POLICY ISSUE
(Notation Vote)

March 2, 2006 SECY-06-0049

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: ACTIONS RELATED TO REGULATION OF MAXIMUM CONTAMINATION LEVELS FOR URANIUM IN DRINKING WATER

PURPOSE:

To provide background to the Commission on the U.S. Environmental Protection Agency's (EPA's) implementation of maximum contaminant levels (MCLs) for uranium in drinking water and the potential impacts to the U.S. Nuclear Regulatory Commission (NRC). The staff also requests approval of recommendations for both interim and long-term solutions to create an effective and efficient regulatory framework for these potential new licensees, as well as agreement on processing an existing license application proposing a multi-site service provider license.

SUMMARY:

EPA finalized an MCL for uranium of 30 micrograms per liter (Fg/L) in December 2000. Before this time, EPA did not have a limit specific to uranium in drinking water and instead regulated uranium content through gross alpha and gross beta limits. EPA's rule became effective in 2003 and requires an initial monitoring phase to be completed by the water treatment facilities by the end of 2007. If the monitoring reveals uranium exceeding the MCL, the treatment facilities may choose to remove the uranium from the water using technologies that could concentrate the uranium to levels above 0.05 percent by weight; thereby requiring licensing

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by NRC or an Agreement State. EPA's rulemaking estimates approximately 500 facilities could exceed the MCL for uranium, which would require the facilities to take action regarding the uranium content of the drinking water. NRC regulations under 10 CFR Part 40 currently require that a water treatment facility that concentrates the source material to a level of greater than 0.05 percent by weight to apply for a specific license. However, if the facility possesses less than 15 pounds of source material at one time and receives less than 150 pounds of source material in a year, the facility could potentially operate under a general license in 10 CFR 40.22, "Small quantities of source material." If more than a few of these facilities require specific licensing, there could be a large impact on NRC and Agreement State resources. In addition, development and implementation of a specific license application could have a resource impact on the treatment facilities. Because the staff believes that the risk associated with these facilities does not warrant the increased controls associated with a specific license, the staff evaluated potential alternatives to the specific licensing of each water treatment facility in order to reduce the potential burden on the drinking water industry and regulatory agencies. Based on the expectation of relatively low impacts to public health and safety, the staff is recommending a new general license unique to drinking water treatment facilities.

Some treatment facilities may choose, or be required, to begin removing uranium from water immediately after the completion of their initial monitoring phase and prior to implementation of the new general license. In most cases, these facilities will require a specific license to possess the uranium under existing regulations. Therefore, to reduce the impact to these facilities during the rulemaking process, the staff also recommends that enforcement discretion be exercised to not cite those facilities for possession, use, transfer, or disposal of source material without an NRC license, provided that certain provisions are met to ensure public health and safety. These expectations would be described in a generic communication issued to drinking water treatment facilities. In the interim, the staff has received a site specific license application from RMD operations, LLC, to be a multi-site service provider. The staff recommends that the Commission direct staff to process the license application, unless other circumstances prevent license issuance. The staff estimates a total of 1.6 full-time equivalent (FTE) are needed in FY 2006 and FY 2007 for a total of 3.2 FTE. These resources are in the agency's current budget.

BACKGROUND:

In December 2000, EPA finalized new drinking water regulations (65 FR 76708) in which EPA announced new MCLs for radionuclides, including an MCL of 30 Fg/L for uranium. Before this change, the drinking water regulations had no specific limits on uranium content, but instead regulated gross alpha and beta in the drinking water. Enclosure 1 provides a more detailed description of EPA's December 2000 drinking water rule, its history, methodology, and implementation. Although NRC commented on the proposed rule, at that time, NRC staff's comments were focused primarily on EPA's development of the technical basis for development of the MCL for uranium as it impacted NRC's decommissioning efforts and high-level waste licensing. During the rulemaking process, neither EPA nor NRC foresaw the potential need to specifically license water treatment facilities. The potential need to specifically license water treatment facilities has been an unintended consequence of the EPA rule, NRC's regulatory framework, and advances in water treatment technology. The most viable technologies during development of EPA's rule were not expected to exceed the exemption threshold of 0.05 percent by weight of source material found in 10 CFR 40.13(a), "Unimportant quantities."

