**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 9, 141, and 142**

**[FRL–6909–3]**

**RIN 2040–AC98**

## National Primary Drinking Water Regulations; Radionuclides; Final Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** Today, EPA is finalizing maximum contaminant level goals (MCLGs), maximum contaminant levels (MCLs), and monitoring, reporting, and public notification requirements for radionuclides. Today's rule is only applicable to community water systems. Today's rule includes requirements for uranium, which is not currently regulated, and revisions to the monitoring requirements for combined radium-226 and radium-228, gross alpha particle radioactivity, and beta particle and photon radioactivity. Based on an improved understanding of the risks associated with radionuclides in drinking water, the current MCL for combined radium-226/-228 and the current MCL for gross alpha particle radioactivity will be retained. Based on the need for further evaluation of the various risk management issues associated with the MCL for beta particle and photon radioactivity and the flexibility to review and modify standards under the Safe Drinking Water Act (SDWA), the current MCL for beta particle and photon radioactivity will be retained in this final rule, but will be further reviewed in the near future.

Some parts of EPA's 1991 proposal, including the addition of MCLGs and the National Primary Drinking Water Regulation (NPDWR) for uranium, are required under the SDWA. Other portions were intended to make the radionuclides NPDWRs more consistent with other NPDWRs, *e.g.*, revisions to monitoring frequencies and the point of compliance. Lastly, some portions were contingent upon 1991 risk analyses, *e.g.*, MCL revisions to the 1976 MCLs for combined radium-226 and -228, gross alpha particle radioactivity, and beta particle and photon radioactivity. The portions required under SDWA and the portions intended to make the radionuclides NPDWRs more consistent with other NPDWRs are being finalized today. The portions contingent upon the outdated risk analyses supporting the 1991 proposal are not being finalized today, in part based on updated risk analyses.

**DATES:** This regulation is effective December 8, 2003. The incorporation by reference of the publications listed in today's rule is approved by the Director of the Federal Register as of December 8, 2003. For judicial review purposes, this final rule is promulgated as of 1 p.m. Eastern Time on December 7, 2000.

**ADDRESSES:** The record for this regulation has been established under the docket name: National Primary Drinking Water Regulations for Radionuclides (W–00–12). The record includes public comments, applicable **Federal Register** notices, other major supporting documents, and a copy of the index to the public docket. The record is available for inspection from 9 a.m. to 4 p.m., Eastern Standard Time, Monday through Friday, excluding Federal holidays, at the Water Docket, 401 M Street SW, East Tower Basement (Room EB 57), Washington, DC 20460. For access to the Docket materials, please call (202) 260–3027 to schedule an appointment.

**FOR FURTHER INFORMATION CONTACT:** For technical inquiries, contact David Huber, Standards and Risk Management Division, Office of Ground Water and Drinking Water, EPA (MC–4607), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 260–9566. For general inquiries, the Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9:00 a.m. to 5:30 p.m. Eastern Standard Time. The Safe Drinking Water Hotline toll free number is (800) 426–4791.

**SUPPLEMENTARY INFORMATION:**

### Regulated Entities

Entities potentially regulated by this rule are public water systems that are classified as community water systems (CWSs). Community water systems provide water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serve an average of at least 25 people year-round. Regulated categories and entities include:

| Category | Examples of regulated entities |
|---|---|
| Industry | Privately-owned community water systems. |
| State, Tribal, Local, and Federal Governments. | Publicly-owned community water systems. |

This table is not intended to be exhaustive, but rather, provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 141.26(a)(1)(i), 141.26(a)(1)(ii), 141.26(b)(1), and 141.26(b)(2) of this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

### Abbreviations and Acronyms Used in This Document

ASTM: American Society for Testing and Materials
AWWA: American Water Works Association
BAT: Best available treatment
BEIR: Biological effects of ionizing radiation
CFR: Code of Federal Regulations
CWS: Community water systems
EDE: Effective dose equivalent
EML: Environmental Measurements Laboratory
FR: Federal Register
ICRP: International Commission on Radiological Protection
IE: Ion exchange
kg: Kilogram
L/day: Liter per day
LET: Low energy transfer
LOAEL: Lowest observed adverse effect level
MCL: Maximum contaminant level
MCLG: Maximum contaminant level goal
mg/L: Milligram per liter
μg/L: Microgram per liter
mGy: MilliGray
mrem: Millirem
mrem/yr: Millirem per year
NBS: National Bureau of Standards
NDWAC: National Drinking Water Advisory Committee
NIRS: National Inorganic and Radionuclide Survey
NIST: National Institute of Standards and Technology
NODA: Notice of Data Availability
NPDWRs: National Primary Drinking Water Regulations
NRC: National Research Council
NTIS: National Technical Information Service
NTNC: Non-transient, non-community
NTNCWS: Non-transient, non-community water systems
pCi: Picocurie
pCi/L: Picocurie per liter
PE: Performance evaluation
PNR: Public Notification Rule
POE: Point-of-entry
POU: Point-of-use
PQL: Practical quantitation level
PT: Performance testing
RADRISK: A computer code for radiation risk estimation
RfD: Reference dose
RO: Reverse osmosis
SM: Standard methods
SMF: Standardized monitoring framework
SSCTL: "Small Systems Compliance Technology List"
SWTR: Surface Water Treatment Rule
TAW: Technical Advisory Workgroup
UCMR: Unregulated Contaminant Monitoring Rule

UNSCEAR: United Nations Scientific Committee on the Effects of Atomic Radiation
USDOE: United States Department of Energy
USEPA: United States Environmental Protection Agency
USGS: United States Geological Survey

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## I. Background and Summary of the Final Rule

### *A. What Did EPA Propose in 1991?*

In 1991, EPA proposed a number of changes and additions to the radionuclides NPDWRs. Among other things, EPA proposed to:

- Set a maximum contaminant level goal (MCLG) of zero for all radionuclides.
- Set a maximum contaminant level (MCL) of 20 µg/L or 30 pCi/L for uranium (with options of 5 pCi/L to 80 µg/L).
- Change the radium standard from a combined limit for radium-226 and 228 of 5 pCi/L to separate standards at 20 pCi/L.
- Remove radium-226 from the radionuclides included in the definition

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of gross alpha, while keeping the gross alpha MCL at 15 pCi/L, since the proposed radium-226 MCL was greater than the gross alpha MCL.

- Change dose limit from critical organ dose (millirems) to "weighted whole body dose" (millirems-effective dose equivalent).
- Require community water systems which are determined by the State to be vulnerable or contaminated to monitor for beta particle and photon radioactivity, rather than at all surface water systems serving a population over 100,000 people (as under the current 1976 rule).
- Establish a monitoring framework more in line with the standardized monitoring framework used for other contaminants.
- Exclude compositing for beta particle and photon emitters.
- Include non-transient, non-community water systems (NTNCWSs) in the regulation.
- Require that each entry point to the distribution system be monitored to ensure that each household in the system received water protective at the MCL.

*B. Why Did EPA Propose Changes to the Radionuclides Drinking Water Regulations in 1991?*

In 1976, National Interim Primary Drinking Water Regulations were promulgated for radium-226 and -228, gross alpha particle radioactivity and beta particle and photon radioactivity. The health risk basis for the 1976 radionuclides MCLs was described in the recent radionuclides Notice of Data Availability (NODA), (65 FR 21575, April 21, 2000). The 1986 reauthorization of the Safe Drinking Water Act (SDWA) required EPA to promulgate MCLGs and National Primary Drinking Water Regulations (NPDWRs) for the above radionuclides, radon and uranium. Also in 1986, EPA published an Advance Notice of Proposed Rulemaking for the radionuclides NPDWRs (EPA 1986), which stated EPA's intent to accomplish this goal. In 1991, EPA proposed changes to the current radionuclides standards and new standards for radon and uranium. EPA determined that both combined radium-226 and -228 and uranium could be analytically quantified and treated to 5 pCi/L. However, EPA concluded that, given the much greater cost-effectiveness of reducing risk through radon water treatment relative to radium and uranium, the feasible levels were 20 pCi/L each for radium-226 and -228 and 20 µg/L (or 30 pCi/L) for uranium. Between 1986 and 1991, EPA made risk estimates based on then-current models and information, as described in the NODA (EPA 2000e) and its Technical Support Document (USEPA 2000h). The 1991 risk estimates[1] indicated that the proposed MCL changes would result in lifetime cancer risks within the risk range of $10^{-6}$ and $10^{-4}$ (one in one million to one in ten thousand) that EPA considers in establishing NPDWRs. The 1991 proposed uranium MCL was based on both kidney toxicity risk and cancer risk. All MCLGs for radionuclides were proposed as zero pCi/L, based on a linear no-threshold cancer risk model for ionizing radiation. A summary of the difference between the 1976 rule and the 1991 proposal are presented in Table I–1. The detailed differences between the 1976 rule and the 1991 proposal can be found in the record for this rulemaking (EPA 1976; 1986; 1991; 2000a).

TABLE I–1.—COMPARISON OF THE 1976 RULE, 1991 PROPOSAL, AND 2000 FINAL RULE

| Provision | 1976 rule (current rule) | 1991 proposal | 2000 final rule |
|---|---|---|---|
| Affected Systems | CWS | CWS + NTNC | CSW. |
| MCLG for all radionuclides. | No MCLG | MCLG of zero | MCLG of zero. |
| Radium MCL | Combined Ra-226 + Ra-228 MCL of 5pCi/L. | Ra-226 MCL of 20 pCi/L<br>Ra-228 MCL of 20 pCi/L | Maintain current MCL based on the newly estimated risk level associated with the 1991 proposed MCL. |
| Beta/Photon Radioactivity MCL. | • ≤ 4 mrem/y to the total body or any given internal organ<br>• Except for H-3 and Sr-90, derived radionucide-specific activity concentrations yielding 4 mrem/y based on NSB Handbood 69 and 2L/d<br>• H-3 = 20,000 pCi/L; Sr-90 = 8 pCi/L<br>• Total dose from co-occurring beta/photon emitters must be ≤ 4 mrem/y to the total body of any internal organ | • 4 mrem/y effective dose equivalent (ede)<br>• Re-derived radionuclide-specific activity concentrations yielding 4 mrem/y ede based on EPA RADRISK code and 2 L/d<br>• Total dose from co-occurring beta/photon emitters must be < 4 mrem/y ede | Maintain current MCL based on the newly estimated risk level associated with the 1991 proposed MCL. This MCL will be reviewed within 2 to 3 years based on a need for further re-evaluation of risk management issues. |
| Gross alpha MCL | 15 pCi/L excluding U and Rn, but including Ra-226. | "Adjusted" gross aplha MCL of 15 pCi/L, excluding Ra-226, radon, and uranium. | Maintain current MCL based on the newly estimated risk level associated with the 1991 proposed MCL. |
| Polonium-210 | Included in gross alpha | Included in gross alpha | Included under gross alpha, as in current rule. Monitoring required under the UCMR rule. Further action may be proposed at a later date. |
| Lead-210 | Not Regulated | Included in beta particle and photon radioactivity; concentration limit proposed at 1 pCi/L. | No changes to current rule. Monitoring required under the UCMR rule. Further action may be proposed at a later date. |
| Uranium MCL | Not Regulated | 20 g/L or 30 pCi/L w/ option for 5 pCi/L–80 g/L. | 30 µ/L. |

[1] The 1991 cancer risk estimates were based on the now-outdated RADRISK model (see the NODA and its Technical Support Document, USEPA 2000e and h).

TABLE I–1.—COMPARISON OF THE 1976 RULE, 1991 PROPOSAL, AND 2000 FINAL RULE—Continued

| Provision | 1976 rule (current rule) | 1991 proposal | 2000 final rule |
|---|---|---|---|
| 224 | Part of gross alpha, but sample holding time too long to capture Ra-224. | Part of gross alpha, but sample holding time too long to capture Ra-224. | No changes to current gross alpha rule. Will collect national occurrence information; further action may be proposed at a later date. |
| adium monitoring | Ra-226 linked to Ra-228; measure Ra-228 if Ra-226 > 3 pCi/L and sum. | Measure Ra-226 and -228 separately | Measure Ra-226 and -228 separately. |
| Monitoring baseline | 4 quarterly measurements. Monitoring reduction based on results: > 50% of MCL required 4 samples every 4 yrs; < 50% of MCL required 1 sample every 4 yrs | Annual samples for 3 years; Std Monitoring Framework: > 50% of MCL required 1 sample every 3 years; < 50% of MCL enabled system to apply for waiver to 1 sample every 9 years. | Implement Std Monitoring Framework as proposed in 1991. Four initial consecutive quarterly samples in first cycle. If initial average level > 50% of MCL: 1 sample every 3 years; < 50% of MCL: 1 sample every 6 years; Non-detect: 1 sample every 9 years. (beta particle and photon radioactivity has a unique schedule—see section III, part—K) States will have discretion in data grandfathering for establishing initial monitoring baseline. |
| Beta particle and photon emitters monitoring. | Surface water systems > 100,000 population Screen at 50 pCi/L/; vulnerable systems screen at 15 pCi/L. | Ground and surface water systems within 15 miles of source screen at 30 or 50 pCi/K. | CWSs determined to be vulnerable by the State screen at 50 pCi/L. |
| Gross alpha monitoring. | Analyze up to one year later | Six month holding time for gross alpha samples; Annual compositing of samples allowed. | As proposed in 1991. |
| Analytical Methods | Provide methods | Method updates proposed in 1991; Current methods were updated in 1997. | Current methods with clarifications. |

*C. What New Information Has Become Available Since 1991? Overview of the 2000 Notice of Data Availability (NODA)*

EPA published a Notice of Data Availability (NODA) on April 21, 2000. This NODA described the new information that has become available since the 1991 proposal and the basis for today's final regulatory decisions. The most significant source of new information is Federal Guidance Report-13 (FGR–13) (USEPA 1999b), "Cancer Risk Coefficients for Environmental Exposure to Radionuclides," which provides the numerical factors used in estimating cancer risks from low-level exposures to radionuclides. The risk coefficients in FGR–13 are based on state-of-the-art methods and models and are a significant improvement over the risk coefficients that supported the 1991 radionuclides proposal. FGR–13 is the latest report in a series of Federal guidance documents that are intended to provide Federal and State agencies technical information to assist their implementation of radiation protection programs. FGR–13 was formally reviewed by EPA's Science Advisory Board and was peer-reviewed by academic and government radiation experts. An interim version of the report was published for public comment in January of 1998. Comments were provided by Federal Agencies, including the Nuclear Regulatory Commission and the Department of Energy, State Agencies, and the public. The final version (September 1999) reflects consideration of all of these comments. The risk analyses supporting today's regulatory decisions are described in detail in the NODA (EPA 2000e) and its Technical Support Document (USEPA 2000h).

The NODA also reported the results from a June 1998 USEPA workshop held to discuss non-cancer toxicity issues associated with exposure to uranium from drinking water. At this workshop, a panel of experts reviewed and evaluated new information regarding kidney toxicity was examined. The findings from this workshop can be found in the NODA's Technical Support Document (USEPA 2000h).

Other important new information includes the results from a 1998 U.S. Geological Survey study which targeted the occurrence of radium-224 and beta particle/photon radioactivity (USEPA 2000e and h). Previously, it was assumed that the alpha-emitting radium-224 isotope rarely occurred in drinking water. If present in drinking water, because of its short half-life (3.6 days) and estimated low occurrence, it was thought that sufficient time would elapse to allow the isotope to decay to low levels before entry into the distribution system. Hence, radium-224 was not thought to appreciably occur in drinking water. This new information indicates that radium-224 significantly (positively) correlates with both radium-228 (correlation coefficient of 0.82) and radium-226 (correlation coefficient of 0.69), suggesting that radium-224 should be evaluated as a potential drinking water contaminant of national concern (USEPA 2000h). The impact of this and other information on decisions regarding radium-224 is discussed in part D of this section. In addition to the radium-224 occurrence information, the USGS study also determined that the majority of the beta particle/photon radioactivity in the samples collected was due to the presence of radium-228 and potassium-40, both naturally occurring contaminants. Since radium-228 is regulated under the combined radium-226/-228 standard and potassium-40 is not regulated, this suggests that most situations in which the beta/photon screening level is exceeded will not result in MCL violations. Of more concern, minor contributions from naturally occurring lead-210 were also reported. Lead-210 occurrence will be studied under the Unregulated Contaminant Monitoring Rule (UCMR).

In addition to this new technical information, the NODA also described the 1996 changes to the statutory framework for setting drinking water NPDWRs. The SDWA, as amended in 1996, requires EPA to review and revise,

as appropriate, each national drinking water regulation at least once every six years. The Act also requires that any revision to an NPDWR "maintain, or provide for greater, protection of the health of persons" (section 1412(b)(9)).

Regarding the setting of new NPDWRs, the SDWA as amended in 1996 gives EPA the flexibility to set an MCL at a level less stringent than the feasible level, if the Administrator determines that the benefits do not justify the costs at the feasible level. If the Administrator makes this finding, the Act directs EPA to set the MCL at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits" (section 1412(b)(6)). This provision applies to uranium only, since it is the only contaminant for which a new MCL is being established by today's regulatory action.

*D. What Are the Rationales for the Regulatory Decisions Being Promulgated Today?*

As previously discussed, EPA is retaining the current MCLs for combined radium-226 and 228, gross alpha particle radioactivity, and beta particle and photon radioactivity and is promulgating a new standard for uranium. The following is a discussion of the rationales supporting these decisions. In addition to the responses to major comments in the following section, responses to each individual comment are in the comment response document which is available for review in the docket for this final rule.

1. Retaining the Combined Radium-226 and Radium-228 MCL

The 1991 proposed changes to the MCLs for combined radium-226 and radium-228 were premised on a cost-effectiveness trade-off between radium mitigation and radon mitigation (a radon standard was also included in the 1991 proposal). This cost-effectiveness argument was used to support a proposal to raise the combined radium-226/-228 MCL of 5 pCi/L to individual MCLs of 20 pCi/L for each isotope. At the time, it was thought that the risks associated with 20 pCi/L of radium-226 and radium-228 were within the $10^{-6}$ to $10^{-4}$ risk range. However, current risk analyses based on Federal Guidance Report-13 (see Part C of this section) indicate that these higher MCLs have associated risks that are well above the $10^{-6}$ to $10^{-4}$ risk range. For details on the basis and findings of this risk analysis, see the NODA (USEPA 2000e) and its Technical Support Document (USEPA 2000h). Since this proposed change would introduce higher risks than envisioned in the original 1976 rule, approaching lifetime cancer risks of one in one thousand ($10^{-3}$) for occurrence at or near the 1991 proposed MCLs, EPA believes that its decision to retain the current combined radium-226/-228 MCL of 5 pCi/L is justified. Under the 1996 Amendments to the Safe Drinking Water Act, EPA is required to ensure that any revision to a drinking water regulation maintains or provides for greater protection of the health of persons (section 1412(b)(9)).

a. Major Comments Regarding Retention of the Combined Radium-226 and Radium-228 MCL

The major comments and responses concerning the retention of the combined radium-226 and radium-228 MCL are summarized in part E of this section ("What are the health effects that may result from exposure to radionuclides in drinking water?").

2. The Final Uranium MCL

a. What Is the Final MCL for Uranium and the Rationale for That Regulatory Level?

