OPTIONS ANALYSIS

ALTERNATIVES TO SPECIFIC LICENSING OF DRINKING WATER TREATMENT FACILITIES

ISSUE

In December 2000, the U.S. Environmental Protection Agency (EPA) finalized new drinking water regulations (65 FR 76708), within which EPA announced new maximum contaminant levels (MCLs) for radionuclides, including an MCL of 30 micrograms per liter (Fg/L) for uranium. Depending upon the technology chosen to reduce the amount of uranium in drinking water, concentrations of uranium could exceed 0.05 percent by weight of source material and thereby require licensing under 10 CFR Part 40, "Domestic Licensing of Source Material." Although a small number of the facilities requiring licensing may be able to operate under the general license in 10 CFR 40.22, "Small quantities of source material," it is expected that, under existing regulations, most impacted facilities would be required to obtain a specific license. The EPA estimates that the average affected treatment plant serves a population of about 1,200 people and very few affected treatment plants serve more than 10,000 people, therefore, even modest regulatory costs could have a significant impact on this class of licensees. In addition, because EPA estimates up to 500 facilities (some industry estimates are considerably higher) could be affected, there could be significant impacts on NRC and Agreement State resources to license and regulate these facilities.

Based on the potential significant impact on resources of the drinking water treatment facilities, NRC and the Agreement States, and the disproportionately low risk from uranium removal operations at drinking water treatment facilities, the staff evaluated options that could potentially relieve or diminish the regulatory burden caused by EPA's rule. These options are discussed below.

Much of the benefit for pursuing alternatives to specific licensing is dependent upon the actual number of drinking water treatment facilities that will be required to treat uranium, as well as whether the technology chosen to treat the uranium will result in concentrations of uranium that will require licensing by NRC. Currently, the staff does not have enough data to make an estimate of how many new licensees could result from EPA's rule, as the range could extend from a few new licensees to thousands of new licensees. Nonetheless, the staff believes that even a handful of new licensees could significantly impact resources currently budgeted for other activities.

EXISTING REGULATORY FRAMEWORK

Section 40.13(a), "unimportant quantities of source material," exempts persons from licensing requirements for the possession and use of source material in concentrations less than 0.05 percent by weight of source material.

Section 40.22, “small quantities of source material,” provides a general license authorizing commercial and industrial firms, research, educational and medical institutions, and Federal, State, and local government agencies to use and transfer not more than fifteen (15) pounds of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material under this general license, may not receive more than a total of 150 pounds of source material in any one calendar year. Persons using this general license are exempt from Parts 19, 20, and 21, unless such persons are also in possession of source material under a specific license. It should be noted that the transfer and disposal of source material held under this general license are still constrained by other NRC regulatory requirements.

OPTIONS TO LICENSING OF DRINKING WATER TREATMENT FACILITIES

The staff has evaluated five options for regulating the possession of uranium by drinking water treatment facilities that concentrate uranium above 0.05 percent by weight of source material. These options include: (1) licensing the facilities under the current regulatory structure (no action); (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; and (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).

OPTION 1: Licensing the Facilities Under the Current Regulatory Structure

Under this option, the staff would not modify existing regulations. The staff currently has two processes to license persons that are not eligible for the exemption in § 40.13(a). These processes include either licensing water treatment facilities under a general license pursuant to § 40.22 or under a specific license pursuant to § 40.32. This option will be the baseline against which all other options are compared.

Section 40.22 allows a person operating under a general license to possess up to 15 pounds of source material at one time and up to 150 pounds per year. Because this general license operates in many ways like an exemption, the impact from using this general license to regulate water treatment facilities would be minimal on most water treatment facilities, NRC, and the Agreement States. A majority of the regulatory costs would be associated with the disposal of uranium. However, the staff believes that this provision will have little applicability to water treatment facilities removing uranium. Due to the large quantities of water treated at even the smallest drinking water treatment systems, removal of even a low concentration of uranium, using certain technologies, described in Enclosure 2, could result in a waste stream containing hundreds of pounds of uranium. Even if site-specific conditions allow the facility to operate within the scope of the § 40.22 general license for a short period of time, many of these facilities will find it more economical to possess greater than 15 pounds of uranium at one time because of processing considerations. Additionally, attempting to stay under this 15 pound limit could result in additional exposures or greater potential for spills because of the more frequent filter media replacements or backwashing that may be required. Therefore, although the

§ 40.22 general license is appealing for both the water treatment facilities and regulatory bodies, most water treatment facilities will find its limitations prohibitive.