In early 2004, the State of Vermont and a water treatment service company separately contacted NRC staff to request information on the applicability of NRC's jurisdiction over any

processing that may be used to treat uranium in water. After researching the issue, including the increased viability of newer technologies, the staff determined that some of these treatment processes,[1] which are otherwise cost-effective, would likely require the facility operator to obtain a specific license because the process can concentrate uranium above the 0.05 percent by weight exemption level in 10 CFR 40.13(a). The costs of developing and implementing a specific license application would be in addition to the cost of treating the water to comply with the EPA rule. Even modest regulatory costs could have an impact on this class of licensee; EPA estimates that the average affected treatment plant serves a population of about 1200 people and very few affected communities serve more than 10,000 people. Depending on the number of facilities that actually require specific licensing, NRC and Agreement State resources would also be significantly impacted.

In the *Federal Register* notice for the final rule, EPA estimated that approximately 500 drinking water systems may be impacted by the regulation. However, the number of affected facilities is uncertain because uranium concentrations in the drinking water have never been systematically measured – some industry estimates suggest that the regulation may potentially impact upwards of 3000 facilities (although this higher number may include individual wellheads rather than individual water treatment systems). The actual number of water treatment facilities that will be required to take action because of high uranium levels will not be known until the end of the monitoring period at the end of 2007. The number of these facilities that will require specific licensing, under existing regulations, will ultimately depend on the treatment technologies or approaches selected by those affected facilities. EPA is also currently conducting studies of 9 drinking water treatment facilities to evaluate uranium and radium concentrations at various points in each facility's systems. The selected facilities will cover a variety of sizes and technologies. EPA expects to collect most of the samples by late spring 2006 and complete their evaluation by late summer. NRC staff is coordinating closely with EPA on this regulatory issue, and when the study is complete, EPA will share their findings with NRC.

Although, EPA's regulation requires that drinking water treatment facilities complete their initial monitoring by the end of 2007, some facilities may complete their initial monitoring much earlier than this deadline. If these early facilities are in violation of the MCL, they are required to immediately begin treating the uranium or enter into a compliance schedule with the State. As a result, some of these facilities that treat the uranium may require specific licensing before the end of 2007. The staff is currently aware of one pilot facility in Virginia that, because of public concern, began treating for uranium immediately after sampling indicated uranium levels above the MCL.[2] The company providing the technology for this pilot facility, R.M.D. Operations, LLC, submitted a specific license application to NRC, dated September 27, 2005, for a performance-based, multi-site license, which would include the pilot facility.

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[1] Ion exchange is currently considered the most viable technology for removing uranium from drinking water. This technology is likely to concentrate the uranium above 0.05 percent by weight. See Enclosure 2 for a description of various drinking water technologies and their potential to require licensing.

[2] Because this facility is responsible for treating only a relatively small quantity of water at this time and the total quantity of accumulated uranium has remained under 15 pounds, this facility expects to be able to continue to operate under an NRC general license (10 CFR 40.22) until sometime in mid-2006; larger water treatment systems or those with higher levels of contamination are expected to require specific licensing in much shorter periods.

Finally, it is important to recognize that the majority of the impacted facilities are located in Agreement States, with the potential for greater impacts on the western United States where uranium resources are more abundant. The other major area affected by the uranium MCL is the Piedmont region of the eastern United States. Florida, New Hampshire, and Vermont are also believed to have localized drinking water systems with uranium in excess of the MCL.

Regulatory Background

The Atomic Energy Act (AEA) of 1954, as amended, defines source material as: (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. It should be noted however, that Section 62 of the AEA only requires licensing of source material after removal from its place of deposit in nature (in this case, after its removal from the primary water stream). NRC's regulations for source material are found in 10 CFR Part 40, "Domestic Licensing of Source Material."

Within the regulations in Part 40, NRC has exempted persons from licensing of certain "unimportant quantities of source material," as listed in § 40.13. Because uranium is ubiquitous in nature, NRC provided an exemption, in § 40.13(a), for the possession and use of source material in concentrations of less than 0.05 percent by weight. The staff expects that at least one technology used to treat drinking water, ion exchange, will result in concentrating uranium to levels that exceed this exemption limit and therefore will require licensing.