With today's rule, EPA is promulgating a uranium MCL of 30 µg/L. The SDWA generally requires that EPA set the MCL for each contaminant as close as feasible to the MCLG, based on available technology and taking costs to large systems into account. The 1996 amendments to the SDWA added the requirement that the Administrator determine whether or not the quantifiable and non-quantifiable benefits of an MCL justify the quantifiable and non-quantifiable costs based on the Health Risk Reduction and Cost Analysis (HRRCA) required under section 1412(b)(3)(C). The 1996 SDWA amendments also provided new discretionary authority for the Administrator to set an MCL that is less stringent than the feasible level if the benefits of an MCL set at the feasible level would not justify the costs (section 1412(b)(6)). This final rule establishing an MCL for uranium of 30 µg/L is the first time EPA has invoked this new authority.

In conducting this analysis, EPA considered all available scientific information concerning the health effects of uranium, including various uncertainties in the interpretation of the results, as well as all costs and benefits, both quantifiable and non-quantifiable. As discussed in more detail below, all health endpoints of concern were considered in this analysis. For some of these, the risk can currently be quantified (*i.e.*, expressed in numerical terms); and for some, it cannot. Similarly, there are a variety of health and other benefits attributable to reductions in levels of uranium in drinking water, some of which can be monetized (*i.e.*, expressed in monetary terms) and others that cannot yet be monetized. All were considered in this analysis. A detailed discussion of each of the principal factors considered follows.

b. MCLG and Feasible Level for Uranium

Since uranium is radioactive and EPA uses a non-threshold linear risk model for ionizing radiation, today's rule sets the MCLG (non-enforceable health-based goal) for this contaminant at zero. The Safe Drinking Water Act requires EPA to set the MCL as close to the MCLG as is feasible, where this is defined as "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration) * * *" [section 1412(b)(4)(D)]. EPA proposed a feasible level of 20 µg/L in its 1991 proposal. In doing so, EPA determined that uranium may be treatable and quantifiable at levels below 20 µg/L, however, levels below 20 µg/L were not considered feasible under the Safe Drinking Water Act. EPA believes the feasible level is still 20 µg/L.

c. Basis for 1991 Proposed MCL and Cancer Risk from Uranium

EPA is required by the Safe Drinking Water Act (section 1412(b)(2)) to regulate uranium in drinking water. In 1991, EPA proposed a uranium MCL of 20 µg/L ("mass concentration") based on health effects endpoints of kidney toxicity and carcinogenicity. In the proposal, EPA estimated that 20 µg/L would typically [2] correspond to 30 pCi/L ("activity"), based on an assumed mass:activity ratio of 1.5 pCi/µg. While such values are known to occur in ground water, this conversion factor does not reflect our "best estimate" today. The best estimate of a geometric average mass:activity ratio is 0.9 pCi/µg for values near the MCL, based on data from the National Inorganics and Radionuclides Survey (see USEPA 2000h). Given the closeness of this

[2] The actual relationship between mass concentration (µg/L) and activity (pCi/L) varies somewhat in drinking water sources, since the relative amounts of the radioactive isotopes that make up naturally occurring uranium (U–238, U–235, and U–234) vary between drinking water sources. The typical conversion factors that are observed in drinking water range from 0.67 up to 1.5 pCi/µg.

value to unity (1 pCi/µg), the available data suggests that, to a first approximation [3], the mass:activity ratio is 1:1 for typical systems. The 1991 proposed MCL of 20 µg/L was determined, at that time, to correspond to a "drinking water equivalent level" (DWEL [4]) with respect to kidney toxicity for a lifetime exposure. The corresponding 30 pCi/L level (based on the 1991 mass to activity conversion) was estimated to have a lifetime cancer risk of slightly below the $10^{-4}$ level.

Because the kidney toxicity health effects and the corresponding non-quantifiable kidney toxicity benefits are a very important consideration in setting the MCL, we first provide background on these effects before discussing the rationale for setting the uranium MCL.

d. Uranium Health Effects: Kidney Toxicity

Each kidney consists of over a million nephrons, the filtration functional units of the kidney. The nephron consists of glomeruli, which filter the blood, and renal tubules (proximal, distal, collecting duct, etc.), which collect the fluid that passes through the glomeruli (the "filtrate"). After the filtrate flows into renal tubules, glucose, proteins, sodium, water, amino acids, and other essential substances are reabsorbed, while wastes and some fraction of electrolytes are left behind for later excretion. The efficiency of this process can be monitored by analyzing urine ("urinalysis"), which reveals the concentrations of the various constituents making up the urine. For example, protein or albumin in the urine (proteinuria or albuminuria) indicates reabsorption deficiency or leakage of albumin, a class of proteins found in blood and which are responsible for maintaining fluid balance between blood and body cells. In the case of uranium toxicity, it is not clear whether long-term exposure may lead to marked albumin loss.

The level of proteinuria in urine is an indication of the degree of kidney toxicity: levels are divided into "trace", "mild", "moderate", or "marked", which are defined by increasing levels of proteinuria. Increased excretion of protein in the urine could be the result of tubular damage, inflammation, or increased glomerular permeability. It should be noted that a gradual loss of nephrons is asymptomatic until the loss is well advanced; the kidneys normally have the ability to compensate for nephron-loss. For example, chronic renal failure occurs when there is around 60% nephron loss. During the gradual loss of functioning nephrons, the remaining nephrons appear to adapt, increasing their capacity for filtration, reabsorption, and excretion.

Uranium has been identified as a nephrotoxic metal (kidney toxicant), exerting its toxic effects by chemical action mostly in the proximal tubules in humans and animals. However, uranium is a less potent nephrotoxin than the classical nephrotoxic metals such as cadmium, lead, and mercury. Uranium has an affinity for renal proximal tubular cells and interferes with reabsorption of proteins, as previously described. Specifically, uranium-induced renal tubular dysfunction in humans is marked by mild proteinuria, due to reduced reabsorption in the proximal renal tubules. Furthermore, the pathogenesis of the kidney damage in short-term animal studies indicates that regeneration of the tubular cells may occur upon discontinuation of exposure to uranium. We do not know if uranium-induced proteinuria is an indicator of the beginning of an adverse effect or whether it is a reversible effect that does not typically result in kidney disease. Based on the uncertainty involved in the ultimate effects, the scientists at our experts workshop (discussed next) treated this effect as an indicator of an incipient change in kidney function that may lead ultimately to frank adverse effects such as breakdown of kidney tubular function. For general information on proteinuria, kidney function, and kidney disease, see the fact sheets at "http://www.niddk.nih.gov/health/kidney/pubs/ proteinuria/proteinuria.htm", "http://www.niddk.nih.gov/health/kidney/pubs/yourkids/index.htm", and "http://www.niddk.nih.gov/health/kidney/kidney.htm" (NIH 2000a, NIH 2000b, and NIH 2000c).

e. New Kidney Toxicity Analyses Announced in the NODA

Since the 1991 radionuclides proposal, EPA has re-evaluated the available kidney toxicity data and, based on the results of an experts workshop (see the NODA, USEPA 2000e, for details), has estimated the DWEL to be 20 µg/L. The DWEL is derived from the Reference Dose (RfD), which is an estimate of a daily ingestion exposure to the population, including sensitive subgroups, that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD (in µg of uranium per kg of body mass per day; µg/kg/day) for uranium was calculated from the Lowest Observed Adverse Effects Level ("LOAEL"), which is the lowest level at which adverse effects were observed to occur. The LOAEL is taken directly from health effects data. The RfD is calculated by dividing the LOAEL by a numerical uncertainty factor which accounts for areas of variability in human populations because of uncertainty in the uranium health database. EPA followed the recommended methodology of the National Academy of Sciences in estimating the uncertainty factor.

As described in the NODA, we reported that our best-estimate of the LOAEL is 60 µg/kg/day, based on rat data. In support of this estimate of the DWEL, EPA has some human data which demonstrates that mild proteinuria has been observed at drinking water levels between 20 and 100 µg/L. In estimating the RfD, we have used an uncertainty factor of 100 (rounded from the product of 3 for intra-species variability, 10 for inter-species variability, and 3 for the use of a LOAEL). Using this uncertainty factor, the RfD is calculated to be 0.6 µg/kg/day. The estimated uncertainty in the RfD spans an order of magnitude (a factor of ten). The 20 µg/L DWEL is calculated by using this RfD and assuming that an adult with a body mass of 70 kilograms drinks 2 liters of water per day [5] and that 80% of exposure to uranium is from water. These calculations are described in more detail in the NODA's Technical Support Document (USEPA 2000h).

The Agency believes that 30 µg/L is protective against kidney toxicity. While 20 µg/L is the Agency's best estimate of the DWEL, there are several reasons, in the Agency's judgment, that demonstrate that there is not a predictable difference in health effects due to exposure between the DWEL of 20 µg/L and a level of 30 µg/L. For instance, variability in the normal range for proteinuria in humans is very large and there is additional variability in proteinuria levels observed at uranium

[3] This is mentioned since, for the sake of simplicity, the reader may thus easily convert between µg/L and pCi/L. However, in current calculations, we use the geometric mean from the NIRS data, which is 0.9 pCi/µg. We reiterate that conversion factors ranging from 0.67 up to 1.5 pCi/µg do occur in drinking water sources.

[4] The drinking water equivalent level (DWEL) (µg/L) is the best estimate of the drinking water concentration that results in the Reference Dose (µg/kg/day), assuming a water ingestion rate of 2 L/day and a body mass of 70 kg.

[5] The standard assumptions for the DWEL are conservative, since the ingestion rate is at the 90th percentile, while the body mass is more typical. Conservative assumptions are used to ensure that the resulting exposure level is protective of individuals that consume significantly more water than typical and children (low body masses).

exposures large enough to induce the effect. In the existing few epidemiology studies, each of which are based on small study populations, there were some persons exposed to over five times the DWEL of 20 µg/L without the observation of effects more serious than mild proteinuria (within the high end of the normal range). An MCL of 30 µg/L represents a relatively small increase over the DWEL compared to the over-all uncertainty in the RfD and the uncertainty in the importance of the mild proteinuria observed for uranium exposures from high drinking water levels (keeping in mind that, as discussed previously, the DWEL is based on the RfD and is an estimate of a no effect level for a population). While it is assumed that risk of an effect (here a mild effect) increases as exposure increases over the RfD, it is not known at what exposure an effect is likely. Given that the uncertainty factor of 100 provides a relatively wide margin of safety, the likelihood of any significant effect in the population at 30 µg/L is very small. EPA, thus, believes that the difference in kidney toxicity risk for exposures at 20 µg/L versus 30 µg/L is insignificant.

f. Costs and Benefits From Regulating Uranium in Drinking Water

As discussed in the NODA, EPA has estimated the risk reductions, monetized benefits, and costs associated with compliance with an MCL of 20 µg/L, 40 µg/L, and 80 µg/L. In the NODA, EPA solicited comment on using its statutory authority provided in section 1412(b)(6) of the Safe Drinking Water Act to set the uranium MCL at a level higher than the proposed level of 20 µg/L, based on its analysis of costs and benefits.

The monetized costs and benefits associated with various MCL options are discussed further in section IV of today's notice and in more detail in the economic analysis support document (USEPA 2000g). Table I–2 shows incremental annual cancer risk reductions, total national annual compliance costs and monetized benefits (excluding kidney toxicity benefits), and the numbers of community water systems predicted to have MCL violations for MCLs of 80, 30, and 20 µg/L (assuming the 0.9 pCi/µg conversion factor for estimating cancer risk reductions and benefits). Keeping in mind that the monetized benefits and risk reductions exclude kidney toxicity benefits, several things can be noted from the analysis. Focusing on the MCL change from 30 µg/L to 20 µg/L (see lower part of table I–2), one can see that the incremental benefits for implementing an MCL of 30 µg/L are three times greater than the incremental benefits for a lower MCL of 20 µg/L, while the incremental annual costs are much closer in magnitude ($54 million vs. $39 million). In terms of incremental cancer cases avoided, the estimated number of cancer cases avoided for an MCL of 30 µg/L is 0.8 annually, while lowering the MCL to 20 µg/L would result in an additional 0.2 cases avoided annually (25% reduction) at an additional cost of $39 million annually (75% increase). Approximately 37% of systems predicted to have MCL violations occur between 30 µg/L and 20 µg/L, resulting in significant increases in annual compliance costs (42% of national compliance costs occur between 30 µg/L and 20 µg/L), while the number of cancer cases avoided increases much less significantly (only 20% of cancer risk reduction occurs between 30 µg/L and 20 µg/L).

Since the kidney benefits are not quantified, this is an incomplete picture, but EPA believes that the uncertainties in the analysis of health effects are such that it is not known whether the risk of mild proteinuria are appreciably different between 20 µg/L and 30 µg/L. Assuming that there is a risk increase, it would be expected to be negligible compared to the risk increase that occurs between the highest uranium levels that occur in drinking water (*i.e.*, approximately 200 µg/L) and an MCL of 30 µg/L. Considering only cancer risk reduction benefits, the annual net benefits [6] for a uranium MCL of 20 µg/L are negative $90 million [7] and for an MCL of 30 µg/L are negative $50 million. Since the cancer risk reduction net benefits are higher at 30 µg/L than at 20 µg/L and the non-quantified kidney toxicity benefits are expected to be substantially the same at 20 µg/L and 30 µg/L, EPA believes an MCL of 30 µg/L maximizes the benefits at a cost justified by the benefits. EPA does not believe that uranium levels above 30 µg/L are protective of kidney toxicity with an acceptable margin of safety. (EPA believes that the margin of safety associated with a 30 µg/L are comparable with those at 20 µg/L.) Further, EPA believes that the net kidney toxicity benefits of an MCL greater than 30 µg/L would be less than those at 30 µg/L. Finally, EPA believes that 30 µg/L is protective of the general population, including children and the elderly.

TABLE I–2.—INCREMENTAL COSTS AND BENEFITS FOR URANIUM MCLS OF 80 µG/L, 30 µG/L, AND 20 µG/L

| Uranium MCL | Exposure change | Incremental annual cancer cases avoided | Incremental annual compliance costs (in millions) | Incremental annual monetized cancer benefits (kidney benefits not monetized) (in millions) | Incremental number of community water systems impacted |
|---|---|---|---|---|---|
| 80 µg/L | ∞–80 µg/L | 0.5 | $16 | $2 | 100 |
| 30 µg/L | 80–30 µg/L | 0.4 | 38 | 1 | 400 |
| 20 µg/L | 30–20 µg/L | 0.2 | 39 | 1 | 290 |
| **Incremental Costs and Benefits for Uranium MCLs of 30 µg/L (µg/L) and 20 µg/L only** | | | | | |
| 30 µg/L | ∞–30 µg/L | 0.8 | 54 | 3 | 500 |
| 20 µg/L | 30–20 µg/L | 0.2 | 39 | 1 | 290 |

**Note:** Numbers are rounded, so numbers resulting from addition and subtraction of the numbers shown may appear to yield incongruous results. However, the numbers shown are calculated using more significant figures and rounded after, which is the appropriate approach for numbers with large uncertainties.

[6] Not incremental net benefits, but net benefits: "Benefits for an MCL in isolation"—"Cost of an MCL in isolation".

[7] Annual net benefits for an MCL of 20 µg/L = $4 million—$93 million, which rounds to negative $90 million; annual net benefits for an MCL of 30 µg/L = $3 million—$54 million, which rounds to negative $50 million. See Table IV–1, "Summary of Costs and Benefits for Community Water Systems Predicted to Be Impacted by the Regulatory Options Being Considered for Finalization", in today's notice and the supporting Economic Analysis (USEPA 2000g) for more details.

g. Administrator's Decision To Promulgate MCL Higher Than Feasible Level

Based on the relatively modest annual cancer risk reductions and the expected modest kidney toxicity risk reductions between 30 µg/L and 20 µg/L (see Table I–2) and the high annual compliance costs for an MCL of 20 µg/L, the Administrator has determined that the benefits do not justify the costs at the feasible level. Furthermore, as previously described, the Administrator has determined that an MCL of 30 µg/L maximizes the health risk reduction benefits at a cost justified by the benefits. In summary, this finding is based on the fact that potential uranium MCLs lower than 30 µg/L have substantially higher associated compliance costs and only modest additional cancer risk reduction and kidney toxicity benefits. EPA has not selected a higher MCL for several reasons. Higher uranium MCLs would still incur implementation and monitoring costs, with benefits greatly diminished because uranium does not occur significantly at levels much higher than 30 µg/L. Additionally, EPA believes that a uranium MCL of 30 µg/L is appropriate since it is protective of kidney toxicity and cancer with an adequate margin of safety. We do not believe that MCL options higher than 30 µg/L afford a sufficient measure of protection against kidney toxicity.

Assuming a conversion factor of 0.9 pCi/µg, an MCL of 30 µg/L will typically correspond to 27 pCi/L, which has a lifetime radiogenic cancer risk of slightly less than one in ten thousand, within the Agency's target risk range of one in one million to one in ten thousand. EPA is aware that circumstances may exist in which more extreme conversion factors (> 1.5 pCi/µg) apply. EPA does not have extensive data on these ratios at local levels, but believes these higher ratios to be rare. In these rare circumstances, uranium activities in drinking water may exceed 40 pCi/L. Although these concentrations are still within EPA's target risk ceiling of $1\times10^{-4}$, EPA recommends that drinking water systems subject to extreme pCi/µg conversion factors mitigate uranium levels to 30 pCi/L or less, to provide greater assurance that adequate protection from cancer health effects is being afforded.

In today's final rule, the Administrator is exercising her authority to set an MCL at a level higher than feasible (section 1412(b)(6)), based on the finding that benefits do not justify the costs at the feasible level (20 µg/L) and that the net benefits are maximized at a level (30 µg/L) that is still protective of kidney toxicity and carcinogenicity with an adequate margin of safety. EPA believes that there are considerable non-quantifiable benefits associated with ensuring that kidney toxicity risks are minimized and has weighed these non-quantifiable benefits in its decision to exercise its discretionary authority under SDWA section 1412(b)(6).