Additionally, it should be noted that NRC is still evaluating a 1999 petition submitted by the State of Colorado and the Agreement States requesting modification of this general license. The staff recommended changes, based in part on the 1999 petition, to this general license in SECY-01-0072, dated April 25, 2001. Although the Commission rejected the staff's rulemaking plan, the Commission directed the staff to collect additional data and provide new recommendations at a future date. The staff has since collected and is analyzing data on general license distributions. The staff will report and provide recommendations, regarding the distribution of generally licensed source material, to the Commission in December 2006. Changes to this regulation could impact any water treatment facilities operating under the § 40.22 general license.

The only existing alternative for facilities which cannot or choose not to operate under the existing general license is specific licensing in accordance with § 40.32. Specific licensing would be a significant expense for water treatment facilities, many of which are not aware that they may soon fall under NRC jurisdiction. Because of the potential number of licensees, a significant amount of unbudgeted NRC and Agreement State resources would have to be devoted to specific licensing of these facilities. Furthermore, depending upon the number of specific license applications received, it may be difficult and costly for NRC and the Agreement States to issue licenses in a timely manner to allow these facilities to operate in compliance with the new drinking water standards. Finally, additional resources would likely be needed to support inspection and future license amendments for these facilities.

Advantages

- Ensures protection of public health and safety and the environment by using existing regulations.
- The regulatory structure is immediately available; no resources will be necessary to develop a new rule.
- If § 40.22 is a viable strategy for operators, resource costs to both the operators and NRC and Agreement States would be minimal (if no future changes are made to § 40.22); however, it is expected that few, if any, operators will be able to operate under this provision.

Disadvantages

- Specific licensing could consume significant amounts of currently unbudgeted staff resources in the licensing arena thus impacting other activities.
- Specific licensing is difficult and costly for NRC and the Agreement States, therefore it may be unlikely that licenses will be issued in a timely manner to allow these facilities to operate in compliance with the new drinking water standards (i.e., treatment may not be allowed immediately after detection because of the required licensing process).
- Specific licensing may be prohibitively burdensome for some licensees (could substantially impact small systems or create a significant financial impact to members of the public who depend on the water).

- Persons operating pursuant to the § 40.22 general license will be difficult to identify because of the lack of reporting requirements in this section; therefore it will be difficult to ensure that the minimal requirements (i.e., possession limits and disposal requirements) are being properly met.
- Resources will be required to develop guidance for both applicants and (NRC and Agreement State) license reviewers; however, cost should be significantly less than any rulemaking option.

Under this option, the staff has also considered two potential strategies that could reduce some of the burden resulting from specific licensing. These suboptions include: (a) allowing a single provider to operate processes at numerous, separate drinking water facilities under a single license and (b) developing a simplified licensing system specific to drinking water treatment systems.

OPTION 1A. Multiple Site, Service Provider License

Under this option, a technology provider would hold a single license to operate processes to remove uranium from numerous, separate drinking water treatment facilities. The licensee would not be the local drinking water treatment facility operator, but instead would be the service provider who operates the technology used to remove the uranium from the water. The technology provider would apply for and hold the license, be responsible for maintaining the safety of the operation, possess the uranium during and after its extraction or concentration, and be responsible for properly transferring and disposing of the concentrated uranium. The licensee could add additional facilities to its license by showing that the new facility falls within the scope of its existing license and environmental analysis.

By letter dated September 27, 2005, R.M.D. Operations, LLC (RMD) applied for such a license and the staff is currently reviewing the application, including environmental and safety evaluation reports. Under the approach proposed by RMD, the licensee would have ownership and possession of the uranium during and after its extraction from the water supply. RMD's application suggests that license amendments to add new facilities to its license would not be necessary; rather, RMD would file a letter of intent with the NRC when adding additional facilities. RMD has proposed to satisfy the NRC's financial assurance requirements in two ways: 1) for publicly-owned facilities, the municipality would provide financial assurance for decommissioning and decontamination; and 2) for privately-owned facilities, the owner would provide acceptable financial assurance. RMD's application does not assume that the water treatment facilities being serviced would require licensing. The staff has not yet determined whether this approach would be adequate to protect public health and safety and the environment, and the staff will have to resolve several issues before granting such a license.

<u>Advantages</u>

- Application and review of a single license, covering multiple water treatment facilities, could reduce the regulatory burden of reviewing numerous separate applications.
- Would likely provide a single, more knowledgeable point of contact ensuring consistency in operations at facilities covered by the multi-site license.

