

November 1, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: EXEMPTION IN 10 CFR PART 40 FOR MATERIALS LESS THAN 0.05 PERCENT SOURCE MATERIAL - OPTIONS AND OTHER ISSUES CONCERNING THE CONTROL OF SOURCE MATERIAL

PURPOSE:

To provide the Commission with recommendations for developing a more risk-informed and coherent set of requirements for licensing source material, including possible revisions to 10 CFR 40.13(a). This paper provides options for resolving the concerns related to the exemption in 10 CFR 40.13(a) for materials less than 0.05 percent by weight source material and questions of jurisdiction over low levels of uranium and thorium. The paper requests Commission approval to: (1) initiate interactions with other agencies including States on roles and responsibilities for controlling exposures to low-level source material, (2) begin certain rulemaking to improve the protection of public health and safety from disposal and transfer of materials containing low concentrations of source material, and (3) develop a rulemaking plan to ensure requirements for exempt and generally licensed material are coherent and risk-informed.

SUMMARY:

This paper provides staff's initial recommendations for revisions to 10 CFR Part 40. At this time, the staff cannot provide specific recommendations on all issues related to Part 40 because not all the technical support documents are complete. The revised draft of the dose assessment report, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," will not be issued until December 1999. However, major aspects of a Part 40 revision can be addressed prior to completion of the dose assessments. Further, some dose information can be found in NCRP Reports and similar documents. The paper discusses options for addressing the jurisdictional and technical issues associated with regulating source material now exempt under 40.13(a), and recommends that the NRC address these broad issues after first interacting with other federal agencies and States involved with the regulation of naturally occurring radioactive materials. It recommends that rulemaking be undertaken to revise 40.51(b) to ensure that transfers of source material at concentrations less than the 40.13(a) concentrations by specific licensees, possibly for purposes of decommissioning and decontamination, do not cause undue risks to the public. Finally, the staff recommends that a rulemaking plan be developed for a rule which would primarily improve control of the exempt and general license distribution of source material, making the regulation of source material more like that for byproduct material.

BACKGROUND:

In a February 2, 1999, Staff Requirements Memorandum (SRM) in response to COMSECY-98-022, "Proposal to Permanently Dispose of 'Unimportant Quantities' of Source Material without a License pursuant to 10 CFR 40.13(a)" (Attachment 1), the Commission requested that the staff provide recommendations for developing a more risk-informed and coherent set of requirements for licensing source material in 10 CFR Part 40, including possible revisions to 10 CFR 40.13(a). In addition, the Commission directed the completion of certain reports and requested that the staff provide options on how to proceed to address the jurisdictional and technical issues associated with regulating source material (excluding uranium recovery), minimizing duplication in regulatory authority between NRC under the Atomic Energy Act (AEA), the States under State law, and the Environmental Protection Agency (EPA) under various Federal statutes.

The exemption in 40.13(a) involves complex issues related to the history of Part 40. The origin of the definition of source material in the AEA relates to its significance as a source for the production of special nuclear material. This is evident in Section 61 of the 1954 Act, as amended, which gives the Commission the authority to add other materials to the definition of source material only if such material is essential to the production of special nuclear material and that doing so is in the interest of the common defense and security. The assumption, when the Act was first promulgated, was that the health and safety impacts of source material were low enough that considerations of protecting the common defense and security would override those with respect to health and safety. In fact, Section 12(a)(2) of the 1946 Act, which concerned the protection of health and safety, did not mention source material. However, the 1954 Act included this requirement in Sections 2d, 63b, and 161b; thereby giving the Commission responsibility for protecting public health and safety from the uses of source material.

The 0.05 percent exemption in 40.13(a) is a remnant of this history, and appears to have been chosen on the basis of what concentrations of source material were necessary to be a useful source of fissionable material. The original definition of source material in Part 40 (1947) excluded all forms of uranium and thorium below this concentration limit. In 1961, the definition was revised to its present form to be consistent with the definition in the 1954 Act. Since that time, only ore below the 0.05 percent concentration has been excluded from the definition of source material. Other forms, "chemical mixtures, compounds, solutions, or alloys," below the same concentration limit are exempted as "unimportant quantities" of source material. In spite of the inclusion of source material in Sections 63b and 161b of the 1954 Act, no change in the original concentration limit was made on the basis of protection of health and safety.

Estimates of possible doses from uranium and thorium suggest that the concentration limit should be lower than 0.05 percent (500 ppm) in order to maintain individual doses below 1 mSv/year (100 mrem/year). Doses exceeding 1 mSv/year (100 mrem/year) can only result in certain operations in

which large quantities of such low concentration material are being handled. To ensure doses are below 1 mSv/year (100 mrem/year) regardless of volume, exempt concentration limits might be more on the order of 10-20 ppm for uranium in equilibrium with its daughters and 50 ppm for thorium. (Thorium achieves equilibrium with its daughters relatively rapidly.) These concentrations are only rough estimates to give a perspective on how significant a change might be needed. In the case of uranium, the NORM daughters' contribution to doses is included. Lowering the concentrations to such levels could lead NRC to regulate many processes that are unrelated to the nuclear fuel cycle and were likely not considered when the 1946 and 1954 Acts were written. Based on the extensive list of minerals containing uranium and thorium presented in NCRP Report No. 118, "Radiation Protection in the Mineral Extraction Industry," the Commission could conceivably regulate much of the mineral extraction industry in the United States.

Because uranium and thorium exist in combination with NORM (naturally occurring radioactive material, usually excluding any AEA material) in nature, activities falling under this exemption also involve NORM. Many of these materials contain radium in concentrations that pose health and safety impacts that are more significant than those from the potentially NRC-regulated materials. The EPA, the Conference of Radiation Control Program Directors, Inc. (CRCPD), and a number of States have been considering regulations to control risks from NORM and TENORM (technologically enhanced naturally occurring radioactive materials, excluding AEA material).

Currently some mineral extraction processes are specifically licensed, although they are not considered "nuclear" operations, because they result from the use, or concentration, of material above 0.05 percent by weight source material. When the staff is made aware of an individual processor dealing with source material in a concentration greater than 0.05 percent, the processor is required to obtain a license. This has typically happened as a result of the processor's own inquiry concerning applicability of NRC regulations. There may be other operations, of which we are not aware, but which in fact should be licensed under Part 40. Seeking these out and licensing them could be a major undertaking and would likely overlap with EPA and State efforts. Once again, the health and safety impacts of NORM and TENORM radioactive elements often exceed those of the source material elements. Some Site Decommissioning Management Plan (SDMP) sites were this type of licensee.