In invoking the discretionary authority of section 1412(b)(6) to set an MCL level higher than feasible, the Agency is in compliance with the provisions of section 1412(b)(6)(B). This provision provides that the judgment with respect to when benefits of the regulation would justify the costs under subparagraph (6)(A) is to be made based on assessment of costs and benefits experienced by persons served by large systems and those other systems unlikely to receive small system variances (*e.g.* systems serving up to 10,000 persons). In effect, the costs to systems likely to receive a small system variance are not to be considered in judging the point at which benefits justify costs. Subparagraph (6)(B) also provides, however, that this adjusted assessment does not apply in the case of a contaminant found "almost exclusively" in "small systems eligible" for a small system variance. Because the contaminants addressed in today's rule are found almost exclusively in small systems and because the Agency has identified affordable treatment technologies for small systems that would need to comply with today's rule (*i.e.*, we do not contemplate granting small system variances), the Agency has not adjusted the proposed MCL pursuant to subparagraph (B).

h. California Drinking Water Regulation

Approximately one-third of the community water systems that are expected to be impacted by the uranium MCL are located in California. Thus, current and likely future practices of these systems is of particular interest. The State of California currently has a drinking water standard for uranium of 20 pCi/L (enforced as 35 µg/L), which it adopted in 1989. EPA has used comments and information from the State of California in considering its MCL for uranium. The California standard is based on the California Department of Health Services' 1989 estimate of the DWEL for kidney toxicity, 35 µg/L. While California has recently proposed revising its non-enforceable public health goal for uranium in drinking water, it is not currently known what the final estimate will be. In response to the NODA, representatives of the California Department of Health Services commented that at uranium levels of 35 µg/L, most of its small water systems were able to use alternate sources of water (new wells) as a means of complying with the standard, but that 20 µg/L would lead to many of these small systems having to install treatment, which, because of waste disposal issues (*i.e.*, inability to safely dispose of hazardous radioactive wastes), could lead to a significant number of small systems being unable to come into compliance through treatment. EPA believes that these comments lend support to the choice of an MCL of 30 µg/L as being both protective of kidney toxicity and a standard that allows for significant use of non-treatment options by small systems, reducing the need for dealing with radioactive waste handling and disposal.

i. Summary of Major Comments on the Uranium Options

(1) Costs and Benefits of Uranium MCLs of 20, 40, and 80 µg/L or pCi/L: Most commenters stated that the benefits of an MCL of 20 µg/L or pCi/L did not justify the costs and suggested that EPA should exercise its authority under SDWA section 1412(b)(6) to set an MCL higher than the feasible level. As discussed previously in this section, EPA agrees that the benefits of an MCL at 20 µg/L do not justify the costs and has exercised its SDWA authority by setting the uranium MCL at a level of 30 µg/L, a level at which EPA believes the benefits do justify the costs.

(2) The Calculation of the Safe Level for Uranium in Water: One commenter suggested that the use of 70 kg as the reference body mass with a "90th percentile ingestion rate" of 2 L/day will lead to a kidney toxicity DWEL that is more protective than the 90th percentile. EPA agrees that it is possible that 20 µg/L is more protective than the 90th percentile value for the general population. EPA has performed a preliminary Monte Carlo analysis of the safe level that replaces point estimates for consumption rate and body mass with distributions based on the available data. Based on this analysis the 90th percentile (for the general population) equivalent level could be as high as 30 µg/L.

(3) Compliance Options for Small Systems for an MCL of 20 µg/L or pCi/L: Several commenters stated that an MCL of 20 µg/L or pCi/L would force small systems to install water treatment, rather than allowing other compliance options like installing new wells or blending water. The commenters

suggested that an MCL of 20 μg/L or pCi/L would pose a significant hardship on small systems with little benefit, including significant costs and technical problems associated with waste disposal. Commenters also suggested that a higher MCL would allow a larger fraction of small systems to use compliance options other than treatment, most notably, new well installation. EPA agrees that a lower MCL does decrease the probability that some non-treatment options could be used, including new well installation and blending. EPA agrees that the benefits of the MCL of 20 μg/L or pCi/L do not justify the costs and thus has chosen a higher MCL. EPA also believes that an MCL of 30 μg/L should allow a greater fraction of small systems to use non-treatment options for compliance, avoiding waste disposal issues and excessive treatment costs.

(4) The Use of a Dual Standard for Uranium: Commenters suggested that the use of a dual standard for uranium to ensure protectiveness of both kidney toxicity and carcinogenicity, *i.e.*, one in μg/L and one in pCi/L, would be unnecessarily complicated, since it would require that both uranium isotopic analyses and mass analyses be performed by each water system. EPA agrees that a dual standard would be unnecessarily complicated and has chosen a single standard expressed in μg/L that is protective of both kidney toxicity and carcinogenicity.

3. Retaining Beta Particle and Photon Radioactivity MCL

With today's rule, EPA is retaining the existing MCL for beta and photon emitters and the methodology for deriving concentration limits for individual beta and photon emitters that is incorporated by reference. The concentrations for these contaminants were derived from a dosimetry model used at the time the rule was originally promulgated in 1976. When these risks are calculated in accordance with the latest dosimetry models described in Federal Guidance Report 13, the risks associated with these concentrations, while varying considerably, generally fall within the Agency's current risk target range for drinking water contaminants of $10^{-4}$ to $10^{-6}$. Accordingly, we are not changing the MCL for beta particle and photon radioactivity at this time.

We also are concerned that under the regulatory changes for the beta particle and photon radioactivity MCL proposed in 1991 [8]) the concentrations of many individual radionuclides have associated lifetime cancer morbidity (and mortality) risks that exceed the Agency's target risk range. A newly proposed MCL expressed in mrem-ede could result in a more consistent risk level within the Agency's target risk range. However, in today's final rule, we are ratifying the current standard since it is protective of public health. At the same time, we believe a near future review of the beta particle and photon radioactivity MCL and the methods for calculating individual radionuclide concentration limits is appropriate. We intend to reevaluate the MCL under the authority of section 1412(b)(9) of the SDWA to ensure that the MCL reflects the best available science. This review will be performed as expeditiously as possible (expected to be 2 to 3 years).

Particular questions that we believe warrant examination as part of such a reevaluation process would include, but are not limited to, the following:

- What additional beta and photon emitters should be regulated?
- What is the appropriate aggregate MCL expression for this category of radionuclides?
- What new information concerning occurrence, analytical methods, health effects, treatment, costs, and benefits would have a bearing on this reevaluation?
- Is there an advantage to setting individual radionuclide concentration limits using a "uniform risk level MCL"?
- If the basis of the current MCL changes, is there an advantage to and legal basis for setting concentration limits for individual beta particle and photon emitters within a guidance document that can be readily updated as scientific understanding improves?
- To what degree, in keeping with the provisions of sections 1412(b)(9) and 1412(b)(3)(A), can the existing methodology for calculating the concentration limits of individual beta and photon emitters be adjusted in accordance with the best available scientific models and information and still meet the requirement that revised regulations provide "greater or equivalent protection to the health of persons"?
- How would any adjustments be reconciled with the requirement that MCLs be set "as close as feasible" to MCLGs?

Finally, we note that there should be no assumption, from the outset of this reevaluation, that the process will necessarily lead to a different set of individual beta and photon emitter concentration limits than those that result from the methodology incorporated by reference in the current and final rule. This reevaluation will involve a complicated set of legal, regulatory, and technical information that will need to be carefully considered.

a. *Summary of Major Comments Regarding the Decision To Retain the Current Beta Particle and Photon Radioactivity MCL*

Of the 70 commenters who responded to the April 21, 2000 NODA, approximately 14 commented on the MCL for beta particle and photon radioactivity. The commenters represented Federal agencies, State governments, local governments, water utilities, water associations, nuclear institute representatives and public interest groups. Seven commenters support EPA's proposal to retain the current MCL and several of these commenters agreed that it was appropriate to review the standard under the six year review process [9]. The commenters that supported EPA's proposal to maintain this MCL felt there was no appreciable occurrence of man-made beta emitters in drinking water, so it was not a pressing public health concern to revise the MCL. Several of these commenters also felt it was appropriate to delay action on lead-210 until more occurrence information becomes available.

Three of the 14 commenters objected to EPA's proposal to retain the current standard and to defer re-evaluation to the statutorily required six year process. These commenters felt that the Agency should propose to update the models used as the basis for the MCL on a shorter time-frame than the six year review process. The commenters felt that deferring the reevaluation of beta/photons to the six year review process would increase and perpetuate the uncertainty involved with standards which are used in waste management and cleanup decisions. One commenter pointed out that most DOE sites with

[8] 4 mrem ede with a look-up table of concentrations different from those calculated using the current MCL and the methodology incorporated by reference in the current rule.

[9] Six Year Review Process—Under the Safe Drinking Water Act (SDWA), the U.S. Environmental Protection Agency (EPA) must periodically review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them. This requirement is contained in section 1412(b)(9) of SDWA, as amended in 1996, which reads, "The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons."

radiological contamination are moving towards the final Record of Decision (ROD) stage (as required as part of site clean-up under the Superfund Program). The commenter felt that delaying the re-evaluation of this MCL until the next six year review process (2002–2008) would occur after most RODs were already in place and it would be too late to incorporate a new MCL into the RODs. The commenter further stated that some ROD commitments will be using clean up standards based on the 1976 values and if the standards are eventually relaxed, the committed RODs (which were based on the 1976 values) will be extremely expensive and may not be justifiable. EPA agrees that review of the MCL for beta particle and photon radioactivity is a priority and, as previously discussed in this section, the Agency intends to review this standard within the general time frame established for the U.S. Department of Energy's (DOE) submission of the licensing application for the Yucca Mountain site.

4. Retaining the Current Gross Alpha Particle Activity MCL

In 1991, EPA proposed excluding radium-226 from adjusted gross alpha particle activity, which is currently defined as the gross alpha particle activity result minus the contributions from uranium and radon (in practice, it is not necessary to exclude radon, since it volatilizes before analysis). The 1991 proposal to increase the combined radium-226/-228 MCL from 5 pCi/L combined to 20 pCi/L each made the adjusted gross alpha definition necessary, since the radium-226 MCL exceeded the adjusted gross alpha particle activity MCL. Besides addressing this inconsistency, at the time EPA believed that the unit risk from radium-226 was small enough that the change in the definition of adjusted gross alpha particle activity would not result in a significant change in health protectiveness. As discussed in the NODA, the 1991 risk analysis was based on the EPA RADRISK model, which is now outdated.

The most current risk analyses are based on FGR–13, discussed previously in today's preamble and in detail in the NODA and its Technical Support Document. These new radionuclide cancer risk coefficients greatly improved health effects analyses indicate that the unit risk from radium-226 is too significant to exclude radium-226 from adjusted gross alpha particle activity without an appreciable loss in health protectiveness. For this reason, today's rule does not change the definition of adjusted gross alpha from the current rule.

Also, as discussed in the NODA, further occurrence data will be collected for polonium-210 and radium-224 (discussed in more detail next) and, based on findings, EPA may propose in the future to address these and/or other contaminants that contribute to gross alpha particle activity through changes to the definition of adjusted gross alpha particle activity. Regardless of the findings concerning polonium-210 and radium-224 occurrence, the gross alpha particle activity standard will be reviewed under the required six year regulatory review process.

a. Summary of Major Comments Regarding the Decision to Retain the Current Definition of the (Adjusted) Gross Alpha Particle Activity MCL

Of the 70 commenters who responded to the April 21, 2000 NODA, approximately 23 commented on issues regarding the gross alpha particle activity MCL and/or whether or not to regulate polonium-210 and/or radium-224 separately. The summary of the comments regarding radium-224 is discussed further in the next section. The commenters represented State governments, local governments, water associations, water utilities, associations of elected officials and public interest groups. Of these 23 commenters, 14 stated that EPA should not regulate polonium-210 and/or radium-224 separately. Some commenters felt either the occurrence of these radionuclides is rare in water supplies or they felt that not enough occurrence data was available to warrant separate limits. EPA agrees that occurrence information should be collected before proposing separate standards. Commenters felt that occurrence information should be gathered under an unregulated contaminant monitoring mechanism, which EPA is doing in the case of polonium-210. Only one commenter supported an immediate separate standard for polonium-210 and quick gross alpha particle activity analysis to ensure that radium-224 was included in gross alpha particle activity measurement. EPA points out that a proposal would be necessary for such actions and that a proposal would require adequate occurrence information. Of those commenters who commented on retaining the current definition of the gross alpha particle activity MCL, including radium-226, most supported retaining the standard as is. However, three commenters stated that radium-226 should not be included in the gross alpha particle activity MCL, since it is already regulated in the combined radium-226/-228 standard. EPA points out that the contribution from radium-226 to the over-all risk from gross alpha particle activity is significant and that removing it would reduce the health protectiveness of the gross alpha particle activity standard. Also, two commenters felt that gross alpha particle activity should only be used as a screening tool (versus a standard) since the commonly occurring alpha emitting radionuclides are already covered under other standards. EPA points out polonium-210 is not regulated under any other standard at this time. The gross alpha particle activity standard will be reviewed under six year review and these and other considerations will be taken into account.

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5. Further Study of Radium-224

As discussed in section I.C., recent studies show that there is a positive correlation between radium-228 and radium-224 (correlation coefficient of 0.82, approximately 1:1). This correlation means that in most situations in which a system has high radium-224 levels, it will also have high radium-228 levels and, with a less degree of certainty, high radium-226 levels. More details on this relationship, including the summary statistics, can be found in the NODA and its Technical Support Document (USEPA 2000e and 2000h). The expected result of these correlations is that high radium-224 levels will be mitigated by enforcement of the combined radium-226/-228 MCL, keeping in mind that treatment for radium does not differentiate between the different isotopes. Since radium-228 is estimated to be eight times more radiotoxic than radium-224, it appears that radium-224 may not be a pressing public health concern compared to the co-occurring regulated contaminant radium-228. The Agency plans to collect additional national occurrence information for radium-224, which may involve coordination with the USGS, and will evaluate whether future regulatory action or guidance is necessary. Radium-224 occurrence data collection activities are not as high a priority as addressing other radionuclide commitments such as the review of the beta particle and photon radioactivity MCL.

For several reasons, a change in the gross alpha particle activity holding time has been determined to be an inappropriate regulatory solution. First, the uncertainty in the national occurrence data does not allow EPA to determine the number of systems out of compliance with the gross alpha particle activity standard due to radium-224 if a

48–72 hour holding time is required. Since this change may result in a significant number of systems out of compliance with the current gross alpha particle activity MCL, EPA would need to issue a proposed amendment before making such a change. Such a proposal would require national level occurrence data for radium-224 in drinking water. Since EPA's next course of action is to collect such data to determine if a proposal is needed, EPA believes that this course of action is the appropriate one.

a. Summary of Major Comments on Radium-224

(1) The Use of a Short Gross Alpha Particle Activity Sample Holding Time to Measure Radium-224: Several commenters stated that the use of a short gross alpha sample holding time to measure radium-224 would raise technical difficulties and would be costly. Several commenters stated that there was not enough information to warrant a change to the gross alpha holding time or to regulate radium-224 separately. EPA agrees with this comment and, as stated in the Notice of Data Availability (NODA; USEPA 2000e), will not change the gross alpha holding time or regulate radium-224 separately in today's final rule. Some commenters stated that it would not be appropriate to change the holding time or to issue a separate standard in the final rule without a proposal. This is in agreement with what the Agency stated in the NODA.

(2) The Need to Regulate Radium-224: One commenter suggested that the radium-224 cancer mortality risk coefficient from Federal Guidance Report-13 (FGR–13) warranted a health concern and warranted regulating radium-224. While EPA agrees that radium-224 is a health concern, the radium-224 cancer mortality unit risk is eight times less than the radium-228 cancer mortality unit risk. In other words, it would take 40 pCi/L of radium-224 to present an equal cancer mortality risk as 5 pCi/L of radium-228. Since the correlation between radium-224 and radium-228 is approximately one-to-one (1:1) in the areas known to be of concern, one would typically expect to find 5 pCi/L of radium-224 associated with 5 pCi/L of radium-228. Since radium-226 and radium-228 also significantly co-occur, EPA believes that in most situations in which radium-224 occurs it would be present at levels lower than 5 pCi/L for systems in compliance with the combined radium-226/-228 standard. Table I–3 shows the predicted increase in risk for water systems in areas in which radium-224 is known to co-occur with radium-228, assuming a 1:1 correlation. This table shows that the presence of radium-224 increases the over-all combined radium risk by 5%–13%, depending on the relative contributions of radium-226 to radium-228 to the MCL of 5 pCi/L. EPA believes that this situation indicates that radium-224 may be of concern in some areas, but also believes that collecting data to determine if radium-224 is of national concern is the appropriate next step for determining if radium-224 should be regulated separately.

TABLE 1–3.—TYPICAL INCREASE IN COMBINED RADIUM RISK DUE TO PRESENCE OF RA-224 FOR WATER SYSTEMS WITH COMBINED RA-226/-228 LEVELS OF 5 PCI/L, ASSUMING A 1:1 CORRELATION OF RA-224 AND RA-228

| Ra–226 (pCi/L) | Ra–228 (pCi/L) | Ra–224 (pCi/L) | Percent increase in risk due to presence of Ra–224 |
|---|---|---|---|
| 5 | 0 | 0 | 0% |
| 4 | 1 | 1 | 5% |
| 3 | 2 | 2 | 8% |
| 2 | 3 | 3 | 10% |
| 1 | 4 | 4 | 12% |
| 0 | 5 | 5 | 13% |

6. Entry Point Monitoring and the Standardized Monitoring Framework

The changes to the existing distribution system-based monitoring scheme proposed in 1991 are promulgated in today's final rule. New monitoring must be performed at entry points to the distribution system, which is meant to ensure that all customers are protected by the radionuclides NPDWRs. The 1976 monitoring scheme ensured that "average customers" were protected, but did not ensure that all customers were served by water at or below the MCL for the various radionuclides.

While EPA is finalizing a change to the point of compliance from a representative distribution system sampling point to all points of entry to the distribution system, EPA realizes that unless data grandfathering is allowed, many systems will have to re-establish monitoring baselines that have been established for many years. The "monitoring baseline" refers to the average contaminant level analytical result that is used for determining the future monitoring frequency. For this reason, EPA is allowing primacy entities (States, Tribes, and other) the option of developing data grandfathering plans that are suited to their individual situations (*e.g.*, occurrence patterns, water system configurations, and other factors) as a part of their primacy packages. This situation will allow primacy entities flexibility to grandfather historical data for determining future monitoring frequencies, while allowing EPA oversight of the process to ensure that the goal of having each entry point in compliance with the MCLs is met. Since future monitoring will be conducted at each entry point, this approach will ensure that compliance is achieved at every entry point.

The new requirements for uranium and radium-228 will mean that initial monitoring baselines for determining future monitoring frequencies will need to be established. Only community water systems that have gross alpha particle activity screening levels greater that 15 pCi/L will be required to monitor for uranium. Thus, many systems will be able to use historical gross alpha data to determine future monitoring frequency under the uranium standard. And, since the current monitoring requirements for gross alpha particle activity already require systems with gross alpha particle activity levels greater than 15 pCi/L to quantify uranium levels (to subtract out the uranium contribution to the gross alpha particle activity), EPA expects that many of these water systems will also be able to grandfather historical uranium data. Given this situation, EPA does not expect uranium monitoring requirements to be overly burdensome to community water systems or drinking water programs.

Community water systems without historical radium-228 data (expected to be those with gross alpha particle

activity levels less than 5 pCi/L and radium-226 levels less than 3 pCi/L) will need to establish an initial monitoring baseline to determine future monitoring frequency. Four consecutive quarterly samples will be required to establish this baseline. However, States and Tribes may waive the last two quarterly samples and determine the initial monitoring baseline on the first two samples if the results for the first two samples are below the detection limit (1 pCi/L), which would be considered a non-detect and would be reported as "zero" (this discussion assumes that radium-226 levels are also non-detects and are reported as zero). Systems with non-detects for radium-228 and radium-226 would have to monitor once every nine years after the initial monitoring period. Other monitoring requirements are discussed in section I.J.

7. Separate Monitoring for Radium-228 and Change to Systems Required To Monitor for Beta Particle and Photon Radioactivity

Separate monitoring for radium-228, proposed in 1991, is promulgated in today's rule. The need for separate monitoring of radium-228 is supported by the occurrence studies supporting the 1991 proposal and new occurrence studies (USEPA 2000e and i), which indicate that the 1976 radium-228 screens are not robust. Since the unit risks for radium-228 are higher than for radium-226 (described in the NODA and its Technical Support Document, USEPA 2000e and h), EPA believes that separate monitoring for radium-228, as proposed in 1991, is essential to enforcing the combined radium-226/-228 standard.

