June 26, 2000

Ms. Cynthia Dougherty, Director
Office of Ground Water and Drinking Water
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0003

Dear Ms. Dougherty:

This letter provides the U.S. Nuclear Regulatory Commission's (NRC's) comments on the U.S. Environmental Protection Agency's (EPA's) "Notice of Data Availability" (NODA), which contains information concerning regulatory action on the National Primary Drinking Water Regulations (NPDWR) for four categories of non-radon radionuclides (65 FR 21576, April 21, 2000).

The NRC staff has identified a number of concerns with EPA's NODA that cut across activities of a number of government agencies (i.e., the U.S. Department of Defense (DOD), the U.S. Department of Energy (DOE, and the NRC). The NRC's primary concerns with the NODA are the lack of scientific basis for the standards and the potential for significant expenditures of resources without a commensurate benefit to public health and safety. Moreover, because the NODA represents such a significant change from EPA's 1991 proposed rule that addressed the same issue, we strongly recommend that the EPA issue a proposal for rulemaking, rather than a NODA, to permit an appropriate review and public comment.

The EPA's actions in the NODA potentially affect a number of activities for which the NRC is either the primary regulatory or implementing authority (e.g., low-level and high-level waste disposal, and decommissioning of sites that fall under NRC regulatory responsibility pursuant to the Atomic Energy Act of 1954). Based on our review of the information provided in the NODA and previous, related EPA proposals (e.g., proposed 40 CFR Part 197 - "Standards for High-Level Waste Disposal at Yucca Mountain, Nevada"), the NRC staff has three major concerns with EPA's proposed actions concerning the NPDWR. We are concerned by EPA's actions that: 1) do not exhibit a sound scientific and technical basis; 2) cannot be justified on health and safety grounds; and 3) will be inappropriately applied to NRC and Agreement State licensees in the absence of an appropriate and comprehensive cost-benefit analysis. Our concerns are summarized below and discussed in detail in an enclosure to this letter.

The EPA's maximum contaminant levels (MCLs) may have appeared to be reasonable standards when they were developed around 1975. However, EPA acknowledges that its current MCLs are based on obsolete methods. In view of what is known today the MCLs for individual radionuclides provide levels of protection that vary significantly (risk values vary more than 1000 fold). We strongly object to the application of MCLs yielding such non-uniform risk levels. EPA's proposed approach would create confusion and unnecessary public alarm about the level of risk that is acceptable and attainable, and could undermine confidence that the health and safety of the public are being protected. Under the NODA criteria (e.g., 0.04 mSv/yr (4 mrem/yr)), living in a brick or stone house as opposed to a wooden home would also

represent a serious public health risk because this represents an increased dose of 0.10 mSv/yr (10 mrem/yr). There is no sound scientific or technical basis for the arbitrary range of protection afforded by EPA's proposal. As a result, the NRC staff considers use of a consistent risk level a more appropriate approach. However, we continue to consider MCLs based on a dose of 0.04 mSv/yr (4 mrem/yr) to be needlessly conservative, based on current understanding of radiation effects on humans and the fact that the variability in natural background radiation exceeds this limit.

Although the EPA MCLs were developed under color of authority of the SDWA, EPA acknowledges that EPA offices use the MCLs for setting standards for environmental clean-up at hundreds of sites that fall under NRC, DOE, and DOD authority. The NRC staff believes it is fundamentally incorrect to apply requirements that were developed under the SDWA for monitoring and testing of public water systems, to address ground-water clean-up more generally. If MCLs are applied to untreated ground water at clean-up sites and at waste disposal facilities that are not used or are not likely to be used as a source of drinking water, significant costs could be incurred without commensurate benefit to public health and safety and the environment.

Sincerely,

/RA/
William F. Kane, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: "Comments on Notice of
Data Availability"

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Comments on Notice of Data Availability

A) PRIMARY CONCERNS

1. <u>The NRC staff objects to the current MCLs because these limits do not have a sound scientific and technical basis.</u>

The EPA's MCLs may have appeared to be reasonable standards when they were developed around 1975. In view of what is known today, however, the MCLs for individual radionuclides provide levels of protection that vary significantly (risk values vary more than 100 fold for beta/photon emitters in Table II-3 (Appendix II, pp. 21605-21614). If similar risk calculations (i.e., 70 years of ingestion of drinking water contaminated to the MCL and using FGR 13 risk factors) were done for the alpha emitters at their MCL (i.e., 15 pCi/liter), risk values would vary more than 1000 fold. We strongly object to the application of MCLs that results in such non-uniform risk levels. Such an approach contributes to confusion about the level of risk that is acceptable and attainable, and undermines confidence that the health and safety of the public are being protected. There is no sound scientific nor technical basis for the arbitrary range of protection afforded by application of MCLs for different radionuclides. An interesting consequence of the way the EPA has proposed to use MCLs for the potential repository at Yucca Mountain is that individuals 10,000 years in the future are afforded a far higher level of protection from iodine-129 than our current population will obtain from radium-226, a common constituent in drinking water.