The staff has undertaken several initiatives related to the exemption in 40.13(a). One of these actions was to include this exemption in the systematic assessment of exemptions, including specifically the Oak Ridge National Laboratory's draft report, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials." The draft dose assessment for this exemption includes estimates of doses from practices and materials known to present the greatest potential for exposure. In some cases, the potential dose could be greater than 1 mSv/year (100 mrem/year). The highest dose estimates involve the inhalation of thorium, particularly by workers processing mineral sands. These estimates were made using dosimetry consistent with the current Part 20 (based on recommendations in ICRP 26 and 30). The dose estimates for thorium inhalation would be considerably less using more recent recommended models in ICRP 72. Regardless of the question of models for the estimation of internal doses, external exposures may also exceed 1 mSv/year (100 mrem/year) when large quantities of material are handled.

The staff also contracted with Advanced Technologies and Laboratories International, Inc. (ATL) to evaluate options for addressing the fact that 40.13(a) was not based on health and safety considerations. [Attachment 2](#), "Options Paper: Exemption in 10 CFR Part 40 for < 0.05% Source Material," provides a more detailed history on the regulations and provides an evaluation of the pros and cons of a number of possible options prepared by ATL (with minor revision by staff). This analysis forms a primary basis for the staff's recommendations.

In addition to the broader concerns related to this exemption, a number of individual licensing cases have raised the issue of licensees using the provisions of 40.13(a) and 40.51(b)(3) and (4) as a means of disposing of low-level source material. One of the recent cases concerned a proposal by Waste Control Specialists concerning transfer of wastes from Metcoa to a RCRA site, which was discussed in COMSECY-98-022. A summary of licensing cases involving transfer to persons exempt under 40.13(a) was presented in SECY-99-136 (May 19, 1999).

There have also been some previous staff actions related to the development of more risk-informed and coherent regulations for the licensing of source material. An Advance Notice of Proposed Rulemaking (ANPRM) was published October 28, 1992 (57 FR 48749), which dealt primarily with the imbalance in the level of control exercised by the NRC in the regulations governing the licensing of source material with those governing the licensing of byproduct material. Following review of the comments on the ANPRM, the staff presented plans for rulemaking for Part 40 in SECY-94-074 (March 18, 1994). However, the ANPRM was later withdrawn (December 14, 1998; 63 FR 68700) because the staff was not yet prepared to determine the best approach for rulemaking to address the issues identified.

Also related to the development of risk-informed regulations for source material is a petition for rulemaking, PRM-40-27 ([Attachment 3](#)), recently submitted by the Officers of the Organization of Agreement States (OAS) and the State of Colorado. The petition concerns the exemption from Parts 19 and 20 provided in the general license contained in 40.22. This exemption allows the possession and use of up to 15 pounds of source material at any time and up to 150 pounds in a year. This petition did not qualify for fast-track consideration under the guidelines in the NRC Regulations Handbook (NUREG/BR-0053). Notice of receipt of the petition was published July 7, 1999 (64 FR 36615). The comment period closed September 20, 1999. Nine comment letters have been received.

DISCUSSION:

- Licensee transfers of source material to persons exempt under 40.13(a).
- Risk-informed and coherent regulations for the licensing of source material.

The exemption in 40.13(a) addresses the point at which uranium and thorium are subject to NRC's regulations. Given that uranium and thorium are ubiquitous, any change to this exemption could have a significant impact on the NRC's regulatory program. Lowering the concentration limit for this exemption (and possibly the corresponding concentration of ore in the definition of source material) would make many more operations and activities subject to Part 40 licensing.

Based on the mission of the NRC under the AEA, it could be argued that NRC authority should be limited to activities related to recovery of thorium and uranium (primarily in support of the nuclear fuel cycle). NRC might retain authority for all materials produced once ore is processed for its uranium and thorium content, even though some of these materials may not enter the fuel cycle (e.g., materials used to make products utilizing uranium and thorium). Naturally occurring uranium and thorium inadvertently concentrated by various other processes might more easily and consistently be regulated along with other naturally occurring materials (by EPA, Occupational Safety and Health Agency (OSHA [EXIT](#)), and the States).

Among the various options evaluated in [Attachment 2](#) are a number of alternatives that involve NRC relinquishing authority for some low-level source material to these other agencies.⁽¹⁾ It should also be noted that those options that use a concentration limit for NRC regulation, would retain dual authority over some materials and continue to present difficulties in determining which activities are subject to NRC licensing.

The staff believes that a legislative option could fully resolve the issues related to this exemption. The most appropriate might be to limit NRC authority to activities related to recovery of uranium and thorium (primarily in support of the nuclear fuel cycle) (Option 4.4.2 in [Attachment 2](#)). However, before requesting a legislative change, agreements with the other agencies that could assume some responsibilities now held by the NRC would be necessary. The staff is concerned that the overall process, including interactions with other agencies, seeking legislative change, and subsequently revising the regulations for consistency with any revised legislation, could involve significant expenditure of resources over a long period of time. The cost of this would have to be recovered from our existing licensees, even though the issue primarily involves unlicensed materials. Moreover, it is unlikely that we would get the precise legislation that we would desire. Since the problems can be addressed in part through administrative action, the staff does not recommend a legislative option at this time.

An option that might be accomplished more quickly and with less expenditure of resources would be to establish a Memorandum of Understanding (MOU) among NRC, EPA, OSHA, and the States. Through an MOU, the other agencies could agree to consider the effects of low-level source material when regulating NORM. This, however, would not change NRC's responsibilities under the AEA. Further evaluation should also be made of the extent to which recent initiatives and ongoing efforts by EPA and the States to regulate NORM or TENORM will protect public health and safety from AEA material as well. Currently it appears that it may be several years before there are clear nationwide regulations governing NORM or TENORM.

Whatever option may ultimately be pursued, the next step should be to interact with these other agencies. This would enable the staff to evaluate how existing and planned regulation of NORM and TENORM will also protect public health and safety from low-level source material and assess the willingness of these agencies to assume responsibility for this material. This interaction could take place at least in part through ongoing systems of interchange: the Interagency Steering Committee on Radiation Standards, NORM Subcommittee; the OAS; and the CRCPD.

Rulemaking issues associated with source material were discussed during the annual meeting of the OAS in Austin, Texas, September 8-10, 1999. The States were concerned with health and safety issues associated with Part 40 and expressed an interest in being involved with any Part 40 rulemakings.

LICENSEE TRANSFERS OF SOURCE MATERIAL TO PERSONS EXEMPT UNDER 40.13(A).

