

November 27, 2006

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Charles L. Miller, Director
Office of Federal and State Materials /RA/
and Environmental Management Programs

SUBJECT: CLOSEOUT OF GENERIC SAFETY ISSUE NMSS-016,
"ADEQUACY OF 0.05 WEIGHT PERCENT LIMIT IN 10 CFR 40"

The Office of Federal and State Materials and Environmental Management Programs (FSME) is closing out generic safety issue NMSS-016, "Adequacy of 0.05 weight percent limit in 10 CFR 40." FSME is closing out this issue based on the collection of policy direction that the Commission provided in staff requirements memoranda (SRMs), issued and reiterated numerous times over the past 8 years, for handling the source material of concern discussed in the generic safety issue. The staff originally planned to close out this generic safety issue by modifying 10 CFR 40.51, "Transfer of source or byproduct material" to codify the Commission's policy direction through rulemaking; instead, the staff is closing out this generic safety issue without finalizing the currently-postponed rulemaking on 10 CFR 40.51.

Issue

The generic safety issue was originally identified for entry into the generic issue management control system in June 1998. The issue originated from concerns that exposures to certain "unimportant quantities" of source material, as defined in 10 CFR 40.13(a) as less than 0.05 weight percent uranium or thorium, could result in annual doses to the public of hundreds of millirem (mrem). Of particular concern were the large bulk quantities of source material that could be generated by source material licensees, as part of their licensed processes, and then potentially transferred to non-licensees for possession under the exemption.

Background

Between 1996 and 1998, the Division of Fuel Cycle Safety and Safeguards (FCSS) received several requests from a single licensee to transfer licensed material containing less than 0.05 weight percent of uranium and thorium to an exempt person, consistent with the requirements in 10 CFR 40.51(b) and 10 CFR 40.13(a). The regulations in 10 CFR 40.51(b)(3) and 40.13(a) allow licensees to transfer source material to any person exempt from the

CONTACT: Gary Comfort, FSME/DILR
(301) 415-8106

licensing requirements of the Atomic Energy Act (AEA) and 10 CFR Part 40, as long as the source material content is less than 0.05 weight percent of the material as a whole. Upon evaluation of the request, the staff determined that under some circumstances, transfer of material in accordance with these regulations could result in doses that exceed the 1 mSv/yr (100 mrem/yr) public dose limit contained in 10 CFR 20.1301(a)(1). In addition, because the regulations do not explicitly provide a regulatory basis for denying such transfers, and because a licensee making such transfers would be complying with the regulations in Part 40 as they are currently written, the U.S. Nuclear Regulatory Commission (NRC) may issue an order to stop a licensee from making such a transfer only when the transfer may result in a potentially hazardous condition that could affect public health and safety. The staff concluded that although a licensee would be in compliance with the regulations in Part 40, doses could occur which are in conflict with the public dose limits contained in 10 CFR 20.1301(a)(1), and that allowing these transfers could set a precedent without resolving that conflict. As a result, the staff informed the Commission of its finding in SECY-98-284, "Transfers of Material Containing Less Than 0.05 Percent by Weight Source Material Under 10 CFR 40.51(b)(3) and (b)(4), and 40.13(a)," dated December 8, 1998. In that same paper, the staff also notified the Commission that it was also developing a range of possible revisions to Part 40 through a contractor report entitled "Options Paper on Exemption in 10 CFR Part 40 for Less Than 0.05 percent Source Material."

In the SRM to SECY-98-284, dated February 2, 1999, the Commission approved transfers with the directions that the projected dose be less than 100 mrem/yr and to notify the Commission if the dose exceeded 25 mrem/yr. Additionally, the Commission issued an SRM to COMSECY-98-022, "Proposal to Permanently Dispose of 'Unimportant Quantities' of Source Material Without a License Pursuant to 10 CFR 40.13(a)," also dated February 2, 1999, in which the Commission directed the staff to complete the contractor's options report and provide its recommendation to the Commission 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 SECY-99-259, "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," dated November 1, 1999, the staff responded and proposed, among other actions, to develop a rulemaking to prevent transfers, under 10 CFR 40.51, to persons exempt from the regulations, under 10 CFR 40.13(a).