The EPA proposal further contributes to confusion about the level of risk that is acceptable by using and portraying risk limits in an ambiguous manner. The EPA cites the policy of maintaining a lifetime risk within a range of $1x10^{-4}$ to $1x10^{-6}$. However, the Notice of Data Availability (NODA) uses a variety of ways to calculate and portray risks that are inconsistent, both within the NODA itself~~,~~ and with previous EPA uses of the risk range. For example:

- The EPA risk policy of $1x10^{-4}$ to $1x10^{-6}$ has been described in guidance documents as applicable to a 30-year exposure (Stephen D. Luftig, OERR, and Stephen D. Page, ORIA; "Distribution of OSWER Radiation Risk Assessment Questions and Answers Final Guidance"; December 17, 1999). Nonetheless, the NODA uses an exposure time of 70 years for estimating risks from drinking water contaminated with beta/photon emitters, thereby magnifying the calculated risk. The NODA points out the "...risks associated with the 1991 proposed MCL of 4 mrem-ede (effective dose equivalent) are above the 10^{-4} risk level (10^{-3} to 10^{-4}) for many of the beta emitters" (p. 21581), but fails to acknowledge the discrepancies in the exposure times between the current risk calculation and previous guidance for implementing the risk range. Many of the beta emitters would not exceed the risk range if a 30-year exposure time were used to calculate risk.

- The EPA's proposal states that EPA's risk range of $1x10^{-4}$ to $1x10^{-6}$ is for morbidity (i.e, cancer incidence), not mortality, for chemical carcinogens, and then proceeds to halve the risk range to account for mortality risk (page 21580). The EPA contradicts this statement that the risk range is one of morbidity later in the NODA in the discussion on the possible limits for uranium (page 21588). One of the regulatory options is to regulate at 40 pCi/l, and "...with an associated

cancer risk level of $1x10^{-4}$ or one in ten thousand, which is the Agency's usual upper cancer risk target." Using FGR 13 and assuming a near-equal mixture of uranium-234 and uranium-238, the mortality risk is approximately $1x10^{-4}$ and the morbidity is $1.7x10^{-4}$. In this instance, the upper cancer risk target is mortality and not morbidity.

- As noted previously, the NODA points out the "...risks associated with the 1991 proposed MCL of 4 mrem-ede are above the 10^{-4} risk level..." The MCL for combined radium-226 and radium-228, as discussed on p. 21584, results in a risk range that also exceeds the 10^{-4} risk ceiling (i.e., potentially as high as $2x10^{-4}$). Using the 1991 limits for beta/photon emitters, a similar risk (i.e., $2x10^{-4}$) to the radium risk is obtained for many of the beta/photon emitters (see Table II-3). Nonetheless, the $2x10^{-4}$ is found not acceptable for the beta/photon emitters (i.e., 1976 values for MCLs are to be used), whereas the radium value remains at the $2x10^{-4}$ risk value. The EPA has not fully explained its rationale for this discrepancy in using the risk ceiling for evaluating MCLs in the 1991 proposal.

- Previous EPA guidance has stated that a risk level $3x10^{-4}$ is essentially equivalent to the presumptively safe level of $1x10^{-4}$ (54 FR 51677, December 15, 1989). However, the NODA portrays risks for beta emitters that are no greater than $3x10^{-4}$ as being unacceptable.

In short, the NODA characterizes and uses risk limits in a manner that fosters confusion about EPA's risk policy, and misunderstanding concerning acceptable risk limits. The EPA fails to offer a sound argument for allowing the risk ceiling to be exceeded in certain instances (e.g., radium-226 and radium-228), while not permitting the 10^{-4} risk ceiling to be exceeded for other applications (e.g., beta/photon emitters). The EPA needs to formulate a consistent risk policy, including guidance (e.g., exposure time for lifetime risk calculations, consistent basis for allowing risk limits to be exceeded).

