential the residual contamination would exceed the limits in § 20.1402) is identified upon completion of activities. The NRC could then advise the general licensee about decommissioning and surveying options and, if necessary, inspect the facility upon completion of such activities.

Because these amendments will provide greater controls on the eventual disposition of the source material, the final amendments are expected to have an insignificant impact on environmental resources compared to the current contamination control and decommissioning requirements for § 40.22 general licensees.

5.2 Revise 10 CFR 40.13(c)(7) Exemption for Thorium Lenses

The existing regulation in § 40.13(c)(7) provides an exemption from licensing for the possession of finished optical lenses containing thorium homogeneously distributed throughout the lens at a

concentration of no greater than 30 percent thorium by weight. Shaping, grinding, or polishing of the lenses is specifically prohibited. In addition, the use of lenses in applications where the lens is in close proximity to the eye (e.g., contact lenses, spectacles, or eyepieces in binoculars or other optical instruments) is also prohibited.

Revised § 40.13(c)(7) expands the exemption to clearly cover thorium-coated lenses and mirrors and to allow the use of uranium in and on lenses and mirrors. The concentration of source material allowed on or within the lens will be reduced from 30 percent by weight to 10 percent by weight; however, lenses containing thorium homogeneously distributed throughout the lens and manufactured prior to the effective date of the rule will continue to be exempt at concentrations up to 30 percent by weight of the thorium. The restrictions on processing and uses currently in § 40.13(c)(7) will continue to apply.

5.2.1 Addition of Uranium and Thorium Coated Lenses to Exemption

Thorium is used as a thin-film optical coating on the surfaces of a lens or entrained within the lens to reduce reflection and glare in the ultraviolet, visible, and infrared light spectra and to increase reflection in the extreme ultraviolet and soft x-ray spectra. In recent years, it has become more practical to apply the thorium as a thin-film coating instead of entraining the thorium within the lens. As a result, the applicability of the current exemption to such coated lenses has been questioned. In addition, the NRC has also become aware that lenses coated with uranium are now being manufactured.

The PNNL report specifically evaluated the use and manufacture of thorium and uranium thin-film optical coatings. Based upon the findings in the report, a lens manufactured with a thin-film of source material contained significantly less source material than those lenses that contained thorium homogeneously distributed throughout the lens. Lenses evaluated in NUREG-1717 incorporated up to 100 grams (g) (0.22 lb) of thorium, while thin-film coated lenses have approximately 0.02 g (0.0007 ounces) of thorium applied to the lens. Routine doses (accounting for external exposures only) from the lenses with thin-film optical coatings of thorium were calculated to be less than 0.004 millirem (mrem) (0.04 microsieverts (μ Sv)) per year to an individual. Doses from uranium coated lenses were found to be even lower. Doses resulting from accidents while using the thin coated lenses were expected to be similarly small. Thin-film coatings of uranium or thorium applied to mirrors would be expected to have similar impacts.

The Commission has a consumer product policy (30 FR 3462, March 16, 1965), which calls for the Commission to monitor the overall impact of its exemptions from licensing. The Commission evaluated the potential exposure impacts from consumer products in the early '60's, again in the late '70's, and more broadly of all of its exemptions in the '90's. The second of these analyses was published as NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," in 1980. As noted in the Section 1.1, Background, the dose assessments from the latest of these evaluations were published as NUREG-1717. The Commission's policy is for consumer products to routinely expose users to only a small fraction of the public dose limit. The estimated doses under routine use conditions for lenses having thin-film optical coatings of uranium and thorium results in only a small fraction of the public dose limit (well below 10 μ Sv (1 mrem) per year). As a result, expanding the exemption for lenses to include lenses or mirrors coated with thorium or uranium will not significantly impact public or occupational health.

5.2.2 *Reduction of Allowable Concentration to 10 Percent by Weight*

The final rule establishes a new concentration limit for source material contained in or on finished optical lenses and mirrors of 10 percent by weight, which is a reduction from the previous 30 percent by weight limit that was applicable to lenses containing thorium. The evaluation in NUREG-1717 assumed that a camera operator used a lens system containing 3 lenses, each containing 100 g (0.22 lb) of thorium and concentrations of 10 percent by weight of thorium. The resulting dose was 200 μ Sv (20 mrem) per year to an operator, and is considered higher than a small fraction of the public dose limit. Although this may be considered an industrial use rather than a consumer product use (thus the higher allowable exposure), the reduction in concentration is warranted due to the availability of alternative materials that can be applied or incorporated to lenses to achieve similar effects. Additionally, the NRC has not been able to identify any persons currently manufacturing lenses using concentrations in excess of 10 percent. This is likely because of the increased prevalence of lenses with thin optical coatings or other materials. Lenses containing thorium homogeneously distributed throughout the lens and manufactured prior to the effective date of the rule would continue to be exempt at concentrations up to 30 percent by weight thorium to account for those lenses still possessed that may be in excess of the final limit of 10 percent by weight.