<u>Disadvantages</u>

- All drinking water treatment facility operators may not choose the same technology provider, leaving the potential for numerous applications. NRC would remain obligated to consider site-specific applications not covered by the multi-site license(s).
- Would be most effective if all Agreement States and NRC recognized an NRC or another Agreement State license (reciprocity); but there is currently no provision for year-round reciprocity.
- The water treatment facility may still require a license because it owns and is ultimately responsible for the water and uranium at its site. The primary concern revolves around who is responsible for cleanup if the original provider (licensee) contract is terminated and either the water treatment facility takes over or another service provider continues service.

OPTION 1B. Simplified Licensing Applicable to all Water Treatment Facilities

Under this option, the staff would implement a standardized and simplified license application which, presuming the licensee closely followed the format and included all required content, could permit a more efficient application approval, including preparation of the license and supporting environmental reviews and documentation.

Advantages

- A standardized license application would simplify the licensing process for the water treatment facility.
- The review of a license that strictly followed a standardized license application could reduce the number of NRC and Agreement State resources expended and speed up the timeliness of the review, presuming applicants provided an application consistent and complete with the specified information requirements (and the application itself did not allow much variance).

Disadvantages

- The potential number of applications could still overwhelm NRC and Agreement State resources.
- Because not all sites are the same and some may use unexpected technologies, there may be a number of facilities that would not use the simplified application, which would impact the resources necessary to complete the reviews.
- NRC and Agreement State resources would be necessary to develop both a standard license application and review guidance, although the process is likely to be less costly than a rulemaking.
- Separate actions for each license application would still be necessary under the National Environmental Policy Act (NEPA), which will likely limit the resource savings.

OPTION 2: Rulemaking Option – New General License

As the current regulatory structure is potentially burdensome for the societal benefit attained by removing uranium from drinking water, and the costs associated with licensing under NRC's current regulatory structure may be prohibitive to many water treatment facilities, the staff has considered changing NRC's current regulations. Under this option, the staff would develop a

new general license through rulemaking, applicable to drinking water treatment facilities that concentrate uranium in excess of 0.05 percent by weight.

To develop the new general license, the staff would establish a technical basis to determine the level of regulation necessary for processes which concentrate or extract uranium from drinking water to provide adequate protection to worker and public health and safety, property, and the environment. These considerations would also need to include disposal requirements. The general license would address both existing technologies and the development of new technologies. Because of this consideration, limitations may be required on the scope of the general license to specific water treatment technologies or conditions to ensure adequate protection of worker and public health and safety, property, and the environment. These restrictions may limit the applicability of the general license, which would result in the need to specifically license a smaller number of drinking water treatment facilities.

A normal notice and comment rulemaking (development of the technical basis, proposed rule, and final rule) would be expected to take approximately 30 months. Thus, if started in early 2006, the final rule would be published in approximately Summer 2008. Because EPA's deadline for compliance is December 2007, some operators will likely have begun removing uranium before implementation of a new general license, and specific licensing by NRC may still be required.

A possible alternative may be to amend NRC's regulations via an interim final rule which would be expected to take approximately 20 months. Under the criteria of the Administrative Procedures Act (5 U.S.C. 553(b)(B)), the Commission will need to determine that prior notice and public comment on this rule would be impracticable, unnecessary, or contrary to the public interest. The staff believes that there may be sufficient basis for concluding that a normal notice and comment rulemaking is impracticable and contrary to the public interest, and therefore, there is good cause for an interim final rule.

There are several reasons why the typical notice and comment rulemaking procedure may not be practicable for publishing such a general license. While EPA was developing its rule, the EPA staff thought that drinking water residuals would legally be considered technologically enhanced naturally occurring radioactive material (TENORM), and therefore not subject to the licensing requirements of the Atomic Energy Act of 1954, as amended. The possible presence of licensable source material was not identified by the NRC during EPA's rule development because the most viable technology at the time was not expected to concentrate uranium more than 0.05 percent by weight of the source material. The technology most likely to concentrate uranium such that licensing is required, ion exchange, had not been applied to full-scale potable water systems and therefore was not closely evaluated at that time. Ion exchange technology has more recently been successfully applied to the treatment of potable water at research facilities and in a commercial setting in some small pilot facilities, operating under a general license pursuant to § 40.22. As noted, the staff still needs to establish a technical basis to determine the level of regulation necessary for a general license, such that it provides adequate protection. Considering the recent technological developments in uranium removal technology, the staff has not yet developed a technical basis. The combination of EPA's compliance deadline of December 2007, with this recent development in technology, has left the NRC with a very narrow window of opportunity to develop an appropriate technological basis and license for these facilities so they do not violate the NRC's licensing requirements. It is impracticable

for the NRC to proceed with the typical notice and comment rulemaking because it would necessitate either publication of the general license prior to proper development of the technological basis or would result in water treatment facilities complying with EPA's rule, while violating NRC licensing requirements.