In addition, today's rule eliminates the previous requirement that all surface water systems serving more than 100,000 persons must monitor for beta particles and photon radioactivity. Beta particle and photon radioactivity monitoring will be performed only by community water systems designated by the State as "vulnerable" or "contaminated". In 1976, the Agency was concerned about nuclear fallout contaminating surface water sources. The Agency anticipated that large surface water systems (*i.e.* systems serving greater than 100,000 persons) would be vulnerable to becoming contaminated by nuclear testing activities. Therefore, the radionuclides regulation required all surface water systems serving more than 100,000 persons and any other systems determined by the State to be vulnerable to monitor for beta and photon emitters.

Since that time above-ground testing of nuclear weapons has been banned, and sources of man-made radiation are not expected, thus, large surface water systems are not automatically vulnerable to beta and photon emitters. As a result, the Agency has reevaluated the 1975 approach, and in today's rule, as proposed in 1991, is removing the requirement for all large surface water systems to monitor for beta and photon emitters, unless they have been designated as vulnerable by the State. The Agency believes that States are in the best position to determine which systems are vulnerable to beta and photon emitters. The EPA is also encouraging States to reevaluate a system's vulnerability to beta photon emitters when conducting source water assessments and provide immediate notification to those systems that have been deemed vulnerable.

8. Future Actions Regarding the Regulation of Radionuclides at Non-Transient Non-Community Water Systems

EPA will not regulate NTNC water systems with today's rule, but may propose to do so in the future. As described in the NODA (USEPA 2000e), EPA considered regulating non-transient non-community (NTNC) water systems for today's final rule, as proposed in 1991. The NODA also described EPA's analysis of the risks faced by customers of NTNC water systems, potential risk reductions, and compliance costs. EPA stated that several options were being considered for finalization: (1) Not regulating NTNC water systems; (2) regulating all NTNC water systems under the same requirements faced by CWSs; (3) regulating targeted NTNC water systems, based on occurrence potential, typical lengths of exposure, the age distribution of typical customers, and other factors; (4) issuing guidance recommending that States require that targeted NTNC systems monitor, and in some cases, mitigate to acceptable levels.

EPA's rationale for not regulating NTNC water systems at this time is based upon consideration of several factors. EPA summarized the results of a conservative Monte Carlo analysis of risks at NTNC water systems in the NODA and discussed the analysis in more detail in its Technical Support Document (USEPA 2000h). After evaluating the available information and the various comments on the NODA, EPA does not believe that exposure to radionuclides by consumers of water from NTNC systems poses an unacceptable health risk. This conclusion is based on consideration of the total pattern of exposure of individuals, considering their consumption of both NTNC water and water from other types of water systems. However, EPA's information for these radionuclides is limited and will be the subject of additional future analyses and reevaluation, together with any new data that can be obtained.

In the immediate future and in consultation with the National Drinking Water Advisory Committee (NDWAC), EPA will further evaluate various approaches to regulating NTNCs generally (including radionuclides). This further analysis will involve examination of additional data and information and will include further analysis of a full range of possible options. In this evaluation, EPA will consider risk analyses for adults and children, occurrence patterns, the national distribution of NTNC water systems, and other factors. In determining the appropriate action, EPA will consider the issue of consistency between the various regulations for chronic contaminants applicable to NTNC water systems, including future rules.

a. Summary of Major Comments on NTNCWSs and EPA Responses

Of the 70 commenters who responded to the April 21, 2000 NODA, approximately 31 commented on the issue of NTNC water systems and the options presented in the NODA. About 75 percent of these 31 commenters oppose regulation of NTNC water systems. While several of the commenters felt that EPA should only require targeted monitoring, many commenters felt that monitoring of NTNC water systems should be left to the discretion of the States. A few commenters felt that EPA should treat NTNC water systems like CWSs and require regulation and some commenters felt partial coverage of targeted NTNC water systems would be appropriate.

Those opposed to the regulation of NTNC water systems felt the cost/benefit and risk analyses presented in the NODA did not support a requirement to regulate. Some of those opposed to regulating NTNC water systems believe EPA needs to gather more information about the occurrence of radionuclides, the amount and percentage of water consumed, and the duration of exposure at NTNC water systems. Many commenters felt that EPA should allow States the flexibility or discretion to determine whether or not to regulate NTNC water systems and leave it to the States to target specific NTNC water systems. Some commenters

suggested that EPA issue guidance that recommends targeted NTNC water systems monitor and meet the CWS MCLs. In addition, some commenters stated that EPA should be consistent in all their rules when considering whether or not to regulate NTNC water systems. EPA believes that all of these comments have merit and that the regulation of radionuclides at NTNC water systems deserves further evaluation along with an analysis of additional data and information. If EPA proposes to regulate NTNC water systems in the future, stakeholders will have future opportunity to comment. Regarding State discretion, States may at any time choose to regulate NTNC water systems, either under a targeted rule or otherwise.

*E. What Are the Health Effects That May Result From Exposure to Radionuclides in Drinking Water?*

Radioactive drinking water contaminants differ from one another in ways that determine their harmfulness. Each radionuclide has a particular half-life and emits characteristic forms of radiation (alpha particles, beta particles, and/or photons). A radionuclide's half-life and concentration determine its radioactivity, *i.e.*, the number of radioactive "decay events" that occur in a particular unit of time. These factors, concentration, half-life, form of radioactive decay, and radiation energy, all determine a particular radionuclide's potential for impacting human health. For a discussion of half-life and the different forms of radioactive decay, see Appendix I ("Fundamentals of Radioactivity in Drinking Water") to the Radionuclides NODA's Technical Support Document (USEPA 2000h).

The potential for harmful health effects from exposure to radioactive compounds results from the ability of ionizing radiation to chemically change the molecules that make-up biological tissues (*e.g.*, stomach, liver, lung) through a process called "ionization." The radiation (alpha and beta particles and photons) emitted by radionuclides is called "ionizing radiation" because the radiation has sufficient energy to strip electrons from nearby atoms as they travel through a cell or other material. Ionization may result in significant chemical changes to biologically important molecules. For example, ionizing radiation can damage important molecules like DNA. DNA is the elementary building block for genes and the chemical that carries genetic information involved in many fundamental biological processes. Damage to the DNA of an individual gene may cause the gene to mutate, changing a cell's genetic code. Such mutation can lead to cancer. Since ionizing radiation may damage genes, it can adversely affect individuals directly exposed as well as their descendants. While much of this cellular damage is repaired by the body, restoring proper biological functions, the net result of an increase in exposure to ionizing radiation is an increase in the risk of cancer or harmful genetic mutations that may be passed on to future generations. (See, EPA's fact sheets on ionizing radiation and associated health effects at http://www.epa.gov/radiation/ionize.htm and in the record of this final rulemaking; (USEPA 1998a and1998c)).

Alpha emitters and beta/photon emitters differ in the magnitude of their biological effects. Alpha particles interact very strongly with matter (*e.g.*, human tissues), transferring their energy through these interactions. Beta particles interact less strongly, which allows them to travel further through tissue before being absorbed. The difference of interest is in the concentration of tissue damage. Alpha particles may damage many molecules over a short distance, while beta particles may damage molecules spread out over a greater distance. The actual number of potentially damaged molecules depends upon the energy of the alpha particle or beta particle (which differs between individual alpha emitters and beta emitters). Photon emissions may also interact with tissues, but they interact over much longer distances (they can pass through the body entirely). Exposure to any of these forms of radiation increases the risk of cancer.

All people are chronically exposed to background levels of radiation present in the environment. Many people also receive additional chronic exposures, including exposure to radionuclides in drinking water, and/or relatively small acute exposures, for example from medical X-rays. For populations receiving such exposures, the primary concern is that radiation could increase the risk of cancers or harmful genetic effects.

The likelihood of developing cancer or genetic mutations from short-term exposure to the concentrations of radionuclides found in drinking water supplies is negligible. However, long-term exposures may result in increased risks of genetic effects and other effects such as cancer, precancerous lesions, benign tumors, and congenital defects. For example, an individual that is exposed to relatively high levels of radium-228 (*e.g.*, 20 pCi/L) in drinking water over the course of a lifetime is projected to have a significantly increased chance of developing fatal cancer (roughly a one in one thousand increased risk if exposed to radium-228 at 20 pCi/L over a lifetime of 70 years).

The probability of a radiation-caused cancer or genetic effect is related to the total amount of radiation accumulated by an individual. Based on current scientific models, it is assumed that any exposure to radiation may be harmful (or may increase the risk of cancer); however, at very low exposures (*e.g.*, drinking water exposures below the MCL), the estimated increases in risk are very small and uncertain. For this reason, cancer rates in populations receiving very low doses of radiation may not show increases over the rates for unexposed populations.

For information on effects at high levels of exposure, scientists largely depend on epidemiological data on survivors of the Japanese atomic bomb explosions and on people receiving large doses of radiation for medical purposes. These data demonstrate a higher incidence of cancer among exposed individuals and a greater probability of cancer as the exposure increases. In the absence of more direct information, that data is also used to estimate what the effects could be at lower exposures. Where questions arise, scientists extrapolate from information obtained from cellular and molecular studies, but these extrapolations are acknowledged to be only estimates. Professionals in the radiation protection field prudently assume that the chance of a fatal cancer from radiation exposure increases in proportion to the magnitude of the exposure.

In the case of uranium in drinking water, we must consider not only carcinogenic health effects but also damage to the kidneys that may result from ingestion. When uranium radioactively decays in the body, it results in increased cancer risks. However, natural uranium isotopes have long half-lives, which means that uranium tends to persist in the body until it is excreted or stored in tissue. As discussed in detail in the Notice of Data Availability (USEPA 2000e), its Technical Support Document (USEPA 2000h), and the Toxicological Review of Uranium (USEPA 2000b) this persistent uranium may result in kidney toxicity. See section I.D.2 for a brief summary of kidney (renal) function and uranium toxicity.

1. Major Comments

Most comments on Health Effects related to three areas of risk estimation: (1) The use of a linear, non-threshold model, (2) not finding a threshold for

radium, and (3) not promoting claimed beneficial effects of ionizing radiation.

a. Linear Non-threshold Model: Some commenters suggested that the Agency abandon the linear nonthreshold (LNT) model it employs to estimate radiation induced carcinogenesis. They suggest a new paradigm should be used.

The Agency disagrees and believes its position is based on weight of evidence and support from national and international groups of experts interested in radiation protection. EPA classifies all radionuclides as Group A (known human) carcinogens. This classification is based on the considerable weight of epidemiological evidence that exposure to high doses of ionizing radiation causes cancer in humans and on the fact that all radionuclides emit ionizing radiation. Radiation has been shown to induce unique DNA damage, mutations, and transformation of cells in culture. The monoclonal nature of cancers is evidence that a single "wild" cell can give rise to a cancer. For alpha particles, it has been shown experimentally that a single alpha passing through a cell is sufficient to induce a mutational event; there are strong theoretical reasons to expect that the same is true for low energy transfer (LET) radiation such as gamma rays. Since a single particle traversal of a cell is the minimum event for radiation exposure, a prudent assumption is that there is no threshold for radiation induced mutations.

To estimate radiogenic cancer risks and to regulate low-dose radiation exposures from continuous intakes of radionuclides in environmental media, EPA uses a linear, non-threshold (LNT) dose-response model. The LNT model permits direct extrapolation of low-dose cancer risks from high-dose exposures—allowing for adjustments, as needed, for differences in radiation quality, dose rate, and exposed populations, including such factors as age at exposure, time since exposure, baseline cancer rates, and gender and assumes that there is no threshold for effects; *i.e.*, it is assumed that exposure to any amount of radioactivity has a finite potential to induce cancers in humans. As noted above, support for the LNT model comes in part from the linear dose-response relationships observed for most types of cancers in the intermediate- to high-dose range for atomic bomb survivors, and from results of molecular and cellular studies. Several such studies have shown that a single radiation track traversing a cell nucleus can cause unrepaired or misrepaired DNA lesions and chromosomal aberrations. Other studies have shown that DNA lesions and chromosomal aberrations can lead to cancer. From these studies, it is assumed that the probability of DNA damage and carcinogenesis is linearly proportional to the dose.

EPA's application of the LNT model to estimate and regulate cancer risks from environmental exposures to radionuclides is entirely consistent with all past and current observations and recommendations of the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR), and the United Nations Scientific Committee on the Effect of Atomic Radiation (UNSCEAR), and the National Radiation Protection Board (NRBP). Citing the recommendations of these national and international advisory bodies, the U.S. Department of Energy, the U.S. Nuclear Regulatory Commission, and other Federal and State agencies with regulatory authority over radioactive materials also apply the LNT model as the basis for setting regulations and guidelines for radiation protection. However, to address these limitations and the uncertainties associated with this model and improve its radiation risk assessments, EPA is actively supporting national and international studies of radiation dosimetry and dose reconstruction, radionuclide biokinetics, quantitative techniques for uncertainty analyses, and long-term follow-up epidemiological studies of populations exposed chronically to low-dose radiation. The Agency also continues to review its policies and positions as new reports and data are published so that the best science is applied.

b. Radium Carcinogenicity Threshold: Some commenters have suggested that there is a threshold for radium carcinogenicity. They generally base this conclusion on the "Radium Dial Painter" studies.

The Agency disagrees. While the "Radium Dial Painter" studies are interesting, they are of limited value for the estimation of risk. First, no one knows the quantity of radium ingested in those studies, so dose estimates are speculative. The intake estimates are based on the body burden the first time the subjects were measured and back-calculated with biokinetics modeling. Moreover, the quantities of radium ingested by the subjects was great enough to cause extensive skeletal pathology and interfere with normal bone metabolism. In addition to problems of radium dosimetry, the high mortality in some groups, and the small numbers of subjects in all exposure groups, would impair use of the data to develop dose response relationships.

Only a small fraction of persons known to have been exposed to radium have been located and their radium content at that time measured. Of 6,675 subjects identified above as being in the data base and as having been exposed to radium, 2,383 have been measured to determine their radium-226 burden. (21 of the 85 osteosarcomas occurred in subjects who had never been measured for radium burden.) Since the radium intake in dial painters is unknown, body burden is known only from the date of first radioassay (usually many years after the radium intake), and metabolism is estimated from other sources, estimates of the radiation dose must be based on a series of poorly verified assumptions. In spite of these inherent problems in the data set, efforts have been made to use the radium dial workers, or some subset of them, to establish a "practical threshold" for radium or other internal emitter exposure.

The "practical threshold" concept is derived from studies of chemical carcinogenesis which include dose levels causing extensive life shortening. Plots of the mean age at tumor onset vs dose indicates an increase in tumor latency with decreasing dose. Extrapolation of these curves to environmental dose levels has led some investigators to conclude at these dose levels tumor latency would exceed the human life span. This "practical threshold" is as an argument for a threshold and against LNT models. The "practical threshold" model has been examined and rejected by experts at the International Agency for Research on Cancer (IARC). The IARC warned in their discussion regarding mean tumor latency or mean age at tumor onset that "care must be taken not to extrapolate the observed tendency for the mean age at onset to increase with decreasing dose below the dose range in which most animals get cancer. Failure to observe this restriction has led to the unjustified speculation that progressively lower and lower human doses of environmental contaminants will produce cancers only at age 200 or 300 years; for refutation, see Peto (1978)."

Even if there were no problems with intake, dose, metabolism, extensive pathology, etc., as mentioned above, the radium dial studies would be uninformative on the subject of the dose response relationship at environmental exposure levels. The number of subjects and their distribution in dose categories is too small. The number of subjects

needed to show a given risk increases as the square of the decrease in dose. For example, if 10 subjects are required to show an radiogenic risk at dose level x, 250 would be needed to show the same risk at dose level x/5, and 1000 at dose level x/10. There just are not enough subjects at lower dose levels to show the risk, giving the illusion of a threshold.

The claims regarding a possible "practical threshold" addressed above are based solely on the bone cancer data. However, bone cancer constitutes only a fraction of the estimated risk from ingested radium. Radium-226 has also been found to induce epithelial cancers in sinuses in the head (due to radon-222 released into the sinus air spaces from the decay of radium-226 in bone). The data in the dial painter study is inadequate to develop a dose response relationship for sinus cancers, however the number of epithelial cancers expected in the dial painters is about the same as the number of bone cancers. The number of bone cancers in the Agency's radium-226 risk model is doubled to get an estimate of combined bone and sinus cancers. In addition to bone cancer, patients treated with radium-224 were found to have significant increases in breast cancer, soft tissue sarcomas, liver cancer, thyroid cancer, cancers of urinary organs, and leukemia. Given our understanding of radium metabolism and the effects of alpha irradiation, it is expected that ingestion of any of the radium isotopes will increase the risks for various types of cancer other than bone. EPA's risk estimates include all these potential sites.

c. "Beneficial Effects" of Radiation: One commenter suggests there are beneficial effects of radiation, "Hormesis" (small doses of radiation are good for you) and "Adaptive Response" (relatively small doses of radiation protect against large doses of radiation).

The Agency finds that, based on available scientific evidence, these phenomena are not relevant to environmental radiation protection. Neither has been shown to occur at environmental dose levels. Neither has been shown to influence the dose response for induction of radiation induced cancer. Hormesis has not been demonstrated in normal healthy active populations of mammals, much less in humans. Adaptive response may have some application in radiotherapy (very high radiation doses), but it is not relevant to environmental exposure levels.

Hormesis is a non-specific phenomenon. Biological, chemical, or physical agents may stimulate hormesis; thus, cold, physical stress, toxic chemicals, antibiotics, as well as ionizing radiation, can be hormetins. Hormesis originally was used to describe a stimulatory effect, which was not inherently good or bad. Recent usage of the term "Radiation Hormesis" implies the discussion relates to beneficial effects. It should not, however, imply absence of radiation carcinogenesis.

The "adaptive response" is also a nonspecific response to stress, which has been observed at the cellular level. An "adaptive response" is observed experimentally when a "conditioning" exposure is given, followed at some later time by a "challenge" exposure, and the response in the "conditioned" organism or cell culture is less than in controls; that is, the conditioning exposure was "protective" against the challenge. In typical studies where cells in culture are given a conditioning dose of radiation in the range of 0.2 to 20 rad (2 to 200 milliGray or mGy), a dose of 100 to 200 rad (1000 to 2000 mGy) given later causes only about 50% as great an effect as that observed in controls with no conditioning exposure. However several points are noteworthy: not all cells respond, effects may be different for cells at different stages in the cell cycle, not all conditioning doses give the same response (sometimes instead of protection there is synergism between doses), the "adaptive" effects are transient, and the timing of the challenge dose may be critical to response. Given these limitations, EPA does not believe it is appropriate at this time to consider such an adaptive response in its assessment of the risks from environmental levels of radiation.

*F. Does This Regulation Apply to My Water System?*

The NPDWRs for combined radium-226 and radium-228, gross alpha particle radioactivity, beta particle and photon radioactivity, and uranium apply to all community water systems.