A general license for the possession and use of source material is also included in Part 40, as § 40.22, "Small quantities of source material." Under this regulation, a water treatment facility could possess and process uranium at any concentration as long as the water treatment facility did not possess more than 15 pounds of source material at any one time and did not receive more than 150 pounds of source material in a calendar year. Facilities operating under this general license are exempt from the requirements of 10 CFR Parts 19, 20, and 21, and therefore would be minimally impacted; however, facilities operating under this general license are still required to transfer and dispose of the source material consistent with the regulations. This general license may be a feasible, low-impact method of licensing some of the smallest water treatment operations or allowing the processor to delay the acquisition of a specific license.

If neither the exemption in § 40.13(a) nor the general license in § 40.22 is applicable to the water treatment facility's particular situation, the operator of the facility will need a specific license issued by NRC or an Agreement State to remove and possess the uranium concentrated or extracted by the treatment process, unless a regulatory alternative is developed.

DISCUSSION:

Anecdotal evidence from the Virginia pilot study indicates potential dose rates near a uranium-removal ion-exchange column of up to 0.3 millirem per hour at the surface. However, the actual exposures will depend on the design and implementation of the water treatment system being used. For example, in the case of the pilot facility in Virginia, the facility is located in a locked shed near the well head and far removed from the actual water treatment facility. Minimal operator interaction is required, and the facility operator estimates actual exposures to be below

1 millirem per year for the workers. The shed is located off the main road and is easily approachable by members of the public; however, monitoring located on the side of the shed indicates exposures that are indistinguishable from background. Based on the staff's understanding of most drinking water treatment facilities, these minimal exposure rates should be common under normal operating conditions. At this time, accident scenarios are also highly speculative, but uranium inhalation scenarios that result in workers receiving higher doses or impacts from the chemical toxicity of the uranium are conceivable, but unlikely. For example, in the case of the ion-exchange technologies, the uranium's preference to the resin is expected to limit the dispersion of the uranium in any accident. However, because there is the potential that doses in certain situations, such as large quantity storage or additional processing for volume reduction, could exceed the public dose limit, some level of regulatory oversight may be warranted. Additionally, some regulatory control may be warranted to ensure protection of the public, workers, and the environment from the improper transportation and disposal of large quantities of uranium recovered from drinking water treatment operations. The amount of uranium which could be removed from drinking water may be significant, and improper handling and disposal, including use in unregulated activities or locations (e.g., as fill material), could increase the potential for exposures above public dose limits. Disposal considerations are discussed in Enclosure 3.

Based on the above considerations, the staff has evaluated existing regulations, as well as alternatives, to ensure that adequate protection of health and safety is maintained without overly burdening the drinking water treatment industry, NRC, or the Agreement States with the significant expenditure of unplanned resources disproportionate to the risk presented by removal of uranium from drinking water. The alternatives developed for regulating the removal of uranium from drinking water are evaluated in detail in Enclosure 4. The options include:

1. Licensing the facilities under the current regulatory structure
2. Developing a new general license specific to drinking water treatment facilities
3. Developing a new exemption specific to drinking water treatment facilities
4. Requesting EPA to rescind their rule specifically for uranium in drinking water
5. Implementing the Jurisdictional Working Group recommendations suggested in 2003, to remove uranium and thorium, not purposefully extracted nor concentrated for the use of the uranium or thorium, from NRC jurisdiction (which would include uranium concentrated at drinking water treatment facilities)

As part of the staff's evaluation of the existing regulatory scheme, the staff also evaluated introducing a new licensing strategy under the existing regulations to allow one or more service providers to operate treatment systems at multiple, independent drinking water facilities under a single license. Under this approach, the service provider, operating under a specific license, would operate filtration equipment at multiple drinking water treatment facilities and take responsibility for the disposal of the source material. R.M.D Operations, LLC, has submitted a request for such a license. The benefit of this approach would be to reduce the number of individual specific licenses that would need to be processed by NRC. However, this multi-site license scheme raises significant policy questions, such as whether it is appropriate to permit a service provider to possess source material or whether the water treatment facilities would also be required to obtain a specific license. Also, the staff needs to determine who is responsible for decommissioning, if the service provider contract is terminated or if there is a change of service providers at a site. These, and other considerations, are discussed further in Enclosure 4, Option 1A.