The Commission approved the staff's recommendation to proceed with rulemaking to prevent transfers under 10 CFR 40.51 without prior NRC authorization in the SRM to SECY-99-259. Subsequently, the staff presented the Commission with a proposed rule in SECY-00-0201, "Proposed Rule - 10 CFR Part 40 Amendments to Require NRC Approval for Transfers from Licensees to Exempt Persons," dated September 25, 2000. The draft proposed amendments, contained a new paragraph, 10 CFR 40.51(e), that stated that transfers under 10 CFR 40.51(b)(3) and (4) are subject to NRC approval, and required a licensee seeking to transfer material to submit information that would allow the NRC to determine the estimated dose resulting from the transfer. In the "Statement of Considerations" (SOC) for the proposed rule, the staff reiterated the Commission's directions provided in the SRM to SECY-98-284 (i.e., that the projected doses from the transfer be less than 100 mrem/yr and that the Commission be notified if the dose exceeds 25 mrem/yr). In the SRM to SECY-00-0201, dated March 29, 2002, the Commission approved publication of the proposed rule and once again, reiterated the previous directions for approval of transfers. However, the Commission stated that these exposure limits were only applicable to requests for disposal and that other activities should be

evaluated on a case-by-case basis “until the Commission’s approach to the release of solid material is resolved.” The proposed amendment to 10 CFR 40.51 was published in the *Federal Register* on August 28, 2002 (67 FR 55175).

Subsequent to the publication of the proposed rule, staff working on the rule identified three then-ongoing activities that had the potential to impact the 10 CFR 40.51 rulemaking. These activities included the ongoing activities of: (1) the Interagency Jurisdictional Working Group (IJWG) Evaluating the Regulation of Low-Level Source Material or Materials Containing Less than 0.05 Percent by Weight Concentration Uranium and/or Thorium; (2) disposition of solid materials; and (3) the U.S. Environmental Protection Agency’s (EPA’s) development of an Advance Notice of Proposed Rulemaking (ANPR), to solicit stakeholder input on a potential regulatory framework to permit disposal of low-activity radioactive waste and mixed waste in Resource and Recovery Act (RCRA) Subtitle “C” facilities. Because of the potential impacts to the 10 CFR 40.51 rulemaking, the staff notified the Commission of its concerns in SECY-03-0106, “Update on Proposed Rule Changes to 10 CFR 40.51,” dated June 24, 2003. In SECY-03-0106, the staff also informed the Commission that the staff intended to postpone publication of the proposed changes to 10 CFR 40.51, as a final rule, until activities related to the IJWG, disposition of solid materials, and EPA’s ANPR on disposal of low-activity and mixed waste were resolved. In the SRM to SECY-03-0106, the Commission did not object to the staff’s postponing the rulemaking and the Commission directed the staff to continue its current practice of reviewing licensees’ requests for transfer or disposal of unimportant quantities of source material under 10 CFR 40.13(a), and, when justified, issue case-specific exemptions based on previous Commission guidance.

Discussion

The staff has continued to periodically evaluate the status of the three ongoing activities that were identified as potentially impacting the rulemaking on transfers of small quantities of source material. The current status of the identified activities is as follows: (1) The activities related to the disposition of solid materials have been formally and indefinitely deferred and, as a result, will not impact the proposed 10 CFR 40.51 rulemaking in the foreseeable future. (2) Although activities related to the IJWG were deferred until recently, in the SRM to SECY-06-0117, dated August 2, 2006, the Commission directed the staff to restart and accelerate the activities of the IJWG. As a result, certain resolutions of IJWG activities could once again impact the eventual need for the 10 CFR 40.51 rulemaking, thus warranting continued deferral of finalization of the proposed rule. (3) Finally, EPA has not completed activities related to its ANPR and has placed these activities on hold because of higher priority activities. Discussions with EPA staff indicate that EPA plans to continue pursuit of the ANPR in the future. Although the eventual outcome of EPA’s effort would not impact the proposed rule language changes to 10 CFR 40.51, should EPA decide to move forward with its ANPR, EPA’s efforts could necessitate significant changes to the policies presented in NRC’s SOC for the proposed rule. The staff continues to believe that the 10 CFR 40.51 rule should not be finalized at this time until a more clear resolution of these activities is reached to avoid the expenditure of potentially unnecessary resources. As a result, the staff continues to prioritize further work on the associated transfer rulemaking as a low priority and has budgeted minimal resources toward any activities related to this activity.