A more appropriate approach would be to set the MCLs at a consistent risk level. The EPA adopted such an approach, in its 1991 proposed regulation, that would have revised the MCLs for many beta/photon emitters, based on a common effective dose equivalent. The NRC staff believes an approach similar to that proposed in 1991 should be adopted, because it would provide a common technical and risk basis for both alpha emitters and beta/photon emitters. That being said, and although the NRC staff considers use of a consistent risk level a more appropriate approach, we continue to consider MCLs based on a dose of 0.04 mSv/yr (4 mrem/yr) to be needlessly conservative, given the current understanding of radiation effects on humans and the fact that the variability of natural background exceeds this limit. We strongly urge the EPA to re-examine the MCLs and set limits that can be justified on health and safety grounds, and protection of the environment. Such an approach for setting MCLs would preclude the confusing variation in applying the risk ceiling exhibited in the NODA and clearly communicate the level of consistent protection afforded the public.

2. The NRC staff objects to MCLs that cannot be justified on health and safety grounds.

The EPA's proposal needlessly establishes more conservative limits than those necessary to protect public health and safety. For example, the MCL for iodine-129 is set at 1 pCi/l -- or approximately 0.002 mSv/yr (0.2 mrem/yr) ede, whereas the international and national public dose limit for exposures from all pathways is 500 times higher, or 1 mSv/yr (100 mrem/yr) ede. Further, the mortality risk, using FGR 13 risk coefficients, from 70 years of drinking contaminated water (at a conservative rate of 2 liters a day and a concentration of 1 pCi/l of iodine-129) is approximately $8x10^{-7}$, which is below the lower value of EPA's risk range. Additionally, the EPA describes reporting requirements in a manner that erroneously implies that contaminant concentrations in drinking water that exceed the MCLs could pose a serious public health risk (e.g., Tier 2 public notice applies to situations with potential to have serious adverse effects on human health, p. 21595). The EPA needs to clarify the level at which concentrations in drinking water that exceed the MCLs for radionuclides pose a serious public health risk. Without such clarification, the EPA may inappropriately alarm the public that any concentration above the MCL is a threat when no threat to public health actually exists. Under the NODA criteria [e.g., annual doses on the order of 0.04 mSv/yr (4 mrem/yr), or substantially less for certain radionuclides], living in a brick or stone home as opposed to a wooden home would also represent a serious public health risk, since this represents an increased dose of 0.1 mSv/yr (10 mrem/yr). In reality, exceeding the MCLs at these very low levels may raise an issue of compliance with somewhat arbitrary EPA requirements, but does not present any serious adverse health concern.

3. The NRC staff objects to the inappropriate application of separate ground-water protection requirements for NRC licensed activities.

The NRC staff fully supports the protection of our nation's drinking water. We acknowledge the importance of developing appropriate health-based requirements, under the SDWA, for monitoring public water systems "at the tap." We also agree that when scientifically based MCLs are exceeded, it is appropriate that users of the drinking water supply system be notified of the violation, and that long-term compliance be achieved. Unfortunately, the EPA continues the practice of regulating other activities (i.e., activities not associated with a public water system) by applying MCLs for the protection of ground water. In such an application the EPA argues that the ground water may only be a potential source of drinking water that could be contaminated at some future time.

NRC licensing of waste disposal requires estimation or projection of long-term doses (hundreds to thousands of years in the future) that are typically a result of potential radionuclide releases to ground water. Conservative dose estimates are made on the assumption that humans will be present to use contaminated ground water without monitoring or benefit of the typical water-treatment measures that are currently applied to most public water systems. Both EPA and NRC staffs support such an approach for evaluating sites where compliance with individual protection standards is based on estimating or projecting future doses. However, the EPA applies the requirements of the SDWA (i.e., MCLs intended to be used as "at-the-tap" standards) to assess compliance. The NRC considers application of "at-the-tap" standards as inappropriate because: 1) the overly conservative MCLs are much more stringent than nationally and internationally accepted standards for radiation; and 2) MCLs are intended for application in the context of drinking water that is actually being supplied to real consumers,

rather than hypothetical users for which routine water treatment, as a remediation measure, cannot be considered because of the hypothetical nature of the analysis.

The NRC protects public health and safety and the environment with an all-pathway dose limit that ensures that risks from all radionuclides and all exposure pathways -- including the ground-water pathway -- are low and provide adequate protection. Separate ground-water protection requirements should not be required for NRC licensees because they are unnecessary for protection of public health and safety and because they lead to inconsistent and irreconcilable results, as described above. We believe that EPA's MCLs will cause confusion and diminish public confidence that adequately protective limits have been established for ground water.