*G. What Are the Final Drinking Water Regulatory Standards for Radionuclides (Maximum Contaminant Level Goals and Maximum Contaminant Levels)?*

The maximum contaminant level goals (non-enforceable health-based target, MCLGs) and maximum contaminant levels (enforceable regulatory limits, MCLs) are listed in table I–4. For the reasons already described, EPA is retaining the existing MCLs for combined radium-226 and radium-228, gross alpha, and beta particle and photon radioactivity. EPA is finalizing an MCL of 30 µg/L for uranium, based on kidney toxicity and cancer risk endpoints. The final MCLGs are zero for all radionuclides, based on the no-threshold cancer risk model for ionizing radiation.

TABLE I–4.—MCLGS AND MCLS FOR RADIONUCLIDES IN DRINKING WATER (OTHER THAN RADON)

| Contaminant | MCLG (pCi/L) | MCL |
|---|---|---|
| Combined Radium-226 and Radium-228 | Zero | 5 pCi/L. |
| Gross Alpha (Excluding radon and uranium) | Zero | 15 pCi/L. |
| Beta Particle and Photon Radioactivity | Zero | 4 mrem/year. |
| Uranium | Zero | 30 µg/L. |

*H. What Are the Best Available Technologies (BATs) for Removing Radionuclides From Drinking Water?*

Under the SDWA, EPA must specify the best available technology (BAT) for each MCL that is set. PWSs that are unable to achieve an MCL may be granted a variance if they use the BAT and meet other requirements (see section I.M for a discussion of variances and exemptions). Table I–5 lists the best available technologies (BATs) for complying with the radionuclides MCLs.

TABLE I–5.—BEST AVAILABLE TECHNOLOGIES (BATS) FOR RADIONUCLIDES IN DRINKING WATER

| Contaminant | BAT |
|---|---|
| Combined radium-226 and radium-228 | Ion Exchange, Lime Softening, Reverse Osmosis. |

TABLE I–5.—BEST AVAILABLE TECHNOLOGIES (BATS) FOR RADIONUCLIDES IN DRINKING WATER—*Continued*

| Contaminant | BAT |
|---|---|
| Gross alpha (excluding radon and uranium) | Reverse Osmosis. |
| Beta particle and photon radioactivity | Ion Exchange and Reverse Osmosis. |
| Uranium | Ion Exchange, Lime Softening; Reverse Osmosis, Enhanced Coagulation/Filtration. |

In addition to BATs, the SDWA, as amended in 1996, requires EPA to list small system compliance technologies (the requirements are described in section I.M). EPA published a list of small systems compliance technologies for the existing radionuclide MCLs in 1998 (63 FR 42032) and issued a guidance document on their use (USEPA 1998f). EPA took comment on small system compliance technologies for uranium in the NODA (USEPA 2000e; 65 FR 21576). Table I–6 is a compilation of all of the small systems compliance technologies for radionuclides, including limitations, required operator skill, raw water quality ranges, and other considerations. Table I–7 shows the small systems compliance technologies listed for: combined radium-226 and radium-228, gross alpha particle radioactivity, beta particle and photon radioactivity, and uranium.

TABLE I–6.—LIST OF SMALL SYSTEMS COMPLIANCE TECHNOLOGIES FOR RADIONUCLIDES AND LIMITATIONS TO USE

| Unit technologies | Limitations (see footnotes) | Operator skill level required [1] | Raw water quality range & considerations [1] |
|---|---|---|---|
| 1. Ion Exchange (IE) | (a) | Intermediate | All ground waters. |
| 2. Point of Use (POU [2]) IE | (b) | Basic | All ground waters. |
| 3. Reverse Osmosis (RO) | (c) | Advanced | Surface waters usually require pre-filtration. |
| 4. POU [2] RO | (b) | Basic | Surface waters usually require pre-filtration. |
| 5. Lime Softening | (d) | Advanced | All waters. |
| 6. Green Sand Filtration | (e) | Basic | |
| 7. Co-precipitation with Barium Sulfate | (f) | Intermediate to Advanced | Ground waters with suitable water quality. |
| 8. Electrodialysis/Electrodialysis Reversal. | | Basic to Intermediate | All ground waters. |
| 9. Pre-formed Hydrous Manganese Oxide Filtration. | (g) | Intermediate | All ground waters. |
| 10. Activated alumina | (a), (h) | Advanced | All ground waters; competing anion concentrations may affect regeneration frequency. |
| 11. Enhanced coagulation/filtration | (i) | Advanced | Can treat a wide range of water qualities. |

[1] National Research Council (NRC). Safe Water from Every Tap: Improving Water Service to Small Communities. National Academy Press. Washington, DC 1997.

[2] A POU, or "point-of-use" technology is a treatment device installed at a single tap used for the purpose of reducing contaminants in drinking water at that one tap. POU devices are typically installed at the kitchen tap. See the April 21, 2000 NODA for more details.

Limitations Footnotes to Table I–6: Technologies for Radionuclides

[a] The regeneration solution contains high concentrations of the contaminant ions. Disposal options should be carefully considered before choosing this technology.

[b] When POU devices are used for compliance, programs for long-term operation, maintenance, and monitoring must be provided by water utility to ensure proper performance.

[c] Reject water disposal options should be carefully considered before choosing this technology. See other RO limitations described in the SWTR Compliance Technologies Table.

[d] The combination of variable source water quality and the complexity of the water chemistry involved may make this technology too complex for small surface water systems.

[e] Removal efficiencies can vary depending on water quality.

[f] This technology may be very limited in application to small systems. Since the process requires static mixing, detention basins, and filtration, it is most applicable to systems with sufficiently high sulfate levels that already have a suitable filtration treatment train in place.

[g] This technology is most applicable to small systems that already have filtration in place.

[h] Handling of chemicals required during regeneration and pH adjustment may be too difficult for small systems without an adequately trained operator.

[i] Assumes modification to a coagulation/filtration process already in place.

TABLE I–7.—COMPLIANCE TECHNOLOGIES BY SYSTEM SIZE CATEGORY FOR RADIONUCLIDE NPDWRS

| Contaminant | Compliance technologies [1] for system size categories (population served) | | 3,300–10,000 |
|---|---|---|---|
| | 25–500 | 501–3,300 | |
| Combined radium-226 and radium-228 | 1, 2, 3, 4, 5, 6, 7, 8, 9 | 1, 2, 3, 4, 5, 6, 7, 8, 9 | 1, 2, 3, 4, 5, 6, 7, 8, 9 |
| Gross alpha particle activity | 3, 4 | 3, 4 | 3, 4 |
| Beta particle activity and phton activity | 1, 2, 3, 4 | 1, 2, 3, 4 | 1, 2, 3, 4 |

TABLE I–7.—COMPLIANCE TECHNOLOGIES BY SYSTEM SIZE CATEGORY FOR RADIONUCLIDE NPDWRS—Continued

| Contaminant | Compliance technologies [1] for system size categories (population served) | | 3,300–10,000 |
|---|---|---|---|
| | 25–500 | 501–3,300 | |
| Uranium | 1, 2, 4, 10, 11 | 1, 2, 3, 4, 5, 10, 11 | 1, 2, 3, 4, 5, 10, 11 |

**Note:** (1) Numbers correspond to those technologies found listed in the table I–6 above.

*I. What Analytical Methods Are for Compliance Monitoring of Radionuclides?*

The approved methods for compliance monitoring of radionuclides are listed in § 141.25. These methods are shown in Table I–8. A large portion of the approved methods for radionuclides were added after the 1991 proposed rule (56 FR 33050). There, the Agency proposed to approve fifty-six methods for the measurement of radionuclides in drinking water (excluding radon). Fifty-four of the fifty-six were actually promulgated in the March 5, 1997 final methods rule (62 FR 10168). In addition to these fifty-four, EPA also promulgated 12 radiochemical methods in the March 5, 1997 final methods rule, which were submitted by commenters after the 1991 proposed rule.

In the March 5, 1997 final methods rule for radionuclides (62 FR 10168), the Agency approved several methods for the analysis of uranium. Specific analysis for uranium can be performed by radiochemical methods, alpha spectrometry, fluorometric (mass), or laser phosphorimetry (mass) (see Table I–8). The radio-chemical method separates and concentrates uranium from potentially-interfering radionuclides and non-radioactive sample constituents. The resulting concentrate, depending on the method, can then be counted by gas flow proportional counting, alpha scintillation, or alpha spectrometry. Results from proportional counting or alpha scintillation counting accurately determine the alpha emission rate from total uranium in the sample; however, the uranium isotope ratio (uranium-234/uranium-238) cannot be determined and the uranium mass cannot be estimated unless an empirical conversion factor is applied to the measured count rate. The use of alpha spectrometry allows for the determination of individual isotopes of uranium and the accurate calculation of the mass of uranium-238 present in the sample. Additionally, the concentration of uranium-234 can be accurately measured, if necessary to assess the radiotoxicity of this isotope.

Both the fluorometric and the laser phosphorimetry methods measure the mass of uranium-238 present in the sample; a conversion factor must be used to convert the mass measurement to an approximate radioactivity concentration in picoCuries. The computed radioactivity is only approximate because the ratio of uranium isotopes must be assumed. The use of mass-type methods is acceptable provided a conversion factor of 0.67 pCi/μg is used to convert the fluorometric or laser phosphorimetry uranium-238 mass result from micrograms to picoCuries. This conversion factor is conservative and is based on a 1:1 ratio of uranium-234 to uranium-238 in uranium-bearing minerals. The scientific literature indicates that the activity ratio varies in ground water from region to region (typically from 0.67 to 1.5 pCi/μg).

EPA recognizes that the mass conversion factor is conservative in that the calculated uranium alpha emission rate based on the mass measurement may be biased low (*i.e.*, underestimated). The use of this conversion factor may result in a larger net gross alpha (gross alpha less the calculated uranium gross alpha contribution), which may require additional testing to resolve. Conversely, the calculated mass of uranium based on gross alpha could be biased high and result in an overestimation, which may require additional testing to resolve. Both situations are protective in that the bias requires additional testing to resolve when the uranium concentration in a sample is near the proposed MCL regardless of which method is used to measure the uranium.

1. Major Comments

a. Request for ICP-MS Method for Uranium: In response to the NODA, several commenters asked EPA to consider the approval of an Inductively Coupled Plasma Mass Spectrometry (ICP-MS) method for uranium analysis (a mass method). Many commenters stated that the ICP-MS method (*i.e.*, EPA 200.8 or SM 3125) is more cost-effective, less labor-intensive and offers greater sensitivity than some of the currently approved methods for uranium analysis. EPA is currently reviewing the ICP-MS method for uranium and will publish a proposal and a final in a future rulemaking.

b. Detection Limit for Uranium: In 1976, the NPDWRs defined the "detection limit" (DL) as the "concentration which can be counted with a precision of plus or minus 100 percent at the 95 percent confidence level (1.96 σ, where σ is the standard deviation of the net counting rate of the sample)." The detection limits for gross alpha, radium-226, radium-228, gross beta and other radionuclides are listed at § 141.25 and reproduced in Table I–9. In the NODA, EPA stated that it would maintain the use of detection limits as the required measures of sensitivity for radiochemical analysis, instead of using the method detection limit (MDL), the practical quantitation level (PQL) and acceptance limits, as was proposed in 1991. Although no comments were submitted about EPA's decision to maintain the use of the detection limits listed in § 141.25, several commenters submitted comments about the appropriate measure of sensitivity for uranium.

Since uranium was not previously regulated, no detection limit is listed in the CFR and none was proposed in 1991. In 1991, the Agency only proposed a PQL (5 pCi/L) and an acceptance limit (±30%) for uranium. Because the NODA was not the appropriate mechanism to propose a detection limit for uranium, the Agency stated that it "may have to adopt the PQL for uranium until a detection limit is proposed." Several commenters disagreed with the use of a PQL and acceptance limits for uranium. They felt that EPA should be consistent with other regulated radionuclides and set a detection limit for uranium as the required measure of sensitivity. The Agency agrees with the commenters and will propose a detection limit for uranium in a future rulemaking before the compliance date of this rule to be consistent with the sensitivity measures used for other radionuclides.

TABLE I–8.—ANALYTICAL METHODS APPROVED BY EPA FOR RADIONUCLIDE MONITORING (§ 141.25)

| Contaminant | Methodology | Reference (method or page number) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | EPA[1] | EPA[2] | EPA[3] | EPA[4] | SM[5] | ASTM[6] | USGS[7] | DOE[8] | Other |
| Naturally occurring: | | | | | | | | | | |
| Gross alpha[11] and beta | Evaporation | 900.0 | p 1 | 00–01 | p 1 | 302, 7110 B | | R–1120–76 | | |
| Gross alpha[11] | Co-precipitation | ..... | | 00–02 | | 7110 C | | | | |
| Radium 226 | Radon emanation | 903.1 | p 16 | Ra-04 | p 19 | 7500-Ra C | D 3454–91 | R–1141–76 | Ra-05 | N.Y.[9] |
| | Radiochemical | 903.0 | p 13 | Ra-03 | | 304, 305, 7500-Ra B | D 2460–90 | R–1140–76 | | |
| Radium 228 | Radiochemical | 904.0 | p 24 | Ra-05 | p 19 | 304, 7500-Ra D | | R–1142–76 | | N.Y.[9] N.J.[10] |
| Uranium[12] | Radiochemical | 908.0 | | | | 7500-U B | | | | |
| | Fluorometric | 908.1 | | | | 7500-U C (17th Ed.) | D 2907–91 | R–1180–76 R–1181–76 | U-04 | |
| | Alpha spectrometry | ..... | | 00–07 | p 33 | 7500-U C (18th or 19th Ed.) | D 3972–90 | R–1182–76 | U-02 | |
| | Laser phosphorimetry | ..... | | | | | D 5174–91 | | | |
| Man-made: | | | | | | | | | | |
| Radioactive cesium | Radiochemical | 901.0 | p 4 | | | 7500-Cs B | D 2459–72 | R–1111–76 | | |
| | Gamma ray spectrometry | 901.1 | | | p 92 | 7120 | D 3649–91 | R–1110–76 | 4.5.2.3 | |
| Radioactive iodine | Radiochemical | 902.0 | p 6 p 9 | | | 7500–I B 7500–I C 7500–I D | D 3649–91 | | | |
| | Gamma ray spectrometry | 901.1 | | | p 92 | 7120 (19th Ed.) | D 4785–88 | | 4.5.2.3 | |
| Radioactive Strontium 89, 90. | Radiochemical | 905.0 | p 29 | Sr-4 | p. 65 | 303, 7500-Sr B | | R–1160–76 | Sr-01 Sr-02 | |
| Tritium | Liquid scintillation | 906.0 | p 34 | H-2 | p. 87 | 306,7500–3H B | D 4107–91 | R–1171–76 | | |
| Gamma emitters | Gamma ray spectrometry | 901.1 902.0 901.0 | | | p 92 | 7120 (19th Ed.) 7500-Cs B 7500-I B | D 3649–91 D 4785–88 | R–1110–76 | 4.5.2.3 | |

[1] "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA 600/4–80–032, August 1980. Available at U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (Telephone 800–553–6847), PB 80–224744.

[2] "Interim Radiochemical Methodology for Drinking Water," EPA 600/4–75–008 (revised), March 1976. Available at NTIS, ibid. PB 253258.

[3] "Radiochemistry Procedures Manual", EPA 520/5–84–006, December 1987. Available at NTIS, ibid. PB 84–215581.

[4] "Radiochemical Analytical Procedures for Analysis of Environmental Samples," U.S. Department of Energy, March 1979. Available at NTIS, ibid. EMSL LV 053917.

[5] Standard Methods for the Examination of Water and Wastewater, 13th, 17th, 18th, 19th Editions, 1971, 1989, 1992, 1995. Available at American Public Health Association, 1015 Fifteenth Street N.W., Washington, D.C. 20005. Methods 302, 303, 304, 305 and 306 are only in the 13th edition. Methods 7110B, 7110 C, 7500-Ra B, 7500-Ra C, 7500-Ra D, 7500-U B, 7500-Cs B, 7500-I B, 750–9I C, 7500–D, 7500-Sr B, 7500–3H B are in the 17th, 18th and 19th editions. Method 7500-U C Fluorometric Uranium is only in the 17th Edition, and 7500-U C Alpha spectrometry is only in the 18th and 19th editions. Method 7120 is only in the 19th edition. Methods 302, 303, 304, 305 and 306 are only in the 13th edition.

[6] Annual Book of ASTM Standards, Vol. 11.02, 1994; American Society for Testing and Materials; any year containing the cited version of the method may be used. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[7] "Methods for Determination of Radioactive Substances in Water and Fluvial Sediments," Chapter A5 in Book 5 of Techniques of Water-Resources Investigations of the United States Geological Survey, 1977. Available at U.S. Geological Survey Information Services, Box 25286, Federal Center, Denver, CO 80225–0425.

[8] "EML Procedures Manual", 27th Edition, Volume 1, 1990. Available at the Environmental Measurements Laboratory, U.S. Department of Energy (DOE), 376 Hudson Street, New York, NY 10014–3621.

[9] "Determination of Ra-226 and Ra-228 (Ra-02)," January 1980; Revised June 1982. Available at Radiological Sciences Institute Center for Laboratories and Research, New York State Department of Health, Empire State Plaza, Albany, NY 12201.

[10] "Determination of Radium 228 in Drinking Water," August 1980. Available at State of New Jersey, Department of Environmental Protection, Division of Environmental Quality, Bureau of Radiation and Inorganic Analytical Services, 9 Ewing Street, Trenton, NJ 08625.

[11] Natural uranium and thorium-230 are approved as gross alpha-particle activity calibration standards for the gross alpha co-precipitation and evaporation methods; americium-241 is approved for use with the gross alpha co-precipitation methods.

[12] If uranium (U) is determined by mass-type methods (*i.e.*, fluorometric or laser phosphorimetry), a 0.67 pCi/µg uranium conversion factor must be used. This conversion factor is conservative and is based on the 1:1 activity ratio of U-234 to U-238 that is characteristic of naturally-occurring uranium in rock.

TABLE I–9.—REQUIRED REGULATORY DETECTION LIMITS FOR THE VARIOUS RADIOCHEMICAL CONTAMINANTS (§ 141.25)

| Contaminant | Detection Limit (pCi/L) |
|---|---|
| Gross Alpha | 3 |
| Gross Beta | 4 |
| Radium-226 | 1 |
| Radium-228 | 1 |
| Cesium-134 | 10 |
| Strontium-89 | 10 |
| Strontium-90 | 2 |
| Iodine-131 | 1 |
| Tritium | 1,000 |
| Other Radionuclides and Photon/Gamma Emitters. | 1/10th of the rule. |

*J. Where and How Often Must a Water System Test for Radionuclides?*

1. Monitoring Frequency for Gross Alpha, Radium 226, Radium 228, and Uranium

The monitoring scheme being finalized today provides for more frequent, but less sample-intensive (on a per compliance site basis), monitoring for systems with a demonstrated inherent vulnerability and reduced monitoring for systems with low contaminant levels, which will apply to most systems. Instead of the current monitoring framework for radionuclides of four samples every four years for results above 50% of the MCL and one sample every 4 years for those at or below 50% (at State discretion), the revised rule calls for one sample every three years for compliant systems with average contaminant levels above 50% of the MCL but at or below the MCL, one sample every 6 years for systems with levels above the detection limit and at or below 50% of the MCL, and every 9 years for systems with levels below the detection limit.