The staff believes that the generic safety issue may be closed at this time because the Commission has provided the staff with consistent direction for handling the transfers related to

this issue. The staff believes that current Commission policy on this issue is known by licensees and therefore the staff expects the closure of this generic safety issue will not result in any significant impact on health and safety or security. The staff acknowledges that the existing language in 10 CFR 40.51 can be interpreted to indicate that a licensee may transfer large quantities of material containing less than the 0.05 weight percent of uranium or thorium to a person exempt from the regulations under 10 CFR 40.13(a). However, the staff believes transfers of the large quantities of source material to persons exempt under 10 CFR 40.13(a) are unlikely to occur without prior NRC approval, because of the Commission's clear policy related to this issue. To date, despite the lack of specific language in 10 CFR Part 40, requiring submittal of approval requests, NRC has received and issued numerous approvals for disposal of such "unimportant quantity" source materials under the Commission's policy, and the staff is not aware of any such transfers that have occurred without prior NRC approval. Additionally, the staff believes that the language in the proposed rule, that has already been issued for public comment, adequately clarifies the Commission's policy for the time being.

Conclusion

Although the staff plans to take further action related to the proposed rule (i.e., publish the final rule or rescind the proposed rule) when EPA finalizes activities related to its ANPR and/or the recommendation of the IJWG is implemented, the NRC staff believes that the existing NRC policy, as described in numerous Commission SRMs, is satisfactory for providing resolution of the generic safety issue. Therefore, the staff is closing generic safety issue NMSS-016.

this issue. The staff believes that current Commission policy on this issue is known by licensees and therefore the staff expects the closure of this generic safety issue will not result in any significant impact on health and safety or security. The staff acknowledges that the existing language in 10 CFR 40.51 can be interpreted to indicate that a licensee may transfer large quantities of material containing less than the 0.05 weight percent of uranium or thorium to a person exempt from the regulations under 10 CFR 40.13(a). However, the staff believes transfers of the large quantities of source material to persons exempt under 10 CFR 40.13(a) are unlikely to occur without prior NRC approval, because of the Commission's clear policy related to this issue. To date, despite the lack of specific language in 10 CFR Part 40, requiring submittal of approval requests, NRC has received and issued numerous approvals for disposal of such "unimportant quantity" source materials under the Commission's policy, and the staff is not aware of any such transfers that have occurred without prior NRC approval. Additionally, the staff believes that the language in the proposed rule, that has already been issued for public comment, adequately clarifies the Commission's policy for the time being.

Conclusion

Although the staff plans to take further action related to the proposed rule (i.e., publish the final rule or rescind the proposed rule) when EPA finalizes activities related to its ANPR and/or the recommendation of the IJWG is implemented, the NRC staff believes that the existing NRC policy, as described in numerous Commission SRMs, is satisfactory for providing resolution of the generic safety issue. Therefore, the staff is closing generic safety issue NMSS-016.

Distribution: RGordon r/f RidsEdoMailCenter
 RidsAcnwMailCenter RidsFsmeOd RidsNmssOd
 DMSSA r/f AMcIntosh, DMSSA RidsSecyCorrespondenceMailCenter

ML062000507

OFFICE:	RBA:DILR	RBA:DILR	Tech Editor	D:DILR
NAME:	GComfort	FCardile	EKraus	DRathbun MD for
DATE:	10/25 /2006	9/20/2006	6/20/2006	9/26/2006
OFFICE:	OGC	EPPAD:FSME	D:FSME	
NAME:	STreby nlo	SFlanders	CMiller MD for	
DATE:	10/25/2006	10/31/2006	11/27/2006	

OFFICIAL RECORD COPY