Potential impacts on drinking water availability could also provide a basis for an interim final rule. If the NRC undertakes a normal notice and comment rulemaking, an appropriate general license may not be in place before the EPA's compliance deadline of December 2007; therefore, in order to comply with NRC regulations, water treatment facilities will be forced to undergo specific licensing. As the typical community affected by EPA's uranium rule is roughly 1,200 people, the resources and staffing required to comply with a specific license may be prohibitively burdensome for the community serviced by the water treatment facility, not to mention the NRC or Agreement State resources needed to process hundreds of license applications. Although a specific license would adequately protect the public health and safety, the staff believes that this protection can be ensured for drinking water treatment facilities with considerably less regulatory burden through a new general license. This approach would not require the intensive resource requirements of a specific license that could force a water treatment facility to cut costs in other ways or charge costs that are too expensive for the local population.

Advantages

- Would minimize regulatory burden for persons operating under the general license, while still maintaining adequate regulatory controls for worker and public health and safety and protection of property and the environment.
- NRC and Agreement State resource expenditures for the monitoring of general licensees would be significantly reduced compared to specifically licensing each operator (e.g., only annual reports, registrations, financial assurance, may be necessary, as determined through the rulemaking process).
- Offers a consistent nationwide approach that can be used in both NRC, and Agreement State, regulated States.
- Service providers, such as RMD, can still provide hardware and technology to drinking water treatment facilities. Additionally, service providers could provide administrative support to meet any general license requirements (e.g., registration and reporting). This approach, however, will place regulatory responsibility with the on-site drinking water treatment facility operator.

Disadvantages

- Some facilities may decide or be required to begin processing uranium prior to completion of rulemaking; therefore, specific licensing of those facilities may be necessary regardless of the relative quickness of an interim final rule (unless such licensing is allowed to be deferred during development of the new rule).
- Significant resources would be expended by NRC and Agreement States to develop rulemaking. If only a few facilities require specific licensing, these resources could be better applied processing the specific license applications.
- There could still be significant costs associated with disposal of the concentrated uranium, which is unusual for a general licensee.

- May not be able to apply to all technologies and still ensure adequate health and safety (particularly those facilities with large quantities of highly concentrated uranium) and thus some specific licensing may still be necessary.

OPTION 3: Rulemaking Option – New Exemption

Under this option, rulemaking would be used to amend the regulations to exempt water treatment facilities that remove uranium in excess of 0.05 percent by weight from licensing requirements, including disposal. Using an exemption could eliminate the need for licensing, thus requiring no resource expenditures by the operators, NRC, or the Agreement States to license the facilities. However, it appears extremely unlikely that an exemption for this class of potential licensees could be justified on a health and safety basis. Depending upon the technologies, concentrations, and quantities involved, it is possible that NRC's 100 millirem per year (mrem/yr) limit could be exceeded in a relatively short period dependent upon the time and frequency of worker exposure. Review of data from a pilot facility in Virginia indicates that the exposure rate on contact from an ion exchange column could be as much as 0.3 millirem per hour, although it is expected that normal operations will result in exposures less than 1 mrem/yr. An exemption from licensing is not typically issued unless it can be shown that "it is unlikely that individuals in the population will receive more than a small fraction, less than a few hundredths, of individual dose limits..." [30 FR 3462]. In addition, an exemption could allow disposal or transfer of large quantities of concentrated uranium to sites at which there could be unnecessary impacts to workers and members of the public.

<u>Advantages</u>

- Would require no expenditure of resources to meet NRC requirements by operators
- NRC and Agreement States would not be required to expend resources on licensing or inspection

<u>Disadvantages</u>

- May not adequately ensure protection of health and safety, protection of property, or the environment during operation or transportation and disposal of material, depending upon the conditions of the exemption.
- Some facilities may decide or be required to begin processing uranium prior to completion of rulemaking and therefore specific licensing of those facilities may be necessary (unless such licensing is allowed to be deferred during development of the new rule).
- Significant resources would be expended by NRC and Agreement States to implement rulemaking.
- May not be able to apply to all technologies and still ensure adequate health and safety (particularly those facilities with large quantities of highly concentrated uranium) and thus some specific licensing may still be necessary.