2. Monitoring Frequency for Beta Particle and Photon Radioactivity

Beta particle and photon radioactivity monitoring will be performed only by community water systems designated by the State as "vulnerable" or "contaminated". A community water systems (both surface and ground water) designated by the State as vulnerable must collect quarterly samples for beta emitters and annual samples for tritium and strontium-90 at each entry point to the distribution system, beginning within one quarter after being notified by the State. Systems already designated by the State must continue to sample until the State reviews and either reaffirms or removes the designation. If the gross beta particle activity minus the naturally occurring potassium-40 beta particle activity at a sampling point has a running annual average less than or equal to 50 pCi/L (screening level), the system may reduce the frequency of monitoring at that sampling point to once every 3 years.

Community water systems (both surface and ground water) designated by the State as utilizing waters contaminated by effluents from nuclear facilities must collect quarterly samples for beta emitters and iodine-131 and annual samples for tritium and strontium-90 at each entry point to the distribution system, beginning within one quarter after being notified by the State. Systems already designated by the State as systems using waters contaminated by effluents from nuclear facilities must continue to sample until the State reviews and either reaffirms or removes the designation. If the gross

beta particle activity beta minus the naturally occurring potassium-40 beta particle activity at a sampling point has a running annual average less than or equal to 15 pCi/L (screening level), the system may reduce the frequency of monitoring at that sampling point to every 3 years.

For CWS in the vicinity of a nuclear facility, the State may allow the CWS to utilize environmental surveillance data collected by the nuclear facility in lieu of monitoring at the system's entry point(s), where the State determines if such data is applicable to a particular water system. Community water systems designated by the State to monitor for beta particle and photon radioactivity can not apply to the State for a waiver from the monitoring frequencies.

Several USGS studies, including the study entitled Gross-beta Activity in Ground Water: Natural Sources and Artifacts of Sampling and Laboratory Analysis, have found that Potassium-40 and Radium-228 appear to be the primary sources of beta activity in ground water. EPA recognizes that naturally occurring potassium could trigger many systems into conducting expensive beta speciation analysis due to exceedance of the screening level. Therefore, as noted above, naturally occurring Potassium-40 analyzed from the same or equivalent sample used for the gross beta analysis may be subtracted from the total gross beta activity to determine if the screening level is exceeded. The potassium-40 beta particle activity must be calculated by multiplying elemental potassium concentrations (in mg/L) by a factor of 0.82. If the gross beta particle activity minus the naturally occurring potassium-40 beta particle activity exceeds the screening level, an analysis of the sample must be performed to identify the major radioactive constituents present in the sample and the appropriate doses must be calculated and summed to determine compliance with § 141.66(d). Doses must also be calculated and combined for measured levels of tritium and strontium to determine compliance.

The regulatory language in § 141.26(b)(6) of today's rule requires systems to monitor monthly at sampling points which exceed the maximum contaminant levels in § 141.66(d) beginning in the next month after the exceedance occurred. There are many circumstances that may arise from this requirement such as collecting and obtaining the results in two separate months, however, the EPA intended this to require all systems to collect the initial monthly sample no later than 30 days following the collection date of the initial MCL exceedance.

The EPA believes that States have evaluated the vulnerability of systems to potential beta emitting sources under the existing rule. Therefore, States should use the existing vulnerability assessments to notify systems of their status and monitoring requirements if they have not provided that notification previously. The EPA is also encouraging States to reevaluate a systems vulnerability to beta photon emitting sources when conducting a systems source water assessment and provide immediate notification to those systems that have been deemed vulnerable.

3. Sampling Points and Data Grandfathering

Because the current radionuclide NPDWRs have been in effect for almost 25 years, States have much historical distribution system data for the regulated radionuclides at most community water systems and have data regarding occurrence patterns at various scales. The monitoring scheme is an attempt to balance two opposing goals: first, to ensure that every entry point is in compliance, and second, to allow States and drinking water systems to make maximal use of the existing distribution system historical data.

To meet the first goal, today's final rule requires that all new monitoring be at the entry point to the distribution system. This will ensure that all entry points are in compliance with the MCLs from now on. But, rather than narrowly prescribing specific criteria for grandfathering existing distribution system data, today's rule provides flexibility to States to devise a grandfathering plan applicable to their own circumstances. In particular, States may devise a plan for determining which systems will need to analyze new samples from each entry point to establish initial monitoring baselines for the currently regulated radionuclides and which can rely on the existing distribution system data for the same purpose (including existing uranium data). EPA had considered more prescriptive options, such as allowing grandfathering for systems with fewer than three entry points, systems serving fewer than 3,300 persons, systems drawing from aquifers of certain characteristics, etc. However, the many competing variables present at the local level make generalizations impractical at the national level. Since the grandfathering plans will be a part of the primacy packages approved by the EPA Regions, EPA will have oversight over these plans. EPA expects that the plans would allow grandfathering only for situations in which it is to be expected that every entry point is in compliance with the MCLs. For example, if a system with five entry points (all of significant flows) has gross alpha monitoring data from a representative point in the distribution system and the result is 75% of the MCL (11 pCi/L), EPA expects that this data would not be grandfathered, since it can not be ruled out that at least one of the entry points has a contaminant level greater than the MCL. On the other hand, if the distribution system sample baseline result is below the detection limit and the State determines that, based on aquifer and other characteristics, the entry points are expected to have fairly uniform contaminant levels, then a State could reasonably determine that this water system should be able to grandfather its distribution system data. EPA will provide an Implementation Guidance to further explain this issue after today's rule is final.

4. Does the Rule Allow Compositing of Samples?

Compositing allows a system to have combined samples analyzed to reduce the costs of monitoring. Compositing of samples is done in the laboratory. The 1976 rule allowed compositing for gross alpha and allowed (but did not recommend) some compositing for beta/photon emitters. Compositing is essentially an issue for the initial round of monitoring for systems without data to grandfather. Once decreased monitoring is in effect, only a single sample will be required and compositing will not be an issue. In general, there are three kinds of compositing: combining samples taken from the same sampling point from different quarters (temporal compositing), samples taken in the same quarter from different sampling points within a system (spatial compositing), and samples taken from different water systems each having one well (inter-system compositing). Inter-system and spatial compositing are not allowed in today's rule, since this kind of compositing defeats the purpose of monitoring at each entry point to the distribution system.

Because compositing lessens the burden on systems and allows for adequate monitoring reliability in some situations, temporal compositing is allowed under circumstances in which the detection limit is low compared to the MCL. In particular, temporal compositing is allowed for uranium, gross alpha radium-226 (provided a DL of 1 pCi/L is met) and radium-228 (provided a DL of 1 pCi/L is met). While

compositing is allowed under these circumstances, compositing of several samples taken at different times provides less information than individual analysis of the samples. For example, if contaminant levels vary appreciably with pumping rates and pumping rates are seasonal, compositing will hide this potentially significant variance. Additionally, if a State allows a system with low contaminant levels to base compliance on two results from different quarters, compositing may not be desirable. If a State wishes to be more stringent and use the highest result of four initial samples to set future monitoring frequency, compositing is not appropriate. However, under some conditions, States may wish to allow water systems to have their samples composited before analysis.

Commenters generally agreed that spatial monitoring was impractical, since it would provide limited information on contaminant levels at individual entry points. Some commenters suggested that the six month holding time for gross alpha would necessitate compositing twice, two samples in the first six months and two in the second six months. Although this type of compositing would be allowed, EPA disagrees that this is necessary, since, for statistical reasons, analysis of four composited samples taken in four different quarters will achieve results of comparable quality (assuming that the analysis is done within the same year that the first sample is taken) to individual analyses of four samples using six month holding times. For this reason, annual compositing at a single entry point is allowed for gross alpha. While several commenters were desirous of maximum compositing flexibility, the technical limitations described rule out some types of compositing, specifically spatial and inter-system compositing.

5. Interpretation of Analytical Results

The Agency recognizes that States have interpreted radionuclide analytical results in a variety of ways, including adding or subtracting standard deviations from the analytical results. The Agency believes that compliance and reduced monitoring frequencies should be calculated based on the "analytical result(s)" as stated in § 141.26(c)(3). It is EPA's interpretation that the analytical result is the number that the laboratory reports, not including (*i.e.* not adding or subtracting) the standard deviation. For example, if a laboratory reports that the gross alpha measurement for a sampling point is 7 ± 2 pCi/L, then compliance and reduced monitoring would be calculated using a value of 7 pCi/L.

*K. Can My Water System Use Point-of-Use (POU), Point-of-Entry (POE)* [10]*, or Bottled Water To Comply With This Regulation?*

EPA has listed: (1) POU ion exchange and POU reverse osmosis as small system compliance technologies for combined radium-226 and radium-228, and beta particle and photon radioactivity; and (2) POU reverse osmosis as a small systems compliance technology for gross alpha particle activity (63 FR 42032; on August 6, 1998, also see Table I–6 and I–7)). While these POU technologies are not considered BAT for large systems, they may be used as BAT under sections 1412 and 1415 of the Act for systems serving 10,000 persons or fewer. Guidance documents were published to support the small systems compliance technology lists ("Small System Compliance Technology List for the Non-Microbial Contaminants Regulated Before 1996," USEPA 1998f). The small system compliance technology list described in section I.H., table I–6, of today's final rule is identical to the 1998 list, with the exception of the addition of small systems compliance technologies for uranium. See section I.H. for details about the lists. POE technologies are not being listed as small systems compliance technologies since they are considered emerging technologies and due to concerns regarding waste disposal and costs. POE technologies (and other technologies) may be added in the future through small system compliance technology updates.

The authority for listing POU technologies as small system compliance technologies comes from section 1412(b)(4)(e)(ii) of the SDWA, which identifies both Point-of-Entry (POE) and Point-of-Use (POU) treatment units as options for compliance technologies. The SDWA identifies requirements that must be met when POU or POE units are used by a water system to comply with an NPDWR. Section 1412(b)(4)(e)(ii) stipulates that "point-of-entry and point-of-use treatment units shall be owned, controlled, and maintained by the public water system or by a person under contract with the public water system to ensure proper operation and maintenance and compliance with the MCL or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems." Other conditions in this section of the SDWA include the following: "If the American National Standards Institute has issued product standards applicable to a specific type of POE or POU treatment unit, individual units of that type shall not be accepted for compliance with a MCL or treatment technique unless they are independently certified in accordance with such standards."

In order to list POU treatment units as compliance technologies, EPA had to withdraw the part of § 141.101 that prohibited POU devices being used to comply with an MCL. To this end, a final rule was published in the **Federal Register** on June 11, 1998 (EPA 1998g). For more details on POU and POE devices, see the supporting guidance document for the small system compliance technology lists (USEPA 1998f).

Public water systems are not allowed to use bottled water to comply with an MCL (63 FR 31932; June 11, 1998). Bottled water may only be used on a temporary basis to avoid unreasonable risks to health, *e.g.*, as negotiated with the State or other primacy agency as part of the compliance schedule period for an exemption or variance.

*L. What Do I Need To Tell My Customers?*

1. Consumer Confidence Reports

On August 19, 1998, EPA issued Subpart O, the final rule requiring community water systems to provide annual reports on the quality of water delivered to their customers (63 FR 44512). The first Consumer Confidence Reports (CCRs) were to be made available to customers by October 19, 1999, and now they are due each year by July 1 (§ 141.152(a)). In these reports, systems must provide, among other things, the levels and sources of all detected contaminants and a description of the potential health effects of any contaminant found at levels that violate EPA or State rules, as part of a broader description of the violation and efforts to remedy it. For MCL or treatment technique violations, specific "health effects language" in Appendix A of Subpart O must be included verbatim in the report. Today's rule updates the Appendix to include health effects language and "likely source"

[10] Point-of-entry (POE) treatment units treat all of the water entering a household or other building, with the result being treated water from any tap. Point-of-use (POU) treatment units treat only the water at a particular tap or faucet, with the result being treated water at that one tap, with the other taps serving untreated water. POE and POU treatment units often use the same technological concepts employed in the analogous central treatment processes, the main difference being the much smaller scale of the device itself and the flows being treated.

information for uranium. This language is consistent both with previously published health effects language for other radionuclides and with the language now required by the Public Notification Rule. Table I–10 shows the health effects language required for the radionuclides for the purposes of CCR and public notification.

TABLE I–10.—STANDARD HEALTH EFFECTS LANGUAGE FOR CCR AND PUBLIC NOTIFICATION

| Contaminant | Standard health effects language for CCR and public notification |
|---|---|
| Beta/photon emitters | Certain minerals are radioactive and may emit forms of radiation known as photons and beta radiation. Some people who drink water containing beta and photon emitters in excess of the MCL over many years may have an increased risk of getting cancer. |
| Alpha Emitters | Certain minerals are radioactive and may emit a form of radiation known as alpha radiation. Some people who drink water containing alpha emitters in excess of the MCL over many years may have an increased risk of getting cancer. |
| Combined Radium (–226 & –228) | Some people who drink water containing radium 226 or 228 in excess of the MCL over many years may have an increased risk of getting cancer. |
| Uranium | Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk of getting cancer and kidney toxicity. |

2. Public Notification

Sections 1414(c)(1) and (c)(2) of the SDWA, as amended in 1996, require that public water systems notify their customers when they are in violation of NPDWRs. In the case of the radionuclides NPDWRs, this only applies to community water systems. On May 4, 2000, EPA revised the minimum requirements that public water systems must meet for public notification of violations of EPA's drinking water standards and other situations that pose a risk to public health from the drinking water. These revisions were promulgated under the Public Notification Rule (PNR), under 40 CFR Part 141, Subpart Q. Water systems must begin to comply with the new regulations on October 31, 2000 (if they are in jurisdictions where the program is directly implemented by EPA), or on the date a primacy State adopts the new requirements (but not later than May 6, 2002). Until the effective date of the new requirements, water systems must continue to comply with the requirements under § 141.32. Subsequent EPA drinking water regulations that affect public notification requirements will amend the PNR as a part of each individual rulemaking.

Public notification of drinking water violations is an important part of the "public right to know" provisions of the 1996 Amendments to the Safe Drinking Water Act. The PNR sets the requirements that public water systems must follow regarding the form, manner, frequency, and content for public notifications. These requirements apply to owners and operators of, in the case of the radionuclides NPDWRs, community water systems. The PNR requires that any regulated system notify its customers when: (1) A violation of a NPDWR occurs; (2) the system obtains a variance or an exemption from a NPDWR; or (3) the system is facing another situation posing a significant risk to public health.

Depending on the severity of the situation, water suppliers have from 24 hours to one year to notify their customers after a violation occurs. EPA specifies three categories, or tiers, of public notification. Depending under which tier a violation situation falls, water systems have different amounts of time to distribute and ways to deliver the notice:

- Immediate Notice (Tier 1): Any time a situation occurs where there is the potential for human health to be immediately impacted, water suppliers have 24 hours to notify people who may drink the water of the situation. Water suppliers must use media outlets such as television, radio, and newspapers, post their notice in public places, or personally deliver a notice to their customers in these situations.
- Notice "as soon as possible" (Tier 2): Any time a water system provides water with levels of a contaminant that exceed EPA or State standards or that hasn't been treated properly, but that does not pose an immediate risk to human health, the water system must notify its customers as soon as possible, but within 30 days of the violation. Notice may be provided via the media, posting, or through the mail.
- Annual Notice (Tier 3): When water systems violate a drinking water standard that does not have a direct impact on human health (for example, failing to take a required sample on time) the water supplier has up to a year to provide a notice of this situation to its customers. The extra time gives water suppliers the opportunity to consolidate these notices and send them with annual water quality reports (consumer confidence reports (CCR)), if the CCR meets the PNR timing, content, and distribution requirements.

The PNR lists the currently regulated radionuclides (combined radium-226 and radium-228, gross alpha, and beta particle and photon radioactivity) as being subject to "Tier 2" public notice requirements for MCL violations and "Tier 3" public notice requirements for violations of the monitoring and testing procedure requirements. Today's rule does not change this designation for the currently regulated radionuclides and adds uranium to the list of contaminants subject to Tier 2 requirements for MCL violations and Tier 3 requirements for violations of the monitoring and testing procedure requirements.

The elements to be included in each public notice are specified under § 141.205(a). All notices must include:

- A description of the violation that occurred, including the potential health effects (as specified in appendix B to subpart Q for MCL violations and the standard language under § 141.205(d)(2) for monitoring violations);
- The population at risk and if alternate water supplies need to be used;
- What the water system is doing to correct the problem;
- Actions consumers can take;
- When the violation occurred and when the system expects it to be resolved;
- How to contact the water system for more information; and
- Standard language encouraging broader distribution of the notice.

The standard health effects language used for public notification is the same as that for CCR, which is provided in Table I–10.

The public notice requirements under 40 CFR 141.203(b)(1) are such that the public water system must provide a Tier 2 public notice to persons served as soon as practical, but no later than 30 days after the system learns of the violation. Posted notices are required to remain in place for as long as the

violation or situation persists, but in no case for less than seven days, even if the violation or situation is resolved. The PNR under § 141.203(b)(2) also requires the public water system to repeat the notice every three months for as long as the violation persists. In contrast, the current rule requires a newspaper notice within 14 days, a notice mailed to all bill-payers within forty-five days, and a repeat notice mailed every three months thereafter until the violation is resolved.

The public notification requirement gives the primacy agency discretion, in appropriate circumstances, to extend the time period allowed for the Tier 2 notice from 30 days to up to three months for the initial notice and to allow repeat notice less frequently than every three months (but no less than once per year). Permission must be granted in writing. Although the discretion given to the primacy agency is fairly broad, the rule specifically disallows extensions of the 30-day deadline for the initial public notice for any unresolved violation. The PNR also does not allow primacy agencies to establish regulations or policies that automatically give "across-the-board" extensions or reductions in the repeat notice frequency for all the other violations.

For the most up-to-date version of the CCR and PNR tables that will be published in the July edition of the Code of Federal Regulations (appendix A to subpart O, and appendices A and B to subpart Q of 40 CFR part 141), visit EPA's Office of Ground Water and Drinking Water's website at "http://www.epa.gov/safewater/tables.html." These on-line tables incorporate changes on an on-going basis.

*M. Can My Water System Get a Variance or an Exemption From an MCL Under Today's Rule?*

There are two kinds of variances applicable to public water systems: "regular variances," which are usually referred to simply as "variances," and "small systems variances." The currently regulated radionuclides are already subject to the provisions for variances and exemptions and nothing in today's rule changes these provisions. The regular variances and exemptions provisions will be discussed later in this section.

As discussed in the NODA, the "Small Systems Compliance Technology List" (SSCTL) for combined radium-226 and -228, gross alpha particle activity, and beta particle/photon emitter radioactivity was published in the **Federal Register** on August 6, 1998 (63 FR 42032), as required by the amended SDWA. The SSCTL list for uranium was published for comment in the radionuclides NODA.

The 1996 SDWA identifies three categories of small drinking water systems, those serving populations between 25–500, 501–3,300, and 3,301–10,000. In addition to BAT determinations, the SDWA directs EPA to make technology assessments for each of the three small system size categories in all future regulations establishing an MCL or treatment technique. Two classes of small systems technologies are identified for future NPDWRs: small system compliance technologies and small system variance technologies.

Small system compliance technologies ("compliance technologies") may be listed for NPDWRs that promulgate MCLs or treatment techniques. In the case of an MCL, "compliance technology" refers to a technology or other means that is affordable for the appropriate small systems (if applicable) and that achieves compliance. Possible compliance technologies include packaged or modular systems and point-of-entry (POE) or point-of-use (POU) treatment units, as described previously.