The staff also evaluated developing a simplified licensing system specific to drinking water treatment facilities. Under this approach, the staff would develop guidance and templates, for license applications and the review of the application, with the intent to minimize the number of resources expended by the drinking water treatment industry, NRC, and the Agreement States required to meet the existing regulatory requirements.

Based on the evaluation of the options, the staff believes that the best alternative is to immediately begin rulemaking to develop a new general license specific to drinking water treatment facilities. The staff believes that this alternative will best maintain public and worker health and safety and ensure proper disposal of accumulated uranium, while minimizing the impact on the drinking water treatment industry, NRC, and the Agreement States. The staff believes that this action could be completed within 30 months, including collection of information necessary to support the technical basis, if it follows the normal rulemaking process. However, the staff believes it would be beneficial to instead develop the rulemaking as an interim final rule, which would allow the rule to be implemented in a much shorter timeframe (approximately 20 months).

During the development of this rule, the staff plans to work with EPA to communicate with the drinking water treatment industry regarding NRC's existing regulations and any possible changes resulting from the proposed rulemaking. It is the staff's understanding that the EPA plans to hold training sessions on the radionuclides rule and their recently released guidance documents; NRC staff will likely participate in such sessions. Additionally, the staff will consider other methods, such as presentations at appropriate conferences, to inform and prepare members of the drinking water treatment industry regarding NRC's oversight. Through such communications, the staff will interact with the stakeholders to develop a clearer understanding of NRC's role, responsibilities, and requirements for regulating the removal of uranium from drinking water.

One common problem for implementing most of the available options is timing. As stated previously, many facilities may opt to treat uranium much earlier than the EPA compliance deadline. As a result, these facilities will require specific licensing if an alternative regulatory strategy cannot be fully implemented before the facility exceeds the exemption limits in § 40.13(a) or the limits for a general license in § 40.22. In Enclosure 5, the staff has evaluated options to temporarily defer specifically licensing these facilities (if necessary) until the chosen option is implemented.

These options include:

1. Enforcing existing regulatory requirements
2. Issuing orders to impose specific requirements within the existing regulatory requirements
3. Exercising enforcement discretion to not cite for possession, use, transfer, or disposal of source material provided certain conditions are met
4. Requesting EPA to defer the compliance date

Based upon the review of these short-term solutions, the staff believes that during the period of rulemaking for this new general license, enforcement discretion should be exercised, so as to not cite those drinking water treatment facilities for possession, use, transfer, or disposal of source material without an NRC license provided that certain conditions are met by the facility to protect public health and safety. Prior to exercising enforcement discretion, the staff would

issue a generic communication (likely in the form of a regulatory issue summary), within 120 days of Commission direction, that would clearly indicate the expectations for operations by the drinking water treatment facilities during the period of enforcement discretion. The generic communication would include information regarding maintaining adequate public and worker health and safety and protection of the environment, proper transportation and disposal, and reporting. A specific license would not be required to operate while rulemaking was ongoing, although a drinking water treatment facility would not be prohibited from applying for a specific license. During the period of enforcement discretion, following publication of the generic communication, NRC or the Agreement States would actively evaluate situations where persons reported concerns impacting worker and public health and safety or improper disposal. If the staff identifies a public health and safety issue that was not envisioned during the development of the enforcement discretion guidance, the staff will revise the guidance to address this new concern, which could result in the need for some water treatment facilities to obtain a specific license for possession and use of the source material.

Additionally, the staff plans to process the R.M.D. Operations, LLC license application, unless the applicant withdraws their license application. Implementation of a new general license does not preclude NRC from issuing a specific license per the applicant's request. If the service provider license is granted, some drinking water treatment facilities may desire to operate under the service provider's specific license, rather than operate under the proposed general license.

Finally, during the development of this paper, NRC staff have met periodically with EPA staff to share information on this issue. NRC staff have kept EPA staff abreast of the issues discussed in this paper and of the staff's planned recommendations. NRC staff will continue to keep their EPA counterparts informed of the status of these issues and plan to continue to meet with EPA on this issue during the development of any rulemaking that may occur.