The issue of licensee transfers of large volumes of material to exempt persons, which might be the situation in waste disposal and decommissioning, could be addressed relatively quickly through rulemaking. A rule could amend 40.51(b)(3) and (4) and possibly 40.13(a) to require prior Commission approval for transfers to persons exempt under 40.13(a). This action is addressed in the Rulemaking Activity Plan as RM #447 (NMSS-C4B-19). It has been on hold pending Commission consideration of the broader issues of 40.13(a). The staff believes that this rulemaking could proceed without the development of a rulemaking plan. The staff would expect to approve transfers under this provision consistent with recent SRMs (e.g. February 2, 1999 on SECY-98-284); that is, transfers would be approved if doses are not expected to exceed 1 mSv/year (100 mrem/year), and the Commission would be informed of situations where approval involves projected doses exceeding 0.25 mSv/year (25 mrem/year). This rulemaking would increase protection of the public health and safety although it might also increase regulatory burden by the imposition of this regulatory approval. If directed by the Commission, the staff would provide a proposed rule to the Commission 6 months from the date of the SRM on this paper.

RISK-INFORMED AND COHERENT REGULATIONS FOR THE LICENSING OF SOURCE MATERIAL.

The dose assessment report, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," is not yet finalized and subsequent analyses of cost and benefits will be needed to complete the systematic assessment of exemptions. Thus, the staff cannot make recommendations on all issues related to the exemptions in Part 40 at this time. However, there are aspects of Part 40 that can be addressed in the interim. [Attachment 4](#) presents a brief discussion of issues related primarily to the control of source material, which could be addressed through rulemaking. They concern the exemptions and general licenses in Part 40, and the distribution of source material for use under the exemptions and general license. These issues were addressed in NUREG/CR-2881, "An Examination of Source Material Requirements Contained in 10 CFR Part 40, Options Paper: Discussion of Major Issues for Revision" and in the ANPRM published October 28, 1992. With the exception of uranium recovery issues, which are being addressed in a separate rulemaking, these are the primary issues that had been identified in the ANPRM. No issues have been identified with the requirements for specific licensees other than distributors and uranium recovery licensees. The requirements are general, non-prescriptive, but adequate to enable the NRC staff to develop risk-informed licensing requirements necessary for health and safety for the particular activities proposed in a license application.

The issues discussed in [Attachment 4](#) can be addressed without the completion of the dose assessment report. The staff will provide additional recommendations concerning the exemptions in the context of developing the rulemaking plan. As discussed in [Attachment 4](#), the staff could begin a rulemaking primarily to improve control over the distribution of source material to persons exempt under 40.13 and to 40.22 general licensees. This rulemaking could also incorporate the Commission's resolution of PRM-40-27. Addressing the issues raised in the petition should involve consideration of options in addition to that suggested by the petitioner and input from the States in this process would be desirable. Therefore, the staff would coordinate a rulemaking plan with the Agreement States and provide the plan to the Commission 12 months after receipt of an SRM on this paper.

The staff notes that a single rulemaking to address the issues discussed in [Attachment 4](#) as well as the issue of licensee transfers to persons exempt

under 40.13(a) might be a somewhat more efficient use of resources. The separate rulemaking on transfers for disposal (RM #447) would be terminated and incorporated into the broader rulemaking to be addressed in the rulemaking plan discussed above. This would, however, delay completion of this specific action, because of the time for the rulemaking plan stage and the longer time needed for the more complex rulemaking. Thus, the staff recommends separate rulemakings to address the two issues.

RESOURCES:

The staff anticipates that 2.5 FTE's each year will be needed in FY 2000 and FY 2001 to implement the activities discussed in this paper. The staff will use primarily existing rulemaking resources, and reprogram as needed to accomplish the effort. Any reprioritization of rulemakings would be done in the context of the semi-annual rulemaking activity plan and the Agency Planning, Budgeting, and Performance Management process. Total resources to achieve a national consensus on the relationship between NORM regulation and the exemption of source material in 40.13(a) are problematic pending the achievement of a national consensus on NORM and TENORM regulation.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed course of action. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed this paper for information technology and information management implications and concurs in it.

RECOMMENDATIONS:

That the Commission:

1. In order to address possible revision of 40.13(a), approve the initiation of interaction with the EPA, OSHA, and the States to explore the best approach to delineate the responsibilities of the NRC and those agencies with regard to low-level source material to include support for a potential legislative change.
2. Approve staff plans to proceed with rulemaking to amend 40.51(b)(3) and (4) to require prior Commission approval for transfers to persons exempt under 40.13(a) in order to fix current licensee problems with 40.13(a).
3. Approve the development of a rulemaking plan to improve the control of distribution of source material to exempt persons and to general licensees, and the incorporation of the resolution of PRM-40-27 in order to make Part 40 more risk-informed.

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Attachments: 1. Feb. 2, 1999, SRM on COMSECY-98-022
2. Options Paper on 40.13(a)
3. PRM-40-27
4. Issues Related to Control of Source Material

ATTACHMENT 2

OPTIONS PAPER:

Exemption in 10 CFR Part 40 for < 0.05% Source Material

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Submitted December 1, 1998

Prepared for
U.S. Nuclear Regulatory Commission

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OPTIONS PAPER: Exemption in 10 CFR Part 40 for <0.05% Source Material

1.0 INTRODUCTION

Section 40.13(a) of 10 CFR Part 40 exempts from licensing any person who receives, possesses, uses, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is less than 0.05% by weight. This exemption has been in Part 40 since 1961. In the course of conducting a systematic assessment of exemptions, the NRC staff recognized that this exemption concerned issues of jurisdiction and interpretation of the intent behind the Atomic Energy Act and that options other than rulemaking should be considered. The purpose of this paper is to identify possible options for dealing with this exemption, along with the pros and cons of each.

2.0 BACKGROUND

The following background information on this matter may be helpful in considering the options.

2.1 Original Definition of Source Material

The Atomic Energy Act of 1946 defined source material as follows: "The term 'source material' means uranium, thorium, or any other material which is determined by the Commission, with the approval of the President, to be peculiarly essential to the production of fissionable materials; but includes ores only if they contain one or more of the foregoing materials in such concentration as the Commission may by regulation determine from time to time." Also, the 1946 Act, in Section 5(b)(2), stated that "...licenses shall not be required for quantities of source material which, in the opinion of the Commission, are unimportant." In implementing the 1946 Act, the Commission established in 10 CFR Part 40, Section 40.2(a), the following definition of source material: "the term 'source material' means any material, except fissionable material, which contains by weight one-twentieth of one percent (0.05%) or more of (1) uranium, (2) thorium, or (3) any combination thereof." No distinction was made with respect to ores containing uranium or thorium. It appears that the Commission selected the 0.05% value primarily on the basis of that concentration of source material that was considered strategically important for the production of special nuclear material. It also appears that concentrations of natural uranium and thorium less than 0.05% were considered "unimportant." The legislative history of the Act indicates that uranium and thorium, as they exist in nature, are not worth regulating unless they are considered important to the production of special nuclear material. It should be noted, however, that the Atomic Energy Act of 1954, as amended, makes it clear in several places that the Commission is to regulate source material, among other things, so as to protect the health and safety of the public (see, for example, Section 2 d. and e., Section 63 b., Section 69 and Section 161 b.).