Small system variance technologies ("variance technologies") are only specified for those system size/source water quality combinations for which no technology meets all of the criteria for listing as a compliance technology (section 1412(b)(15)(A)). Thus, the listing of a compliance technology for a size category/source water combination prohibits the listing of variance technologies for that combination. While variance technologies may not achieve compliance with the MCL or treatment technique requirement, they must achieve the maximum reduction that is affordable considering the size of the system and the quality of the source water. Variance technologies must also achieve a level of contaminant reduction that is "protective of public health" (section 1412(b)(15)(B)). The process for determining small system compliance technologies and small system variance technologies is described in more detail in the guidance document, "Small System Compliance Technology List for the Non-Microbial Contaminants Regulated Before 1996" (USEPA 1998f).

In the case of the currently regulated radionuclides, *i.e.*, combined radium-226 and -228, gross alpha particle activity, and total beta particle and photon radioactivity, there are no variance technologies allowable since the SDWA (section 1415(e)(6)(A)) specifically prohibits small system variances for any MCL or treatment technique which was promulgated prior to January 1, 1986. The Variance and Exemption Rule describes EPA's interpretation of this section in more detail (see 63 FR 19442; April 20, 1998).

Stakeholders provided input regarding the small system compliance technologies for combined radium-226 and -228, gross alpha emitters, and beta particle and photon radioactivity, and uranium that are listed in section I.H. The small system compliance technologies for the radionuclides regulated since 1976 were listed and described in the **Federal Register** on August 6, 1998 (63 FR 42032) and in an accompanying guidance manual (EPA 1998b). Small systems compliance technologies for uranium were evaluated subsequent to the 1998 list, and presented in the Small Systems Compliance Technology List for the Radionuclides Rule (USEPA 1999a). Small systems compliance technologies for uranium were evaluated in terms of each technology's removal capabilities, contaminant concentration applicability ranges, other water quality concerns, treatment costs, and operational/maintenance requirements. This list was published for comment in the April 21, 2000, Notice of Data Availability (USEPA 2000e). No comments were received.

Small system compliance technology lists are technology specific, but not product (manufacturer) specific. Product specific lists were determined to be inappropriate due to the potential resource intensiveness involved. Information on specific products will be available through another mechanism. EPA's Office of Research and Development has a pilot project under the Environmental Technology Verification (ETV) Program to provide treatment system purchasers with performance data from independent third parties.

The currently regulated radionuclides are already subject to the provisions for "regular variances" and exemptions. Uranium will be subject to the same provisions. Variances generally allow a system to provide drinking water that may be above the maximum contaminant level on the condition that the quality of the drinking water is still protective of public health. The SDWA (1415(a)) requires that any system obtaining a variance must enter into a compliance schedule with the primacy entity as a condition of the variance. An exemption, on the other hand, is intended to allow a system with compelling circumstances an extension of time before the system must comply with applicable SDWA requirements.

An exemption is limited to three years after the otherwise applicable compliance date, although extensions up to a total of six additional years may be available to small systems under certain conditions.

*N. How Were Stakeholders Involved in the Development of This Rule?*

EPA has consulted with a broad range of stakeholders and technical experts. EPA held a two-day stakeholders meeting on the radionuclides rule in Washington, DC on December 11–12, 1997. The meeting was announced in the **Federal Register** and open to any one interested in attending in person or by phone. During the meeting, EPA discussed a range of regulation development issues with the stakeholders, including the statutory requirements, the stipulated agreement, MCLs for each of the radionuclides, new scientific information on health effects, occurrence, analytical methods, treatment technologies, and the current and proposed monitoring framework. The presentations generated useful discussion and provided feedback to EPA regarding technical issues, stakeholder concerns and possible regulatory options. Participants in EPA's stakeholder meeting included representatives from the Association of Metropolitan Water Agencies (AMWA), Association of State Drinking Water Administrators (ASDWA), American Water Works Association (AWWA), National Association of Water Companies, State departments of environmental protection, State health department, State drinking water programs, Federal agencies, environmental groups, and local water systems. The public docket for this final rulemaking contains the meeting summary for EPA's stakeholder meeting on radionuclides in drinking water.

In addition, during the regulation development process, EPA gave presentations on the radionuclides regulation at meetings of the AWWA, ASDWA and EPA State/Regional conferences, and met with States from Regions 2, 3, 7, and 8 regarding radionuclides issues and the upcoming final rule. EPA participated in AWWA's Technical Advisory Workgroup (TAW), which meets annually to discuss technical issues including treatment, occurrence, and health risks. State public health departments and drinking water program representatives of both large and small drinking water districts participated in TAW meetings. EPA also held frequent conference calls with interested State drinking water programs about the development of the rule. In addition, EPA made presentations and received input at Tribal meetings in Nevada, Alaska, and California. Finally, EPA held a one-day meeting with associations that represent State, county, and local government elected officials on May 30, 2000, and discussed five upcoming drinking water regulations, including radionuclides. See section V.I "Executive Order 13132" for more information about the meeting.

The Agency utilized the feedback received from the stakeholders during all these meetings in developing today's final rule.

*O. What Financial Assistance Is Available for Complying With This Rule?*

Various Federal programs exist to provide financial assistance to State, local, and Tribal governments to administer and comply with this and other drinking water rules. The Federal government provides funding to States and Tribes that have a primary enforcement responsibility for their drinking water programs through the Public Water Systems Supervision (PWSS) Grants program. Additional funding is available from other programs administered either by EPA or other Federal agencies. These include the Drinking Water State Revolving Fund (DWSRF) and Housing and Urban Development's Community Development Block Grant Program. For example, the SDWA authorizes the Administrator of the EPA to award capitalization grants to States, which in turn can provide low cost loans and other types of assistance to eligible public water systems. The DWSRF assists public water systems with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Each State has considerable flexibility to determine the design of its program and to direct funding toward its most pressing compliance and public health protection needs. States may also, on a matching basis, use up to ten percent of their DWSRF allotments for each fiscal year to assist in running the State drinking water program.

Under PWSS Program Assistance Grants, the Administrator may make grants to States to carry out public water system supervision programs. States may use these funds to develop primacy programs. States may "contract" with other State agencies to assist in the development or implementation of their primacy program. However, States may not use program assistance grant funds to contract with regulated entities (*i.e.*, water systems). PWSS Grants may be used by States to set-up and administer a State program which includes such activities as: public education, testing, training, technical assistance, developing and administering a remediation grant and loan or incentive program (excludes the actual grant or loan funds), or other regulatory or non-regulatory measures.

*P. How Are the Radionuclides MCLs Used Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)?*

The framework for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) includes the expectation that contaminated ground waters will be returned to beneficial uses whenever practicable (see § 300.430(a)(1)(iii)(F)). Section 121(d) of CERCLA requires on-site remedial actions to attain MCLGs and water quality standards under CWA when relevant and appropriate. The NCP (§ 300.430(e)(2)(i)(B) and (C) clarify that MCLs or non-zero MCLGs established under SDWA will typically be considered relevant and appropriate cleanup levels for ground waters that are a current or potential source of drinking water.

EPA's guidance on complying with these requirements are contained in an EPA document entitled "Presumptive Response Strategy and Ex-Situ Treatment Technologies for Contaminated Ground Water at CERCLA Sites, Final Guidance," (October 1996. OSWER Directive 9283.1–12). A discussion of the flexibility of EPA's guidance under CERCLA on the attainment of drinking waters in ground water is contained in section 2.6 "Areas of Flexibility in Cleanup Approach" (pp 15–19) of the 1996 OSWER directive. The discussion in the 1996 OSWER directive regarding monitored natural attenuation and determining beneficial uses of groundwater has been updated by the following EPA guidance documents: (1) "Use of Monitored Natural Attenuation at Superfund, RCRA Corrective Action, and Underground Storage Tank Sites" (April 1999. Final OSWER Directive 9200.4–17P), and (2) "The Role of CSGWPPs in EPA Remediation Programs" (April 4, 1997, OSWER Directive 9283.1–09).

*Q. What Is the Effective Date and Compliance Date for the Rule?*

Much of today's rule will involve retaining current elements of the radionuclides NPDWR. Those portions of the final rule that are unaffected by the upcoming regulatory changes are

already in effect. MCLs for gross alpha, beta particle and photon radioactivity, and combined radium-226 and -228 will be unchanged and are already in effect. Regarding water systems that are currently out of compliance with the existing NPDWRs for gross alpha, combined radium-226 and -228, and/or beta particle and photon radioactivity, States with primacy and EPA will renegotiate, as necessary, enforcement actions that put systems on compliance schedules as expeditiously as possible.

Under the Safe Drinking Water Act, the final rule becomes effective three years after promulgation December 8, 2003. Under the Standard Monitoring Framework (SMF), systems usually have three years to complete the initial monitoring cycle of four consecutive quarterly samples. In order to synchronize the monitoring periods for radionuclides with the Standardized Monitoring Framework and alleviate potential laboratory capacity problems, the end of the initial monitoring period will be December 31, 2007. EPA expects that States will phase-in monitoring over this period and determine compliance upon completion of each water system's initial monitoring schedule. For example, the fraction of water systems that begin monitoring in the first year would have compliance determinations made at the end of the first year, based upon the average results of the four quarterly samples. New monitoring includes initial monitoring for uranium, the new monitoring requirements for radium-228, and new initial monitoring under the requirements for entry points. Data grandfathering discretion for existing monitoring data to determine future monitoring schedules is discussed in sections I.D and I.J. Combined radium-226 and radium-228 MCL violations which result from the new requirement for separate radium-228 monitoring will be treated as "new violations" and will be on the same schedule as other new violations (e.g. uranium). Water systems with existing monitoring data for radium-228 and uranium that demonstrate that they are not in compliance with the MCL will be out of compliance on the effective date of the rule.

*R. Has EPA Considered Laboratory Approval/Certification and Laboratory Capacity?*

The ultimate effectiveness of the approved regulations depends upon the ability of laboratories to reliably analyze contaminants at relatively low levels. The Drinking Water Laboratory Certification Program is intended to ensure that approved drinking water laboratories analyze regulated drinking water contaminants within acceptable limits of performance. The Certification Program is managed through a cooperative effort between EPA's Office of Ground Water and Drinking Water and the Office of Research and Development. The program stipulates that laboratories analyzing drinking water compliance samples must be certified by U.S. EPA or the State. The program also requires that certified laboratories must analyze Proficiency Testing (PT) samples [formerly called Performance Evaluation (PE) samples], use approved methods and pass periodic on-site audits.

1. Laboratory Approval/Certification

As discussed in the April 21, 2000 NODA, EPA recently privatized the PT program, including the Water Supply (WS) studies. The decision to privatize the PT studies programs was announced in the **Federal Register** on June 12, 1997 (62 FR 32112). The notice indicated that in the future the EPA would issue standards for the operation of the program, while the National Institute of Standards and Technology (NIST) would develop standards for private sector PT suppliers and would evaluate and accredit PT suppliers. The private sector would develop and manufacture PT samples and conduct PT studies.

2. Laboratory Capacity: Laboratory Certification and PT Studies

The availability of laboratories is also dependent on laboratory certification efforts in the individual States with regulatory authority for their drinking water programs. Until June of 1999, a major component of many of these certification programs was their continued participation in the current EPA Water Supply (WS) PT program. As discussed previously, NIST is administering the program to accredit a provider for PT samples for radionuclides. States also have the option of approving their own PT sample providers. The extent to which the PT program will affect short-term and long-term laboratory capacity for radionuclides will be assessed after PT providers are approved by NIST or the States. However, EPA anticipates that radionuclide PT samples will be available in time to allow for laboratory certification before compliance monitoring is required.

3. Summary of Major Comments Regarding Laboratory Capacity and EPA Responses

In the April 21, 2000 NODA, the Agency stated that it is difficult to ascertain how and if externalization of the PT program will affect radiochemical laboratory capacity and the cost of radiochemical analyses. In the absence of definitive information, the Agency solicited public comments on this subject. The Agency stated in the NODA that it recognized that PT externalization may be an implementation issue for at least three reasons:

- The externalization of the radionuclides PT studies program may cause short-term disruption in laboratory accreditation;
- Requiring NTNCWSs to monitor under the Standard Monitoring Framework will add approximately 20,000 systems to the universe of systems that are already required to monitor;
- And the radon rule will be implemented at approximately the same time as the radionuclides rule.

To alleviate potential laboratory capacity problems that could result, the Agency solicited comments on whether or not to extend the initial monitoring period to four years (instead of three years). Of the 70 commenters who provided comments on the radionuclides NODA, 15 commented on laboratory externalization and its related issues. The major concerns raised by the commenters and the Agency's responses to them are provided below.

a. Laboratory Certification, Availability of PT Samples and Costs of PT Samples: Several commenters noted there is currently no certification process through which laboratories can receive State certification for radionuclide analyses due to the lack of availability of PT samples. Some commenters noted that only one PT provider has volunteered to provide PT samples for radionuclides and based on their inquiries, PT sample costs are too high. Commenters believe the high costs of PT samples will affect the resulting costs of the radiochemical analyses (by increasing operational costs). Several commenters felt EPA should reconsider the privatization of PT program. Commenters stated that EPA must ensure that an adequate number of laboratories are available to perform accurate measurements and provide data of good quality for compliance and enforcement efforts.

After evaluating public comment, EPA published its final decision about the externalization of the PT Program in the June 12, 1997 final notice (62 FR 32112). Currently, the PT program for radionuclides is being privatized, *i.e.*, operated by an independent third party provider accredited by the National Institute of Standards and Technology (NIST). EPA believes this program will

ensure the continued viability of the existing PT programs, with EPA maintaining oversight. NIST is in the process of approving a provider for PT samples for radionuclides. To alleviate concerns about the costs of PT samples, States have the option to approve PT sample provider(s) themselves. The Agency anticipates that radionuclide PT samples will be available in time to allow for laboratory certification before compliance monitoring is required.

b. Laboratory Capacity: Commenters stressed the impact that the externalization of the PT program, this regulation and the radon regulation would have on laboratory capacity and workloads of the laboratories. Some commenters felt the externalization and high costs of PT samples would decrease the number of radiochemical laboratories and in affect decrease laboratory capacity. Also, commenters felt that if EPA required 48–72 hour turn around times for gross alpha (to catch the alpha particle contribution from radium-224) or monitoring of regulated radionuclides by NTNCWSs, radiochemical laboratories would not be able to address the additional demand for analytical services. EPA agrees that laboratory capacity could be effected by the externalization of the PT program. In an effort to alleviate potential laboratory capacity problems, EPA has agreed to extend the initial monitoring period from three to four years. Extending the initial monitoring period will spread the burden on the laboratories as well as the costs associated with the monitoring. In addition, EPA is allowing systems to grandfather existing data on currently regulated radionuclides and composite under certain circumstances (for more information on compositing and grandfathering, see section I.J. In addition, because EPA has decided not to require a 48 to 72 hour turn around time for gross alpha particle activity nor to regulate NTNCWSs, the potential burden on laboratory capacity should be alleviated.

## II. Statutory Authority and Regulatory Background

### *A. What Is the Legal Authority for Setting National Primary Drinking Water Regulations (NPDWRs)?*

The SDWA requires EPA to promulgate regulations pertaining to public water systems. Specifically, section 1412(b)(4) requires that EPA set a health-based goal called a maximum contaminant level goal (MCLG) as a target for setting an enforceable standard, the maximum contaminant level (MCL). The MCLG is determined by studies of the health effects of contaminants on animals under laboratory conditions or humans via epidemiological studies. The MCLG is the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. The Safe Drinking Water Act requires EPA to set the MCL as close to the MCLG as is "feasible," which is defined as "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration) * * *" [section 1412(b)(4)(D)]. Additionally, section 1412(b)(6) provides that if the Administrator determines that at the feasible level, the benefits do not justify the costs, EPA can set a standard which maximizes the health risk reduction benefits at a cost that is justified by the benefits. In today's rule, EPA is invoking these authorities with respect to the uranium standard. Section 1412 (b)(9) requires that any revisions to NPDWRs maintain or provide for greater protection of the health of persons.

### *B. Is EPA Required To Finalize the 1991 Radionuclides Proposal?*

The SDWA requires that EPA issue MCLGs for the currently regulated radionuclides in drinking water and establish a NPDWR for uranium. When EPA failed to finalize the 1991 proposal, a citizen group brought suit to establish a schedule for finalizing the appropriate portions of the proposal. Following the 1996 amendments to the SDWA, the plaintiffs and EPA agreed on a schedule for completing the revisions to the radionuclides rulemaking by either finalizing applicable parts of the 1991 proposal or affirming the validity of the current rule with an explanation of why the current rule is preferable. With respect to uranium, EPA has no current rule, and is required to finalize a uranium regulation on the same schedule as gross alpha particle activity, combined radium-226 and -228, and beta particle and photon radioactivity. This agreement was reflected in a stipulation of the parties in litigation in U.S. District Court in Oregon.

## III. Rule Implementation

### *A. What Are the Requirements for Primacy?*

This section describes the regulations and other procedures and policies primacy entities have to adopt, or have in place, to implement today's final rule. States must continue to meet all other conditions of primacy in 40 CFR part 142.

Section 1413 of the SDWA establishes requirements that primacy entities (States or Indian Tribes) must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include:

(1) Adopting drinking water regulations that are no less stringent than Federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act,

(2) Adopting and implementing adequate procedures for enforcement,

(3) Keeping records and making reports available on activities that EPA requires by regulation,

(4) Issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by sections 1415 and 1416, and

(5) Adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the Public Water Supply Supervision Program, as authorized under section 1413 of the Act. In addition to adopting the basic primacy requirements, States may be required to adopt special primacy provisions pertaining to a specific regulation. These regulation-specific provisions may be necessary where implementation of the NPDWR involves activities beyond those in the generic rule. States are required by § 142.12 to include these regulation-specific provisions in an application for approval of their program revisions. These State primacy requirements apply to today's final rule, along with the special primacy requirements discussed below.

To implement today's final rule, States are required to adopt revisions to § 141.25—Analytical methods for radioactivity; § 141.26—Monitoring frequency and compliance requirements for radioactivity in community water systems; appendix A to subpart O—Regulated contaminants; appendix A to subpart Q—NPDWR violations and other situations requiring public notice; appendix B to subpart Q—Standard health effects language for public notification; § 142.16—Special primacy requirements; and new requirements § 141.55—Maximum contaminant level goals for radionuclides; and § 141.66—Maximum contaminant levels for radionuclides.

### *B. What Are the Special Primacy Requirements?*

In addition to adopting drinking water regulations at least as stringent as the

Federal regulations listed above, EPA requires that States adopt certain additional provisions related to this regulation to have their program revision application approved by EPA.

The State's request for approval must contain the following:

(1) If a State chooses to use grandfathered data in the manner described in § 141.26(a)(2)(ii)(C) of this chapter, then the State must describe the procedures and criteria which it will use to make these determinations (whether distribution system or entry point sampling points are used).

(i) The decision criteria that the State will use to determine that data collected in the distribution system are representative of the drinking water supplied from each entry point to the distribution system. These determinations must consider:

(A) All previous monitoring data.

(B) The variation in reported activity levels.

(C) Other factors affecting the representativeness of the data (*e.g.*. geology).