If lenses containing thorium or uranium in concentrations greater than 10 percent by weight were to be manufactured in the future, they would require a specific license for possession. The NRC is unaware of any situation where health and safety of the public or protection of the environment would be impacted if such lenses could not be possessed under exemption. Because the NRC is unaware of situations where lenses are currently being manufactured for use under the exemption in excess of 10 percent by weight, the only notable distinction between the no-action alternative and the rulemaking is that the final action will prohibit future distribution without an NRC reevaluation. However, future distribution is unlikely in the no-action alternative because the products are no longer being manufactured nor is there an expectation that they would be manufactured in the future. Therefore, it is unlikely that the reduction of the concentration limit would have a significant impact on environmental resources.

5.3 Revise the definition of “unrefined and unprocessed ore” in 10 CFR 40.4

The existing regulation in § 40.13(b) provides an exemption from licensing for unrefined and unprocessed ore. A clarifying amendment to the definition of “unrefined and unprocessed ore” in § 40.4 is being made in the final rule in response to comments to indicate that activities related to the sample analysis of an unprocessed ore and a few other specified activities are not considered to be processing and that the ore would remain exempt under § 40.13(b) after these limited types of activities. While this is a clarification, generally in line with the original intent, it somewhat expands the exemption under § 40.13(b). The inclusion of sample analysis of unprocessed ore is primarily to ensure consistency with § 65 of the Atomic Energy Act of 1954, as amended, which states, in part that “reports shall not be required with respect to (a) any source material prior to its removal from its place of deposit in nature, or (b) ...the reporting of which will discourage independent prospection for new deposits.” It is also intended to prevent unintended impacts to analytical laboratories that could be placed in the position of being in violation of NRC regulations because they did not know that a sample contained enough source material to exceed the regulatory limits until after sampling. The rule also clarifies that simple handling of soils/sands such as sieving or encapsulation does not cause the material to come under licensing requirements. The primary intent of the original definition was to allow mines to

transfer ores without having to obtain a specific license. This was accomplished by exempting from licensing those activities where the ore was not physically or chemically changed. Neither sieving nor encapsulation result in physical or chemical changes to the ore itself. Overall, there is expected to be a minimal impact on environmental resources as a result of this clarification.

5.4 Revise 10 CFR 40.13(c) and (d)

Paragraphs (c) and (d) of § 40.13 provide exemptions from licensing for many products containing source material. The specific provisions of § 40.13(c) evaluated in this section are: § 40.13(c)(2)(i) – glazed ceramic tableware; and (iii) – glassware. Paragraph (d) of § 40.13 provided an exemption from licensing for uranium contained in detector heads for use in fire detection units.

The NRC's final action is to restrict the exemption for glazed ceramic tableware to include only those previously distributed products and delete the exemption for uranium contained in detector heads for use in fire detection units. The NRC is reducing allowable concentration levels of source material to levels for glassware; however, previously distributed glassware will still be exempted at the previous concentration level. In addition, the introductory paragraph of § 40.13(c) is being revised to specifically indicate that a person using these products is exempt from 10 CFR Parts 19, 20, and 21.

NUREG-1717 identified that these provisions are for products that have never been used or manufactured (detector heads), are no longer being manufactured (glazed ceramic tableware), or are no longer being manufactured at concentration levels originally established in the exemption (glassware). Because the final action is not intended to change the regulatory status of any products previously distributed in conformance with the provisions of the regulations applicable at the time, the exemptions for tableware and glassware distributed before the effective date of the final rule will continue; all newly manufactured products will be required to meet the amended, lower concentration limits.

Because the NRC is unaware of situations where products are currently being distributed under the exemption being removed or distributed containing concentrations higher than those being established, the only notable distinction between the no-action alternative and the rulemaking is that the preferred action will prohibit future distribution without the NRC's reevaluation. However, future distribution is unlikely because the products are outmoded or potentially considered frivolous. Therefore, it is unlikely that the amendments to these exemptions will have a significant impact on environmental resources.