Although the EPA has performed a limited cost/benefit analysis for the proposal for changes from the 1976 values, it has not performed a cost-benefit analysis for the implementation of MCLs in any other activity. The NRC agrees that the EPA cost-benefit analysis should not consider other programs to which MCLs may be applied. However, the NRC is not aware of any prohibitions from conducting cost-benefit analysis when EPA attempts to apply MCLs in these other contexts, such as cleanups pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, and the Nuclear Waste Policy Act. Additionally, the NRC is not aware that any cost-benefit analyses were performed when MCLs were applied to these other programs. The EPA should identify where cost-benefit analyses have been performed for applying the MCLs to other areas of regulation or explain why such analyses are not warranted. In the absence of an appropriate and comprehensive cost-benefit analysis, the EPA should not require the expenditure of potentially significant resources to prevent potential contamination of ground water without commensurate benefit to public health and safety and the environment.

B) OTHER CONCERNS WITH EPA'S NODA

1. NRC staff questions the assumptions that would require analysis of uranium.

On p. 21588 of the NODA, the EPA suggests a set of compliance methods for uranium sampling. Specifically, the uranium content is acceptable if: (1) the gross alpha results are below 3 pCi/l; (2) the gross alpha is between 3 pCi/l and 5.5 pCi/l, and the total uranium mass is less than 20 μg/l; or (3) the gross alpha is greater than 5.5 pCi/l, and an isotopic analysis shows that total uranium is less than 20 pCi/l. The requirements to verify mass are based on an extremely conservative assumption that only uranium-238 is present in the water. The NRC questions whether pure uranium-238 is a reasonable assumption at any water supply system in the United States. Additionally it is not clear, in the proposal, why the gross alpha test may underestimate uranium by a factor of 3.62.

2. NRC staff questions the compliance determination with regard to a single entry point.

The EPA proposal is to adopt the 1991 proposal of monitoring the concentration in water entering a distribution system. The NRC staff notes the value in this, as it is a conservative estimate of what individuals may receive from distribution systems that have multiple entry points that result in non-uniform mixing. The NRC staff notes that because the NODA is based on "at-the-tap" concentrations, it should permit use of additional monitoring of actual

concentrations at the nearest resident from an entry point, to quantify the actual risks. This is especially important for systems where multiple entry points exist in close proximity to one another. The current wording in the compliance determination sections (e.g., p. 21593) provides little flexibility, especially considering the very low risks associated with this NODA.

3. <u>The NRC staff considers that required use of the NBS Handbook 69 inappropriately and unnecessarily complicates evaluation of compliance with MCLs.</u>

We disagree with the EPA proposal that would maintain the current wording of the beta/gamma MCL. The current regulation, at 40 CFR 141.16, uses outdated science, and relies on a text that is difficult to acquire and interpret (the NBS Handbook 69, which was published in 1959). The NODA continues EPA's practice of using the critical organ approach, even though the EPA acknowledges that better estimates of risk exist. The EPA has noted that the scientific models used to create NBS Handbook 69 have been superseded by more recent biokinetic models to estimate dose or risk, most recently by FGR 13 (p. 21580 and Appendix II). EPA, though, chooses to continue the reference to NBS Handbook 69. Unlike FGR 11, which calculates the effective dose equivalent from an intake, or FGR 13, which calculates a risk from an intake, NBS Handbook 69 consists of tables of allowable air and water concentrations for workers. The user must do a number of calculations to convert the concentrations, which are based on much higher allowed worker doses [with organ limits up to 300 mSv (30 rem)] and different water intake rates (2.2 liters versus 2.0 liters), to concentrations consistent with the 0.04 mSv (4 mrem) critical organ limit of 40 CFR 141.16. We suggest that the EPA forgo placing direct reference to the methodology for determining dose (currently NBS Handbook 69) in the regulation. In this manner, determinations of compliance with the MCLs can remain current with developments in the radiation protection field rather than be bound to hard-to-use, outdated methodologies.

C) IDENTIFICATION OF TYPOGRAPHICAL AND CONTENT ERRORS

1) The NRC noted that in the summary attachment to the letter dated April 27, 2000, from James D. Taft, the EPA claims that uranium-238 is non-radioactive (last paragraph of page 1). The NODA does not make this claim and does note that uranium-238 is radioactive, albeit at a lower specific activity than uranium-234 or uranium-235. It appears that the summary was trying to contrast the chemical and radioactive hazards of uranium. Any isotope can have both chemical and radioactive considerations (e.g., uranium-234, or lead-210). The summary should be revised to remove any statements that uranium-238 is non-radioactive.

2) On p. 21584, Column 1 - the exponent on the risk range at the end of the first bullet should be 10^{-4} not 10^{-5}.

3) On p. 21584, Table III-1 - the current risk estimate for radium-228 should be $2x10^{-4}$, not $2x10^{-5}$.

4) On p. 21577, “Units of Measurement” - - change the following:

USSCEAR to UNSCEAR;
Mgkd (milligram per kilogram per day) to mgkd; and
mgd (million gallons per day) to Mgd.