AGREEMENT STATE ISSUES AND INTERACTIONS:

As most of the impacted facilities appear to be in Agreement States, those regulatory agencies could see the biggest resource impact. At least five of the impacted Agreement States have already contacted NRC about the uranium MCL and asked how NRC plans to regulate drinking water treatment facilities. Although development of a new general license may require modification of Agreement State regulations, the staff believes that costs for adoption of a new general license will be offset by the savings to most Agreement States by not having to conduct reviews and issue numerous specific licenses. The staff plans to coordinate extensively with the Agreement States during the development of any new rule.

ENFORCEMENT CONSIDERATIONS:

Under the recommended approach, the staff would expect to exercise enforcement discretion, to not cite drinking water treatment facilities for possession, use, transfer, or disposal of source material without an NRC license. However, because of the staff's concern regarding the proper disposal of large quantities of source material and the potential negative impact on public perception that could result from using a blanket discretion approach, the staff plans to issue a generic communication. The generic communication would provide information to the drinking water treatment facilities with conditions that must be met and maintained in order for the NRC to exercise enforcement discretion. These provisions would precede the eventual requirements to be developed during the rulemaking for the general license and may forecast the staff's initial views of the future rulemaking activity.

As long as the drinking water facility met the provisions described in the generic communication, the staff would exercise enforcement discretion to not cite the drinking water treatment facility for possession, use, transfer, or disposal of the source material without an NRC license. Should the staff determine, at any time, that the provisions described in the generic communication are not being met, they could find the drinking water treatment facility operator in violation of the regulations and require the operator to apply for a specific license. The period of enforcement discretion would end upon implementation of the new general license.

RESOURCES:

To finalize and implement the recommended rulemaking to create a new general license specific to drinking water treatment facilities, 3.2 full-time equivalent (FTE) positions are estimated to be required to complete this action. The staff has prioritized this action as high and estimates that 1.6 FTE will be used in fiscal year (FY) 2006 and 1.6 FTE in FY 2007 to support this rulemaking. The 1.6 FTE includes 1.3 FTE from NMSS and 0.3 FTE from other offices. NMSS has coordinated with the other offices regarding these resources. Contract support will be used to help support development of this rule. The staff estimates that $30,000 for FY 2006 and $50,000 for FY 2007 will be needed for contract support. These resources are included in the Office of Nuclear Material Safety and Safeguards' (NMSS's) current budget and Agency-wide prioritization of resources. A detailed schedule will be provided to the Commission within 60 days of the staff receiving approval from the Commission to move forward with the recommended action or for any other action directed by the Commission, if appropriate.

The information on resources and schedule reflect the current environment. If a significant amount of time (greater than 30 days) passes or the Commission provides the staff direction that differs from or adds to the staff's recommended action(s), this section of the paper would need to be revisited after issuance of the draft staff requirements memorandum.

COMMITMENTS:

Should the Commission approve the staff's recommendations, the staff will provide the Commission a schedule to publish an interim final rule for a new general license specific to drinking water treatment facilities within 60 days. In addition, the staff will issue a generic communication (likely in the form of a regulatory issue summary), within 120 days of the Commission's direction, providing information to drinking water treatment facilities regarding provisions that they are required to meet in order for enforcement discretion to apply, while the staff develops the new rule.

RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve the staff's plans to develop a new general license specific to drinking water treatment facilities as an interim final rule;
2. Authorize the use of enforcement discretion to minimize the impact on the drinking water treatment industry, NRC and the Agreement States, until a new general license is implemented;

3. Direct staff to issue a generic communication to describe NRC expectations with regard to water treatment facilities, and;
4. Direct the staff to continue to process the R.M.D. Operations, LLC, license application as a multi-site service provider, unless other circumstances prevent license issuance.

COORDINATION:

The Office of the General Counsel has no legal objection to the recommendations in this paper. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Background on EPA's 2000 Drinking Water Regulations for Radionuclides
2. Technical Background: Methods for Compliance with EPA Regulations
3. Disposal of Uranium Removed from Drinking Water
4. Alternatives to Specific Licensing of Drinking Water Treatment Facilities
5. Options to Defer Specific Licensing of Drinking Water Treatment Facilities

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