The amendment to the introductory paragraph of § 40.13(c) will clearly state that a person possessing a product under an exemption in § 40.13(c) is not only exempt from obtaining a license or meeting the requirements of 10 CFR Part 40, but also is not required to meet the notification and training requirements of 10 CFR Part 19, the health and safety requirements of 10 CFR Part 20, and the reporting requirements in 10 CFR Part 21. Because this is the current practice under the exemption, the addition of this clarifying language will not affect any environmental resources.

5.5 No Action

The no-action alternative is to maintain the status quo.

The no-action alternative would not address identified public health and safety concerns. General licensees would continue to possess source material in quantities or isotopic concentrations that could significantly exceed public health and safety limits while still being exempt from 10 CFR Parts 19 and 20. Confusion regarding disposal requirements would continue, thus potentially permitting licensees to dispose of source material in unlicensed disposal facilities. In addition, not implementing contamination controls would allow the licensee to potentially abandon source material in place and thus expose other persons to dose levels normally not allowed for unrestricted use. Although the no-action alternative would not adversely affect any environmental resources, this alternative would not provide the improvements to health and safety that could result from the preferred action.

With respect to the reduction of concentrations allowed by the modification of or the deletion of certain exemptions, the no-action alternative would have no perceptible difference than the preferred action because it appears that no one is manufacturing those products at levels that they would be impacted. The no-action alternative would not expand the exemption for thin-coated optical lenses and, thus, would not adversely affect any environmental resources.

6.0 Conclusion

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's implementing regulations in Subpart A of 10 CFR Part 51, not to prepare an environmental impact statement for this rulemaking because the Commission has concluded on the basis of this environmental assessment that this rule is not a major Federal action significantly affecting the quality of the human environment. While most of the revisions fall under a categorical exclusion, the revisions to § 40.22 primarily provide additional limitations on, or clarify what a general licensee is allowed under the general license, thus potentially reducing the impact on environmental resources from the status quo. Similarly, certain exemptions are being revised or deleted to limit the future use of certain products containing source material. Although the NRC is expanding the exemption from licensing in § 40.13(c)(7) to allow coated lenses, the NRC's evaluation indicated that these products contain significantly less source material than those previously authorized under the exemption.

The determination of this environmental assessment is that there will be no significant impact to any environmental resources from this action and therefore the actions do not warrant the preparation of an environmental impact statement. A finding of no significant impact (FONSI) was published in the *Federal Register* concurrently with the publication of the proposed rule for public comment (75 FR 43425, July 26, 2010). No comments were received regarding the EA. The Commission considered the possible impacts from revisions made in the final rule and reaffirms this determination. Accordingly, the FONSI will be restated concurrently with the publication of the final rule.

7.0 List of Agencies and Persons Consulted

The NRC has determined that the preferred action is not a type of activity that has potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act. Additionally, the NRC has determined that Section 7 consultation with the U.S. Fish and Wildlife Service is not required because the preferred action will not affect listed species or critical habitat.

8.0 Sources Cited

Administrative Procedure Act of 1946, 5 U.S.C § 551 *et seq.* (1946).

Code of Federal Regulations, Title 10, Energy, Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations."

Code of Federal Regulations, Title 10, Energy, Part 20, "Standards of Protection Against Radiation."

Code of Federal Regulations, Title 10, Energy, Part 21, "Reporting of Defects and Noncompliance."

Code of Federal Regulations, Title 10, Energy, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Code of Federal Regulations, Title 10, Energy, Part 40, "Domestic Licensing of Source Material."

Code of Federal Regulations, Title 10, Energy, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," Subpart A, "National Environmental Policy Act – Regulations Implementing Section 102(2)."

Code of Federal Regulations, Title 10, Energy, Part 70, "Domestic Licensing of Special Nuclear Material."

Code of Federal Regulations, Title 10, Energy, Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."

Code of Federal Regulations, Title 10, Energy, Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC."

Nuclear Regulatory Commission (U.S.) (NRC). NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," NRC: Washington, D.C. June 2001.

Nuclear Regulatory Commission (U.S.) (NRC). NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," NRC: Washington, D.C. 1980.

Pacific Northwest National Laboratory, PNNL-16148, Rev. 1, "Risk Assessment for Current and Projected Uses of Source Material under a U.S. NRC General License and Exemption Criteria," February 2007.

PRM-40-27, Letter from Stanley R. Marshall and Robert Quillen to Secretary, U.S. Nuclear Regulatory Commission (May 10, 1999).

Products Intended for Use by General Public (Consumer Products) (30 FR 3462; March 16, 1965).