2.2 Subsequent Definition Changes

The Atomic Energy Act of 1954 changed the definition of source material to read as follows: "The term 'source material' means (1) uranium, thorium, or

any other material which is determined by the Commission pursuant to the provisions of section 61 to be source material; or (2) ores containing one or more of the foregoing materials, in such concentration as the Commission may by regulation determine from time to time." The primary difference from the 1946 Act is the deletion of the phrase: "peculiarly essential to the production of fissionable material," although the concept was embodied in Section 61 of the 1954 Act. Section 62 of the 1954 Act states, as did the 1946 Act, that "...licenses shall not be required for quantities of source material which, in the opinion of the Commission, are unimportant." To conform with the 1954 Act, the Commission revised the definition of source material in 10 CFR Part 40 (Section 40.4) to read as follows: "*Source Material* means: (1) Uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of: (i) Uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material" (26 FR 284, January 14, 1961). The change in the source material definition also added the phrase "any physical or chemical form" to the first part of the definition. As noted above, the Commission also provided in Part 40 an exemption from licensing for any chemical mixture, compound, solution, or alloy in which the source material content by weight is less than 0.05% (Section 40.13 (a)). Thus, the Commission carried forward the 0.05% value that was established earlier. The Commission noted in its Notice of Proposed Rulemaking on amending Part 40 (25 FR 8619, September 7, 1960) that as a result of this exemption the change in the definition of source material was not expected to have any effect on the licensing program. An exemption from licensing was also provided for unrefined and unprocessed ore (Section 40.13(b)) without regard to source material concentration (note that ores containing less than the 0.05% concentration are not source material by definition). A definition for the word ore was not provided in the Atomic Energy Act of 1946, the Atomic Energy Act of 1954, as amended, or in 10 CFR Part 40. The above cited Notice of Proposed Rulemaking indicates that this exemption would eliminate the need for miners to have a license to transfer source material, as was required by existing regulations at that time. The Notice also states that the Act does not require a license for the mining of source material, nor do the implementing regulations.

2.3 Advance Notice of Proposed Rulemaking--1992

On October 28, 1992, an Advance Notice of Proposed Rulemaking on an overall revision of 10 CFR Part 40 was published in the Federal Register (57 FR 48749) for public comment. With respect to the 0.05% exemption, the comments received may be summarized as follows; a number of commenters expressed concern with regard to a possible lowering of the 0.05% limit. They noted that many naturally-occurring materials contain uranium and/or thorium in concentrations just below the 0.05% limit, and a lower limit would result in NRC regulatory involvement in a wide variety of activities, many of which are not related to the nuclear fuel cycle. One commenter suggested that the exemption be based on the Department of Transportation definition of radioactive material (0.002 Ci/g) or changed to a radiation dose standard. Another commenter noted that NRC has not identified any specific health hazards or concerns that would justify lowering the 0.05% limit. A commenter provided information on its use of zircon and fused zirconia products. Another commenter recommended that the exemption be clarified so that it does not permit waste disposal by transfer of such material to unlicensed persons. One commenter raised a question as to whether or not NRC intended to require a specific license authorization for use of the 0.05% exemption and the submission of annual reports of transfers of material pursuant to the exemption. These comments should be considered in making decisions concerning the options identified for dealing with this matter.

3.0 DISCUSSION

3.1 Difficulty in Demonstrating Adequate Level of Safety

The present issue with the exemption in Section 40.13(a) is the difficulty in demonstrating, based on the revised Part 20 and other data, that an adequate level of safety can be shown to exist in the possession, use, and disposal of source material for the wide variety of potential activities that could be carried out under this exemption. For example, this exemption has permitted the incorporation of uranium and thorium into consumer products such as dentures, eyeglasses, and eyepieces without prior safety review and approval. It was also a factor in a proposal to import from Canada wastes containing low levels of source material. Further, since uranium and thorium are naturally-occurring elements and are ubiquitous, inadvertent concentration of uranium and thorium to levels above the 0.05% value may occur in certain industries, particularly those involved in mineral extraction, without the awareness by industry of the need for a license or the knowledge of the regulatory authorities. This latter situation raises a question of the practicality of compliance by industry with the condition of the exemption and the enforcement of the condition by NRC. However, it should be noted that the Commission staff has never seen fit over the years to take any action to modify this exemption based upon whatever information became available with regard to the use of the exemption.

3.2 Concentrations and Potential Doses

Recent assessments of potential health and safety risks from uranium and thorium, lead to significant changes in radiation dose estimates, which suggest that in certain situations source material below the exempt concentration limit could result in radiation exposures of the public exceeding 100 mrem/year. A draft study by the Environmental Protection Agency (EPA) on diffuse naturally-occurring radioactive material (NORM) appears to support this view. Further, a draft ORNL report prepared for NRC entitled "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," indicates that the annual average effective dose equivalent to an industrial worker handling bulk zircon products could potentially range from 250 mrem to 3500 mrem. The dose estimates in the draft ORNL report are based on dose calculation methodology reflected in Part 20, but as pointed out in a report containing peer review comments on the ORNL draft, the use of the more recent guidance of the International Commission on Radiological Protection, ICRP Publication 72, 1996, would lower the dose estimates for inhalation significantly.

The 0.05%, by weight, source material limit translates to about 339 pCi U/g for natural uranium and 116 pCi Th/g for natural thorium. These levels are approximately 34 times and 12 times, respectively, greater than the levels that the NRC has typically used for releasing contaminated sites under Option 1 of the 1981 Branch Technical Position, "Disposal or Onsite Storage of Thorium or Uranium from Past Operations." Under some circumstances, the potential doses could greatly exceed NRC's limit of 25 mrem/year for unrestricted release of decommissioned sites. Further refinements in the radiation dose estimates should give a clearer picture of the safety significance of this matter.

3.3 Possible Transfer as Waste to Exempt Persons

Another matter which should be addressed with respect to this exemption concerns the possible transfer of source material by licensees to exempt persons as a means of waste disposal. Section 40.51(b)(3) allows licensees to transfer source material to any person exempt from the licensing requirements of 10 CFR Part 40 to the extent permitted by the exemption. A similar provision in Section 40.51(b)(4) permits such transfer to persons in an Agreement State who have been exempted from the licensing requirements and regulations of that State to the extent permitted under such exemption. Since Part 20 only applies to licensees, persons exempt from licensing pursuant to Section 40.13(a), or equivalent Agreement State regulation, are not required to comply with the radiation safety controls of 10 CFR Part 20. Also, the decommissioning requirements of 10 CFR Part 40, or of equivalent Agreement State regulations, are not applicable to exempt persons. The use of these provisions by licensees with source material contamination could result in substantial cost savings (up to hundreds of millions of dollars) as compared with waste disposal and decommissioning costs involved in meeting the requirements of 10 CFR Part 20 and license conditions. In dealing with specific cases, the NRC staff has usually held that waste disposal by licensees is governed only by Part 20 and that Section 40.13(a) is not intended to be used by licensees as a mechanism for waste disposal. The regulations, however, can easily be interpreted otherwise and licensees may not consult NRC on the matter. Also, if the recipient claims a use for the material, there is nothing in the regulations that can be interpreted to preclude transfers to license exempt persons.