OPTION 4: Administrative Option - Request EPA to Rescind Rule

Under this option, NRC would formally request EPA to rescind its radionuclide rule in respect to uranium. However, rescinding the rule may be in conflict with the Safe Drinking Water Act of

1974, as amended. Additionally, even if the rule were rescinded, any facilities which had already identified high uranium levels could face public pressure to treat the water for uranium.

Advantages

- If EPA agreed to this option, there would be no resource costs to operators, NRC, and Agreement States resulting from this rule (except for facilities that decided to treat for uranium anyway).
- Would reduce the potential impact to workers (from lack of need to concentrate, store, or dispose of uranium).
- Would remove concerns regarding disposal of concentrated uranium.

Disadvantages

- Unlikely that EPA will agree to rescind the 2000 Radionuclides rule for uranium.
- Would potentially cause members of the public to consume water with uranium at higher levels than implementation of EPA's 2000 radionuclide rule would allow.
- EPA would be required to expend resources rescinding rule as related to uranium.
- May confuse public as to why the rule is considered no longer necessary.

OPTION 5: Implement the 2003 Jurisdictional Working Group Recommendations

In 2003, as part of the recommendations from an Interagency Jurisdictional Working Group evaluating the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration of uranium and/or thorium, the staff recommended that uranium and thorium not purposefully extracted or concentrated for the use of the uranium or thorium be removed from NRC jurisdiction (see SECY-03-0068). Because the primary purpose of extracting uranium from drinking water is not for the use of the uranium, implementation of the approach suggested in SECY-03-0068 would remove such uranium from NRC jurisdiction and allow the States and EPA to regulate the uranium removed from drinking water as naturally occurring radioactive material. Although the staff requirements memorandum indicated agreement with this approach, the Commission believed that the legislative approach, which the staff believed would be necessary to implement this strategy, was not feasible at that time.

Advantages

- Removes regulatory costs for operators and NRC and Agreement States for licensing, although individual states could implement some resource costs on operators.
- Provides a more consistent national policy for treatment of uranium in drinking water.

Disadvantages

- Unlikely to be acted upon, given the current environment requiring the regulation of radionuclides and Congress's recent action on similar legislation.
- Legislative change is often a lengthy process.
- Facilities may decide or be required to begin processing prior to completion of the legislative change and therefore specific licensing of those facilities may be necessary

anyway (unless such licensing is allowed to be deferred during development of a new rule).

- Significant resource costs to NRC, States and EPA, to develop appropriate legislation and amend existing regulations or promulgate new regulations.
- May create some confusion to operators in the short-term as to who is the appropriate regulatory authority.

RECOMMENDED APPROACH

OPTION 2: The staff believes that development of a new general license would be the most efficient approach to provide an adequate level of protection to workers and public health and safety and the environment, while minimizing the resource expenditures for both drinking water treatment facility operators, NRC, and the Agreement States. The staff recommends implementing this approach through an interim final rule, which would be expected to completed in approximately 20 months; however, if the requirements for an interim final rule cannot be justified, the staff believes the final rule could still be implemented within a period of 30 months.

The staff believes that resources that might be expended to specifically license even a small number of these facilities could quickly exceed the resources necessary to develop this new general license. In addition, the costs under the general license approach would be relatively small for drinking water treatment facilities compared to costs associated with specific licensing. The most significant caveat is that the staff cannot clearly identify the number of potential licensees at this time, because many facilities are in the initial stages of monitoring the uranium content of their drinking water. Additionally, many of these facilities could select approaches that do not require specific licensing.

The staff does not have enough information at this time to determine whether it may be more efficient and less costly for facilities to use technologies that may be more expensive or difficult to implement, but have no regulatory costs associated with NRC jurisdiction. It should be noted that technologies that do not significantly concentrate uranium in their water will likely lose a higher percentage of their product (i.e, the water) in order to stay under the 0.05 percent limit; this may not be a viable option for areas with limited water resources.

At this time, based upon available data, the staff believes that there will be a significant number of facilities that will be required to treat drinking water for uranium and choose technologies that require specific licensing, such that moving forward with this rule is recommended.

Despite these significant unknowns, based upon the data available, the staff believes that Option 2 is the most appropriate choice to continue to adequately protect worker and public health and safety while significantly reducing the costs to the public and the drinking water treatment industry, and potentially reducing long-term regulatory costs to the NRC and the Agreement States.