3.4 Potential Impact on Other Industries

Actions taken with respect to the 0.05% exemption should also consider possible impacts on the exemptions for unrefined and unprocessed ore and for rare earths provided in sections 40.13(b) and 40.13(c)(1)(vi), respectively. Possible impacts on the licensing and regulation of uranium milling and mill tailings should also be considered. The possible ramifications of any contemplated changes to this exemption, however, need to be carefully considered so that NRC is not drawn unnecessarily into regulating ore processing operations and other activities which involve low concentrations of source material, particularly where hazards from materials other than uranium and thorium predominate (e.g. hazardous chemicals and radium). Examples of such processing operations and activities include mineral extraction for copper, titanium, zirconium, molybdenum, and lead/zinc; phosphate processing, including fertilizers; and coal ash.

3.5 Authorities of Other Agencies

Certain of the options identified below involve changes in NRC authority with respect to regulation of source material. The effects of changes in NRC authority on the regulatory programs of other federal agencies and the States need be considered in pursuing such options. A number of federal statutes administered by other federal agencies, mainly EPA, include authority to regulate source material, thus creating situations of possible dual regulation by NRC and the agency involved. Various working relationships have been developed to facilitate implementations of the laws. Examples of such statutes administered by EPA include the Clean Air Act, as amended, Safe Drinking Water Act, Marine Protection Research and Sanctuaries Act (ocean dumping), and the Atomic Energy Act of 1954, as amended, pertaining to environmental standards for the uranium fuel cycle, uranium and thorium mill tailings and management, and disposal of high level and transuranic radioactive waste.

On the other hand, there are other federal statutes and/or implementing regulations of other federal agencies dealing with radioactive materials and other hazardous substances which exclude byproduct, source and special nuclear material from their coverage. The Solid Waste Disposal Act, including the Resource Conservation and Recovery Act amendments, administered by the EPA, exclude from the definition of "solid waste", "source, special nuclear or byproduct material as defined by the Atomic Energy Act of 1954, as amended." The Toxic Substances Control Act, also administered by the EPA, excludes from coverage any source material, special nuclear material or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act). Regulations promulgated by the Occupational Safety and Health Administration of the U. S. Department of Labor pursuant to the Occupational Health and Safety Act of 1970 provide that employers who possess or use source material, byproduct material or special nuclear material under a license issued by the NRC and in accordance with the requirements of 10 CFR Part 20 shall be deemed to be in compliance with the radiation protection provisions of OSHA regulations. (A similar provision exists with respect to employers regulated by the NRC agreement States.) Thus, it appears that in these latter three instances, any material containing natural uranium and/or thorium that is excluded from the definition of source material in NRC regulations would fall within the jurisdiction of EPA and OSHA.

To the extent that the States may be involved in the Options identified, notice should be taken of Section 8.4 of 10 CFR Part 8, an interpretation by the General Counsel regarding NRC jurisdiction over nuclear facilities and materials under the Atomic Energy Act. Briefly, the interpretation points out that the Atomic Energy Act of 1954 had the effect of pre-empting to the federal government the field of regulation of nuclear facilities and byproduct, source and special nuclear material from the standpoint of radiological health and safety. Section 274 of the Act provides for the discontinuance of some of the NRC regulatory authority over source, byproduct and special nuclear material in States which enter into an Agreement with the NRC. Section 274 of the Act also makes it clear that there should be no "dual regulation" with respect to these materials for purpose of protection of the public health and safety from radiation hazards. The Section 274 Agreements require the agreement States to use their best efforts to assure that their regulatory programs for protection against radiation hazards will continue to be compatible with the NRC's program for regulation of byproduct, source and special nuclear materials. Contemplated changes in the NRC program for regulating source material should be coordinated with the Agreement States at an appropriate time.

4.0 OPTIONS

The options identified for addressing this exemption are listed below and are discussed along with the pros and cons of each option. Given that changes in this exemption are considered necessary to provide assurance of adequate protection of public health and safety, the basic courses of action appear to be (a) tighten regulatory control over this category of source material, (b) divest NRC from having regulatory authority over this category of source material, thus allowing other Federal and State agencies to regulate such material, and (c) establish administrative arrangements through Memoranda of Understanding whereby other Federal agencies would regulate in this area. These courses of action may be accomplished by rulemaking, Memoranda of Understanding and/or legislative changes in the Atomic Energy Act of 1954, as amended. Some of the options identify possibilities for modifying the NRC regulatory framework for source material that go beyond the 0.05% exemption in relieving NRC of certain regulatory authority should this approach be considered worthwhile pursuing in more detail.

4.1 No Change. The exemption would be continued in its present form.

Pros

- a. Efforts being taken by EPA and the States to regulate naturally-occurring radioactive material would tend to control the risk from any uranium and/or thorium that may also be present. In some cases, however, uranium or thorium could be the dominant concern and whatever controls exist may not adequately protect against the potential hazards.
- b. No change in the impacts on NRC, licensees or persons using source material pursuant to the 0.05% exemption.

Cons

- a. Current estimates of potential health and safety risks from source material exemptions in Part 40, based on the draft ORNL report, "Systematic Assessment of Exemptions for Source and Byproduct Materials," indicate there can be significant health and safety impacts from some uses of source material within the exemption (e.g. bulk zircon sands), and thus a need for some safety controls. Estimated annual average effective radiation doses for workers handling bulk zircon products could range from 250 up to 3500 mrem.
- b. The scope of activities permitted under the exemption is so broad that it is difficult to justify the adequacy of the exemption from a health and safety standpoint.
- c. The broad nature of this exemption has permitted the incorporation of uranium and thorium into consumer products, such as eyeglasses, eye pieces, and dentures without prior safety review and approval.
- d. The exemption, combined with the transfer provisions of Part 40, may be used by licensees as a means of waste disposal to avoid the higher costs involved in complying with 10 CFR Part 20 and decommissioning requirements.
- e. Overall regulation is inconsistent since NRC may not be aware of all non-fuel cycle activities that may inadvertently concentrate source material to levels greater than the 0.05% concentration limit. Considerable additional resources would be needed to find such situations.

4.2 Rulemaking Options

4.2.1 ELIMINATE THE EXEMPTION.

The exemption would be deleted from the regulation and any activities carried out under the exemption would have to meet existing general license conditions or be specifically licensed.

Pros

- a. Eliminates health and safety concerns with the exemption.
- b. Avoids the need to evaluate and justify possible alternate concentration limits, or other restrictions, and their ramifications on the NRC regulatory program.

Cons

- a. Increases the regulatory workload by requiring that activities that were formerly exempt from licensing be specifically licensed or meet the conditions of a general license, in some cases perhaps unjustifiably. If a general license were established to cover such activities, however, it would be less burdensome than specific licensing. Regulatory fees would be an additional burden on the new licensees which could give rise to complaints.
- b. Since uranium and thorium are ubiquitous, this option could result in the need to license a wide variety of substances and activities, many of which might involve very low concentrations of source material and therefore present minimal health and safety risk. Questions could be raised as to whether such a situation represented a proper use of resources. As a practical matter, the establishment of a "below regulatory concern" threshold would be necessary for proper implementation of this option.
- c. Would cause NRC to regulate operations in the non-nuclear mineral extraction industry where hazards from materials other than uranium and thorium may predominate.
- d. Could cause interface problems between NRC and EPA (and possibly the States), since EPA is in the process of developing regulations for controlling diffuse sources of naturally-occurring radioactive material.

4.2.2 LOWER THE CONCENTRATION LIMIT.

Lower the concentration limit in the exemption to a level that can be justified from a health and safety standpoint based on the revised Part 20.

Pros

Provides a justifiable basis for the exemption based on current radiation protection standards.

Cons

- a. Increases the regulatory workload on NRC and the impact, including fees, on those subject to regulation by requiring licenses for a wide variety of activities that were previously exempt from licensing.
- b. Could cause NRC to regulate activities in the non-nuclear mineral extraction industry (both processing operations and waste handling and disposal) where the principal hazards may arise from materials other than uranium or thorium.
- c. Would be necessary to gather data and perform safety analyses to justify a new concentration limit and to assess its ramifications on the industry, the NRC and the States.
- d. Could cause interface problems between NRC and EPA (and possibly the States) since EPA is in the process of developing regulations for controlling diffuse sources of naturally-occurring radioactive material.
- e. A single concentration limit covering all situations could lead to regulation which is not consistent on a risk basis. In order to control all situations to an adequate health and safety level, some situations would be regulated where the risks are much lower.

4.2.3 SPECIFY THE ACTIVITIES THAT CAN OR CANNOT BE CONDUCTED.

The activities that can or cannot be conducted under the exemption could be specifically prescribed. For example, using the exemption as a basis for the introduction of uranium or thorium into consumer products or for receiving source material contamination for the purpose of waste disposal could be prohibited, so that a specific license is required for such purpose.

Pros

Would limit the activities to those whose safety can be justified for the 0.05% concentration limit.

Cons

- a. Increases the regulatory workload on NRC and the impact, including fees, on those subject to regulation by requiring licenses for activities that were previously exempt from licensing.
- b. Could result in enforcement difficulties since the identity of users may not be known.
- c. Could cause interface problems between NRC and EPA (and possibly the States) since EPA is in the process of developing regulations for controlling diffuse sources of naturally-occurring radioactive material.

4.2.4 A COMBINATION OF LOWER CONCENTRATION LIMITS WITH SPECIFIED ACTIVITIES.

The Pros and Cons of options described in 4.2.2, Lower the Concentration Limit, and

in 4.2.3, Specify the Activities That Can or Cannot Be Conducted, apply to this option. An additional pro for this option is that a better consistency with risk levels might be possible.

4.2.5 LIMIT NRC REGULATORY CONTROL OF SOURCE MATERIAL (REGARDLESS OF CONCENTRATION)

The NRC regulatory control of source material could be limited (regardless of concentration) to processing which is primarily for recovery of uranium and/or thorium based on an interpretation of the intent of the Atomic Energy Act of 1954, as amended. The interpretation would be that NRC regulatory controls over source material concern primarily the nuclear fuel cycle and extend only to activities directly related to source material recovery and the subsequent use of recovered materials. The main objective would be to exclude from NRC regulatory control uranium and thorium inadvertently concentrated by various mineral extraction processes and other activities, but not recovered or separated. Such a change in NRC regulatory control could be accomplished through a legal interpretation of the Atomic Energy Act published in 10 CFR Part 8 Interpretations. Implementing changes would need to be made in Part 40. Arrangements would need to be made for EPA, OSHA and the States to incorporate those activities no longer controlled by NRC into their control programs for the industries involved. EPA would be concerned with the radiation exposure of the population and environmental protection and OSHA with worker safety. The States would work with both agencies in coordinating their control programs in these areas. NRC's authority to set limits for and regulate strategic quantities of source material would not be affected by the interpretation. The possession and use of uranium and thorium after recovery would continue to be regulated by NRC, and would include such activities as incorporation of uranium and thorium into consumer products.

Pros

- a. Would allow the NRC to concentrate its resources on the regulation of processing activities directly related to uranium recovery and subsequent utilization of the recovered materials.
- b. Would allow EPA, OSHA, and the States to have a comprehensive control program over all aspects of activities involving low concentrations of naturally-occurring radioactive material (diffuse NORM) where the material is not being processed primarily for its source material content.
- c. Would allow the potential hazards of uranium and thorium to be placed in proper perspective with the potential hazards of other materials which may be significantly greater, e.g. chemicals and radium.

- d. Would not change the NRC authority to control uranium and thorium from a strategic standpoint.
- e. Would reduce the number of agencies involved in regulating low concentrations of radioactivity.

Cons

- a. Could be viewed by some as an abdication by NRC of its health and safety responsibilities for the activities involved.
- b. There may be some limitations in the authorities of EPA, OSHA and the States to control the activities NRC would forego regulating which would need to be addressed.
- c. Would require increased NRC resources in the short term to prepare the interpretation and coordinate with other affected Federal agencies and the States.
- d. Difficulties may arise in defining and implementing the concept - "processing primarily for recovery of uranium and/or thorium," although the experience gained in implementing the uranium mill tailings legislation may be helpful.

4.2.6 ADD A DEFINITION OF THE WORD "ORE" TO 10 CFR PART 40

The definition of source material in Part 40 (Section 40.4) reads as follows: " *Source Material* means: (1) Uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one twentieth of one percent (0.05%) or more of: (i) Uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material." The word "ore" is not defined in Part 40 or in the Atomic Energy Act of 1954, as amended. Under this option, a definition of the word "ore" would be added to 10 CFR Part 40 such that materials falling within the definition of ore and containing less than 0.05%, by weight, uranium or thorium are not source material as defined in Part 40 and are thus outside the scope of NRC regulation. (Note: Under the Act, the NRC is given the authority to determine the concentration value for the ore.) In defining the word "ore", care must be taken not to affect the definition of byproduct material contained in Section 40.4 of 10 CFR Part 40 which is "the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes." To accomplish the objective, "ore" could be defined as "any natural or native matter that may be mined and treated for the extraction of any of its constituents or any chemical mixture, compound, solution, or alloy." Returning to the source material definition, if any of the materials included in the definition of ore contain less than 0.05%, by weight, uranium, thorium or any combination thereof, such materials would not be source material and would not be regulated by the NRC. If this definition of ore were adopted, the exemption from licensing in Section 40.13 (a) would no longer be necessary. Materials that no longer fall within the definition of source material would be subject to the regulatory control of EPA, OSHA and the States.

In implementing this option, it would be necessary to amend the material transfer provisions of Part 40 (Sections 40.51(b)(3) and (b)(4)) so that there is assurance that licensees will meet decommissioning and waste disposal requirements and the Part 20 clean-up criterion of 25 mrem/year for unrestricted release which became effective August 20, 1997. These requirements apply to the licensee regardless of the concentration of source material involved. Licensees may need to be reminded that it is the purpose of the Part 20 regulation to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in Part 20 (Section 20.1001(b)).

Selection of this option should not affect the NRC regulatory program for uranium milling and mill tailings since the definition proposed above would allow the Commission to continue to permit licensees to use either natural ore or feed materials other than natural ore for the purpose of extracting uranium and/or thorium, with assurance that the resulting tailings or wastes meet the definition of byproduct material (Section 40.4). This aspect is discussed more fully in the ANPR referred to above under the heading Mills and Mill Tailings (57 FR 48752) and in NUREG/CR-5881, An Examination of Source Material Requirements Contained in 10 CFR Part 40, (see page 7).

Pros

- a. The exemption in Section 40.13 (a) of 10 CFR Part 40 could be deleted.
- b. Provides safety for this class of source material through regulation and control by EPA, OSHA, and the States.
- c. Requires only minor amendments to Part 40 to implement the concept.
- d. Reduces the number of agencies involved in regulating low concentrations of source material.
- e. Falls conveniently into EPA's program for controlling materials with low concentrations of naturally occurring radioactive material.
- f. Conserves NRC resources in the long term.

Cons

- a. The definition of ore needed to accomplish the intended purpose would not conform to the usual usage of the term as found in the dictionary - a mineral containing a valuable constituent for which it is mined and worked, or a source from which a valuable matter is extracted.
- b. Would require expenditure of NRC resources in the near term to coordinate the proposed NRC action with the EPA, OSHA and the States.

4.3 Memoranda of Understanding Option.

Negotiate a memorandum of understanding with EPA and OSHA whereby these agencies would agree to regulate source material in concentrations less than 0.05%, by weight, (or some agreed to higher concentration) instead of NRC. Under this option these agencies would regulate the <0.05%, by weight, category using their own authorities or on behalf of NRC, as necessary. The rationale for EPA and OSHA being involved with this category of material is that they already have responsibilities for controlling the materials that contain low concentrations of uranium and thorium because of other naturally-occurring radioactive materials and chemical constituents.

Pros

- a. Would be responsive to the analyses which indicate that certain activities carried out under the exemption may result in radiation exposures in excess of 10 CFR Part 20 limits.
- b. Conserves NRC resources which would be necessary to deal with the exemption.
- c. Falls conveniently into EPA's programs for controlling materials with low concentrations of naturally-occurring radioactive material and OSHA's programs for worker safety.
- d. Decreases the number of Federal agencies involved in regulating low concentrations of naturally occurring radioactive material.
- e. Avoids rulemaking, or seeking legislative changes which would involve the Congress in a specific and narrow area of regulation.
- f. Provides flexibility for changes in arrangements established by the memorandum of understanding based on experience.

Cons

- a. Requires increased NRC resources in the short term to develop, coordinate, and pursue the memorandum of understanding with EPA and OSHA and coordinate it with the States.
- b. Legal difficulties may arise in developing the working arrangements among the agencies.

4.4 Legislative Options

4.4.1 SEEK RELIEF FROM REGULATORY AUTHORITY OVER LOW CONCENTRATIONS

Seek legislative changes in the Atomic Energy Act of 1954, as amended, to relieve NRC from having regulatory authority over low concentrations of source material, e.g. less than 0.05%, or possibly some higher concentration. It is noted that EPA is considering a rough dividing line of 2 nanocuries/gram between diffuse naturally-occurring radioactive material and discrete sources in developing its regulatory framework for such materials. For sake of comparison, 2 nanocuries/gram of natural uranium is equivalent to a concentration by weight of about 0.3%. Such change in NRC authority could be accomplished by a change in the definition of source material in the Atomic Energy Act of 1954, as amended, so that the threshold for NRC regulation would be a specified concentration of uranium and/or thorium. The authority for the regulation of uranium and thorium milling would remain unchanged. Authority for regulating uranium and thorium in concentrations below the specified level would be assumed by the EPA and OSHA, in conjunction with the States, all of which have regulatory authority over non-source material hazards in this area. EPA would be concerned with the radiation exposure of the population and environmental protection and OSHA with worker safety. The States would work with both agencies in coordinating their control programs in these areas. For those applicable EPA and OSHA statutes which exclude regulation of source material, e.g. Toxic Substances Control Act, changing the definition of source material in the Atomic Energy Act of 1954, as amended, as indicated above, would have the effect of giving EPA and OSHA jurisdiction over uranium and thorium in concentrations below the specified value that is chosen. The legislation would be prepared so that NRC's authority for safeguarding strategic quantities of source material is not affected. Transition arrangements may be needed to phase out NRC licenses for materials that will no longer be regulated by NRC. A request for Congressional action could open up other areas for consideration, such as regulation of "mixed waste" and possibly result in changes in NRC's authority other than those being requested.

Pros

- a. Eliminates NRC jurisdiction over the source material in a concentration lower than that set forth in the revised legislation.
- b. Conserves NRC resources in the long term for other regulatory activities.
- c. Falls conveniently into EPA's programs for controlling materials with low concentrations of naturally-occurring radioactive material.

- d. Decreases the number of Federal agencies involved in regulating activities involving low concentrations of naturally-occurring radioactive materials.

Cons

- a. Would require increased NRC resources in the short term to develop, coordinate, and pursue the legislative changes with the Congress, States and other appropriate Federal agencies.
- b. Could increase interaction with EPA and OSHA in situations where an activity involves a range of concentrations of source materials (both above and below whatever limit is established as a threshold for NRC authority).

4.4.2 SEEK CHANGES TO LIMIT NRC AUTHORITY TO ACTIVITIES RELATED TO RECOVERY OF URANIUM AND THORIUM (PRIMARILY IN SUPPORT OF THE NUCLEAR FUEL CYCLE)

Seek legislative changes in the Atomic Energy Act of 1954, as amended, to relieve NRC from having regulatory authority over source material processing (regardless of concentration) which is not primarily for recovery of uranium or thorium. Such a change would limit NRC's authority to source material activities which are primarily in support of the nuclear fuel cycle. The intent would be to exclude from NRC regulatory authority uranium and thorium inadvertently concentrated by various mineral extraction processes and other activities, but not recovered or separated. There would be provisions made for EPA, OSHA, and the States to incorporate such activities into their control programs for the industries involved. EPA would be concerned with radiation exposure of the population and environmental protection and OSHA with worker safety. The States would work with both agencies in coordinating their control programs in these areas. As noted in Section 4.4.1 of this report, such a transfer of authority to EPA and OSHA could be accomplished by changing the definition of source material in the Atomic Energy Act of 1954, as amended, so that it included only those processing operations which are primarily for uranium or thorium recovery. NRC would retain its authority to set limits for and regulate strategic quantities of source material. The possession and use of uranium and thorium after recovery would continue to be regulated by NRC, which would include such activities as incorporation of uranium and thorium into industrial and consumer products. Transition arrangements may be needed to phase out NRC licenses for materials that will no longer be regulated by NRC. A request for Congressional action could open up other areas for consideration such as "mixed waste" and possibly result in changes in NRC authority other than those being requested.

Pros

- a. Would allow the NRC to concentrate its resources on the regulation of processing activities directly related to uranium recovery and subsequent utilization of the recovered materials.
- b. Would allow EPA, OSHA and the States to have a comprehensive control program over all aspects of activities involving low concentrations of naturally-occurring radioactive material where the material is not being processed primarily for its source material content.
- c. Would allow the potential hazards of uranium and thorium to be placed in proper perspective with the potential hazards of other materials with which they are associated, e.g. chemicals and radium.
- d. Would reduce the number of Federal agencies involved in regulating low concentrations of naturally-occurring radioactive material.

Cons

- a. Requires increased resources in the short term to develop, coordinate and pursue legislative changes with the Congress, States, and other appropriate Federal agencies.
- b. May experience difficulty in defining and implementing the concept - "processing primarily for recovery of uranium and/or thorium," although the experience in implementing the uranium mill tailings legislation may be helpful.

4.4.3 SEEK CHANGES TO LIMIT NRC AUTHORITY TO ACTIVITIES IN SUPPORT OF THE NUCLEAR FUEL CYCLE AND RARE EARTH PROCESSING.

Same as Option 4.4.2 above except that, in addition, NRC would retain regulatory authority for rare earth processing, as well as for uranium and thorium recovery. The NRC authority to regulate consumer products and the rare earth industry where uranium and thorium may be present would not be changed.

Pros

Would continue the established NRC regulatory program for protection of health, safety, and the environment for an activity which involves processing operations where uranium and/or thorium concentrations are at levels comparable to those found in uranium milling activities.

Cons

Would be inconsistent with the purpose, as stated in Option 4.4.2, of limiting NRC regulatory to source material processing which is primarily for recovery of uranium or thorium and primarily in support of the nuclear fuel cycle.

Issues Related to Control of Source Material

1. What products/materials and how much are distributed for use under exemptions?

Problem: Reporting requirements imposed on distribution (5 year reports of byproduct material distributed, no reports of source material distributed) do not result in submission of sufficient, timely, and informative reports for NRC to determine what products and how much source material and byproduct material is distributed annually for exempt use. Thus, there is much uncertainty in any evaluation of resultant exposures of the public. Although efforts have been made in the process of developing the dose assessments to obtain additional information on materials distributed, there are limitations to the completeness of information that can be obtained voluntarily from the industry. At best, these methods of collecting information provide only a one time look, rather than providing the ability to see how the various practices change over time.

Solutions:

- For source material, selectively require specific licenses for distribution (not unprocessed ores, some rare earths and <0.05 percent) and annual material transfer reports.
- The NRC could develop a composite annual report of what products and how much byproduct material and source material is distributed for exempt use. This would provide better basis for regulatory decisions and for informing the public.

2. How much source material is distributed for use under the general license in 40.22? To whom? How should NRC better ensure the safety of those using 40.22?

Problem: Although this general license was not included in the draft dose assessment report, it is clear that the amounts of source material allowed could result in exposures above 1 mSv/year (100 mrem/year) to workers at facilities exempt from Parts 19 and 20. A recent petition, PRM-40-27, addresses this issue and suggests conditions under which the exemption from Parts 19 and 20 for these general licensees should not apply. However, there are currently no requirements specifically for those distributing source material for use under 40.22; and thus no regulatory mechanism for the NRC to identify the general licensees or get information on what material types and quantities are distributed. Without knowledge of the identity and location of the general licensees, it would be difficult to enforce restrictions on the general licensees.

Solution: Rulemaking to require licenses specifically for distribution to 40.22 general licensees along with a requirement for material transfer reports, similar to those required under 32.52 and 32.56 for distributors of byproduct material to general licensees. Further restrictions on the general license and/or removal of the exemptions from Parts 19 and 20 in 40.22(b) should also be considered as part of resolving PRM-40-27.

3. Are the regulations for exempt products containing source material adequate to protect public health and safety? Are they risk-informed?

Problem: Generally the exemptions for source material are associated with higher potential doses than those for byproduct material. Yet, relatively few requirements are imposed on distributors of exempt products containing source material. There are considerable controls over the distribution of exempt products containing byproduct material. Clearly there is not a risk-informed framework in the regulations concerning exemptions. Generally, the requirements for the distribution of byproduct material to exempt persons would provide a model for requirements for the distribution of source material; however, each exemption should be evaluated in the context of establishing risk-informed regulations.

Solution: Based on the results of the systematic assessment of exemptions and the risk review, consider both adding requirements for distribution of source material and modifying or deleting requirements for byproduct material. However, even with the results of these efforts, it will be very difficult to determine which types of requirements are appropriate for source material distributors without more information on the specific products and materials. Establishing a simple exempt source material distribution license with limited requirements including annual reporting of material transfers would provide a regulatory mechanism for obtaining information on what products and how much source material is distributed for exempt use. Additional provisions could be considered on a much firmer basis in the future.

Staff Recommendation:

As suggested under Issues 1. and 3., a rulemaking should be undertaken to establish a simple exempt source material distribution license with limited requirements including annual reporting of material transfers. The same rulemaking could also include establishing a distribution license (as in Issue 2.) for those who distribute to 40.22 general licensees. This staff recommendation would be similar to that made in SECY-94-074 (March 18, 1994), referred to as "Phase I rule."

This rulemaking would provide at least part of the regulatory basis for resolving each of these issues. After more information is obtained on the types and quantities of materials distributed, and the impacts of the various exemptions can be better evaluated, a future rulemaking might be considered to place additional requirements on these distributors.

1. The options include the use of a new, expanded definition of ore (Option 4.2.6), which would be different than that mentioned in SECY-99-012. As noted in Attachment 2, such a change would not be expected to impact the uranium recovery program.