(2) A monitoring plan by which the State will assure all systems complete the required monitoring within the regulatory deadlines. States may update their existing monitoring plan or use the same monitoring plan submitted for the requirements in § 142.16(e)(5) under the National Primary Drinking Water Regulations for the inorganic and organic contaminants (*i.e.* the Phase II/V Rules). States may note in their application any revision to an existing monitoring plan or note that the same monitoring plan will be used. The State must demonstrate that the monitoring plan is enforceable under State law.

There are many ways that a State may satisfy the special primacy requirements. The Agency intends to issue guidance regarding ways to satisfy these requirements, but States have the flexibility to develop individual programs appropriate for the circumstances within each State.

*C. What Are the Requirements for Record Keeping?*

The current regulations in § 142.14 require States with primacy enforcement responsibility to keep records of analytical results to determine compliance, system inventories, sanitary surveys, State approvals, vulnerability determinations, monitoring requirements, monitoring frequency decisions, enforcement actions, and the issuance of variances and exemptions. These records include:

(1) Any determination of a system's vulnerability to contamination by beta and photon emitters (§ 142.14(d)(4)); and

(2) Any determination that a system can reduce or increase monitoring frequency for gross alpha particle activity, gross beta particle and photon radioactivity, uranium, radium-226 and 228. The records must include the basis for the decision, and the repeat monitoring frequency (§ 142.14(d)(5)).

Since these requirements are generally included in § 142.14(d)(4) and (5), revisions to the rule are not necessary.

*D. What Are the Requirements for Reporting?*

Currently, States must report to EPA information under § 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. These reporting requirements remain unchanged and apply to the radionuclides as with any other regulated contaminant.

*E. When Does a State Have To Apply for Primacy?*

The State must submit a request for approval of program revisions that adopts the uranium MCL, implementing regulations, and other revisions promulgated in today's final rulemaking within two years of the publication date of today's rule unless EPA approves an extension per § 142.12(b). To maintain primacy for the Public Water Supply Supervision (PWSS) Program and to be eligible for interim primacy enforcement authority for future regulations, States must adopt today's rule. Interim primacy enforcement authority allows States to implement and enforce drinking water regulations once State regulations are effective and the State has submitted a complete and final primacy revision application. To obtain interim primacy, a State must have primacy with respect to each existing NPDWR. Under interim primacy enforcement authority, States are effectively considered to have primacy during the period that EPA is reviewing their primacy revision application.

*F. What Are Tribes Required To Do Under This Regulation?*

Currently, no federally recognized Indian tribes have primacy to enforce any of the drinking water regulations. EPA Regions implement the rules for all Tribes under section 1451(a)(1) of SDWA. Tribes would need to submit a primacy application in order to have the authority to implement the radionuclides NPDWRs. Tribes with primacy for drinking water programs are eligible for grants and contract assistance (section 1451(a)(3)). Tribes are also eligible for grants under the Drinking Water State Revolving Fund Tribal set aside grant program authorized by SDWA section 1452(i) for public water system expenditures.

*IV. Economic Analyses*

Under Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the finalized changes to the Radionuclides NPDWRs and submit the impact analysis to the Office of Management and Budget (OMB) as part of the rulemaking process. EPA has prepared an Economic Analysis (USEPA 2000g) to comply with the requirements of this Order. This section provides a summary of the information from the economic analysis regarding estimates of the costs and benefits related to the changes to the existing radionuclides NPDWRs and the uranium NPDWR being finalized today. The economic analysis is an update to the Health Risk Reduction and Cost Analysis (USEPA 2000f) announced in the NODA (USEPA 2000e) and summarized in the NODA's Technical Support Document (USEPA 2000h). The updates to the economic analysis reflect comments received on the NODA. This section will not repeat all of the material presented in the NODA and in some cases will refer back to that notice. Changes made in response to comments will be highlighted.

*A. Estimates of Costs and Benefits for Community Water Systems*

Two requirements under today's rule are expected to incur costs and benefits: the adoption of the uranium MCL of 30 μg/L and the requirement for separate monitoring of radium-228, which is expected to result in additional systems in violation of the combined radium-226/-228 MCL of 5 pCi/L. EPA estimates that these requirements will result in annual compliance costs of $81 million in 1999 dollars, with $25 million of this annual cost being due to mitigation of systems newly in violation of the radium-226/-228 standard due to new monitoring requirements, $51 million due to mitigation of systems in violation of a uranium MCL of 30 μg/L, $ 4.9 million due to monitoring and reporting by CWSs, and $ 0.06 million due to new implementation costs for States. While these represent new compliance costs, most water systems will experience reduced compliance costs in the long-term because of reduced monitoring frequency for systems with low contaminant levels under the Standardized Monitoring Framework. The basis for these estimates, and

alternate cost estimates using different assumptions are described later in this section.

State implementation and CWS start up costs are estimated to be $10 million annually for the first three years. Of this $10 million, approximately $ 0.25 million are State start up costs with the remainder being comprised by CWS start up costs (USEPA 2000d). Over the first twenty-three year period, the implementation costs for States and CWSs are estimated to be $ 4.9 million annually (included in the annual compliance costs reported previously). These costs include preparation of the primacy application, training, planning, and other compliance preparations, and monitoring and reporting costs for PWSs.

The treatment/non-treatment compliance unit costs and national costing assumptions used in the Economic Analysis (USEPA 2000g) are standard and are consistent with those used for estimating the costs of compliance the other recently proposed drinking water rules. The updated Technologies and Costs document (USEPA 2000i) provides unit capital and "operations & maintenance" costs for water treatment plants, including residuals disposal costs. Typical model small system treatment costs ranged from $ 0.25 to $ 3 per kilogallon of water treated, with associated annual per household costs ranging from $20 to $250, with the value depending upon water system size and water quality. Large system model unit costs ranged from $0.17 to $ 0.28 per kilogallon treated, with associated annual per household costs ranging from $14 to $23.

For various reasons (see the NODA's Technical Support Document for details, USEPA 2000h), the estimate of monetized benefits associated with compliance of today's rule are more uncertain than the costs estimates. In the case of the requirement for separate monitoring for radium-228, cancer risk reduction benefits of $1.7 million annually are expected. While the net benefits for this monitoring change are expected to be negative, this monitoring change is essential for enforcing the combined radium-226/-228 standard. In the case of the uranium standard, the benefits are difficult to monetize, since the number of kidney toxicity cases avoided cannot be estimated using current risk models. For this reason, the uranium kidney toxicity benefits are considered to be "non-quantified benefits" for this rule. As discussed in detail in part D of section I ("Rationale for the Final Uranium MCL"), we consider these non-quantified kidney benefits to be a significant part of this assessment of costs and benefits.

The uranium cancer risk reduction benefits are estimated to be $3 million annually, which, we reiterate, do not include the non-quantified kidney toxicity risk reduction benefits. As discussed in the NODA, there are significant uncertainties associated with any estimate of drinking water benefits, including uncertainties in the unit risks used to estimate risk reductions and the various health endpoints that cannot yet be fully quantifitied.

Other non-quantified benefits include those related to the technologies used to remove radium and uranium from ground water (*e.g.*, water softening technologies like ion exchange, lime softening, and membrane softening and iron removal technologies like green sand filtration and oxidation/filtration). EPA does not have enough information to estimate these benefits, but believes that they could be significant. Examples of benefits related to water softening include reductions in excessive calcium and manganese carbonate scaling in distribution systems, water heaters, and boilers and reductions in soap and detergent use. Examples of benefits related to iron removal include improvements in color and taste and reduction in staining of clothes, sinks, and basins.

*B. Background*

1. Overview of the 1991 Economic Analysis

Many of the options proposed in 1991 economic analysis are not being finalized today. Today's discussion will focus on the analysis of costs and benefits of the options that are being finalized: a final uranium standard and separate monitoring for radium-228. The 1991 economic analysis (USEPA 1991) estimated the annual cost of compliance with a uranium MCL of 20 µg/L to be $55 million, affecting approximately 1,500 systems, the vast majority of them being small systems. The 1991 estimate of the annual cost of compliance with a uranium MCL of 40 µg/L was $23 million. The current estimate of the cost of compliance with a uranium MCL of 20 µg/L is $93 million, impacting 900 systems, most of them small.

2. Summary of the Current Estimates of Risk Reductions, Benefits, and Costs

Table IV–1 shows the summarized results for EPA's analysis of risk reductions, benefits valuations, and costs of compliance (see USEPA 2000g for more detailed break-downs of the risk reductions, costs, and benefits by system size). The risk reductions and cost estimates are based on the estimated range of numbers of community water systems predicted to be out of compliance with the uranium MCL of 30 µg/L and the systems that are predicted to be out of compliance with the current combined radium-226/-228 standard of 5 pCi/L because of the new requirement for separate radium-228 monitoring. The best estimate values shown are the midpoints from ranges that are based on the two occurrence model methodologies described in the NODA (USEPA 2000e), the "direct proportions" and "lognormal model" approaches. As described in the NODA, these two approaches are expected to serve as "low-end" and "high-end" occurrence estimates, respectively.

Eliminating the combined radium-226/-228 monitoring deficiency [11] is predicted to lead to 295 (range of 270 to 320) systems out of compliance with an MCL of 5 pCi/L, affecting 420,000 persons (range 380,000 to 460,000). A uranium MCL of 30 µg/L is predicted to impact 500 systems (range 400 to 590), affecting 620,000 persons (range 130,000 to 1,100,000). The estimates of occurrence and risk reductions for a uranium MCL of 30 µg/L are based on the assumption that the activity-to-mass ratio in drinking water is 0.9 µg/pCi. Based on the available information, the average activity-to-mass ratio for the various uranium isotopes in drinking water typically varies from 0.7 to 1.5 pCi/µg.

The estimated cancer morbidity risk reduction for the option addressing the combined radium monitoring deficiency is 0.4 (0.3 to 0.5) cancer cases avoided annually, with an associated annual monetized benefit of $1.7 million (range of $1.2 to $2.2 million). The annual cancer morbidity risk reduction estimated for a uranium MCL of 30 µg/L is 0.9 cases/year (range 0.1 to 1.6). The associated annual monetized benefit related to uranium cancer risk reduction is $3 million (range from $0.2 to $6 million) [12]. The risk reductions and

[11] The monitoring deficiency is corrected by requiring the separate analysis of radium-228 for systems with gross alpha levels below 5 pCi/L and radium-226 levels below 3 pCi/L.

[12] The Agency has agreed to consider the July 27, 2000 recommendations of its Science Advisory Board (SAB) concerning discounting of benefits in future drinking water regulations. In particular, the SAB recommended that quantitative adjustments to benefits be considered with respect to timing of risk (*e.g.*, consideration of a lag or latency period before the resulting cancer fatality) and income growth. The SAB also recommended that other possible adjustments to benefits estimates be considered in a qualitative manner. We have not made any such adjustments to the benefits associated with today's rule since the principal benefits are non-quantifiable (avoidance of kidney toxicity due to reductions in exposure to uranium). We do not

benefits shown for uranium do not include those related to kidney toxicity, which are non-quantifiable (cases avoided cannot be estimated). As discussed in section I.D.2 of today's final rule, these non-quantifiable benefits are projected to be preventing a series of adverse affects on the functioning of the kidney such as proteinuria (*e.g.*, reabsorption deficiency or leakage of albumin), that could ultimately lead to a more widespread breakdown in kidney tubular function. Such effects on tubular function would be manifested by an impaired ability of the kidneys to filter and reabsorb nutrients and to excrete urine.

Annual compliance costs are estimated to be $25 million (range $16 to $35 million) for the option addressing the combined radium monitoring deficiencies. Annual compliance costs for the uranium NPDWR are predicted to be $51 million (range from $9 to $92 million). In addition to these mitigation related compliance costs, water systems are expected to incur $4.9 million annually in monitoring and reporting costs. As demonstrated by this analysis the estimated range of central-tendency annual compliance costs exceed the ranges of central-tendency annual monetized benefits for both provisions finalized today.

TABLE IV–1.—SUMMARY OF COSTS AND BENEFITS FOR COMMUNITY WATER SYSTEMS PREDICTED TO BE IMPACTED BY THE REGULATORY OPTIONS BEING CONSIDERED FOR FINALIZATION

| Options | Numbers of systems impacted [1] (population exposed above MCL) | Estimated lifetime radiogenic cancer morbidity risk at MCL [2,3,4] | Total cancer cases avoided annually (fatal cases) | Best-estimate value of avoided cancer cases, in millions of $/year) | Best-estimate of annual compliance costs, in millions of $/year) |
|---|---|---|---|---|---|
| **Systems predicted to be impacted by corrections to the monitoring deficiencies for combined radium-226 and -228** | | | | | |
| Eliminate combined radium monitoring deficiency. | 295 systems (420 K persons). | $1\times10^{-4}$ | 0.4 (0.3) | 1.7 | 25 |
| **Systems predicted to be out of compliance with proposed options for uranium MCL** | | | | | |
| Uranium at 30 µg/L | 500 systems (620 K persons). | $1\times10^{-4}$ (assumes 30 pCi/). | 0.9 (0.6) (Total Number of kidney toxicity cases cannot be accurately estimated, but expected to be substantial) | 3.0 Kidney toxicity benefits range from prevention of mild proteinurea to possible more serious impaired kidney tubular function | 51 |

**Notes:** Compliance costs do not include monitoring and reporting costs, which comprise an additional $5 million annually. Ranges based on directly proportional versus lognormal distribution approach.

[1] Compared to the initial baseline (*i.e.*, occurrence data are adjusted to eliminate existing MCL violations) for combined radium. Occurrence data is unadjusted for uranium-options.

[2] 1x10 is equivalent to "one in ten thousand", EPA's usual upper limit of acceptable cancer incidence (morbidity) risk for contaminants in drinking water.

[3] These risk estimates are based on several simplifying assumptions and are only meant to be illustrative. The reported combined radium risk is based on an "occurrence weighted average" for radium-226 and radium-228 ($2.3\times10^{-5}$ per pCi/L). The "best-estimate" for a particular situation would depend on the actual levels of Radium226 and Radium228 that comprise the combined level of 5 pCi/L. Regarding uranium risks, since the individual uranium isotopes that make up naturally-occurring uranium have cancer morbidity risks that are similar in magnitude (6.4 to $7.1\times10^{-11}$ per pCi), the assumptions about isotopic prevalence are not important. Here, we assumed that the simple average applied ($3.83\times10^{-6}$ per pCi/L).

[4] Kidney toxicity is not considered in this estimate of risk or monetized benefits.

3. Uncertainties in the Estimates of Benefits and Cost

The models used to estimate costs and benefits related to regulatory measures have uncertainty associated with the model inputs. The types and uncertainties of the various inputs and the uncertainty analyses for risks, benefits, and costs are qualitatively discussed in this section.

a. Uncertainties in Risk Reduction and Benefits Estimates

For each individual radionuclide, EPA developed a central-tendency risk coefficient that expresses the estimated probability that cancer will result in an exposed individual per unit of radionuclide activity (*e.g.*, per pCi/L) over the individual's lifetime (assumed to be 70 years). Two types of risks are considered, cancer morbidity, which refers to any incidence of cancer (fatal or non-fatal), and cancer mortality, which refers to a fatal cancer illness. For this analysis, we used the draft September 1999 risk coefficients developed as part of EPA's revisions to Federal Guidance Report 13 (FGR–13, EPA 1999e). FGR–13 compiled the results of several models predicting the cancer risks associated with radioactivity. The cancer sites considered in these models include the esophagus, stomach, colon, liver, lung, bone, skin, breast, ovary, bladder, kidney, thyroid, red marrow (leukemia), as well as residual impacts on all remaining cancer sites combined.

There are substantial uncertainties associated with the risk coefficients in FGR–13 (EPA 1999e): researchers estimate that some of the coefficients may change by a factor of more than 10 if plausible alternative models are used to predict risks. While the report does not bound the uncertainty for all radionuclides, it estimates that the central-tendency risk coefficients for uranium-234 and radium-226 may change by a factor of seven depending on the models employed to estimate

believe that adjustments to these monetized cancer avoidance benefits estimates for either timing or income growth would materially affect our benefits assessment or decisions resulting from overall consideration of the benefits and costs of the regulatory standard.

risk.[13] Ranges that reflect uncertainty and variability in the risk coefficients have been used to conduct a sensitivity analysis of risk reductions and benefits, the results of which are reported in Economics Analysis (USEPA 2000g).

Since the available occurrence data do not provide information on the contribution of individual radionuclides or isotopes to the total activities of gross alpha or uranium, there is uncertainty involved in the assumptions about isotopic ratios. These and other uncertainties related to occurrence information (*e.g.*, uncertainty in extending the NIRS database results to the national level) also contribute to uncertainty in the estimates of impacts. Other inputs that were used in the sensitivity analysis of risk reductions and benefits are the age- and gender-dependent distributions of water ingestion, which are used in estimating lifetime exposure, and the credible range for the "value of a statistical life."

b. Uncertainty in Compliance Cost Estimates

Regarding uncertainty in the compliance cost estimates, these estimates assume that most systems will install treatment to comply with the MCLs, while recent research suggests that water systems usually select compliance options like blending (combining water from multiple sources), developing new ground water wells, and purchasing water (USEPA 2000g). As discussed in the NODA, preliminary data (202 compliance actions from 14 States) on nitrate violations suggest that only around a quarter (25%) of those systems taking action in response to a nitrate violation installed treatment, while roughly a third developed a new well or wells. The remainder either modified the existing operations (10–15%), blended (15%), or purchased water (15–20%). Similar data for radium violations from the State of Illinois (77 compliance actions) indicate that around a quarter of systems taking action installed treatment, while the majority (50–55%) purchased water, with the remainder (20–25%) either installing a new well, blending, or stopping production from the contaminated well or wells. EPA will continue to gather information regarding the prevalence of treatment versus non-treatment options for compliance for other contaminants. At this time, this data is considered preliminary and will be used for comparisons only.

To evaluate the potential variability in the compliance cost estimates, EPA has performed a sensitivity analysis for uncertainties in the decision tree by varying the assumed percentages for the modeled compliance options. Since per system costs are much higher for very large systems, the assumptions used in the large water system size categories can be expected to dominate the variability in national costs. The sensitivity analysis results are reported in the Economic Analysis (USEPA 2000g).

4. Major Comments

Following is a summary of the major comments received on the analysis of costs and benefits for the finalization of the radionuclides rule.

a. Retention of radium-226/-228 MCL of 5 pCi/L: Several commenters suggested that the costs and benefits of compliance with the existing radium-226/-228 MCL should be included in the analysis of the costs and benefits of the finalization of today's rule, because "systems currently in non-compliance with the combined radium MCL are in that situation because of EPA's proposed rule changes in 1991." EPA disagrees with this comment since all of MCLs for the currently regulated radionuclides, including radium-226/-228 have been fully enforceable since 1976. While some may argue that the radionuclides rules were "National Interim Primary Drinking Water Regulations" (NIPDWRs) between 1976 and 1986, NIPDWRs were fully enforceable. In addition, six years elapsed between the re-authorization of the Safe Drinking Water Act (1986), which finalized all NIPDWRs, and the 1991 proposal. Given the fact that 25 years have elapsed since this MCL became an enforceable standard, EPA believes that it is appropriate to consider only the costs and benefits of the changes that are being made in the current standards. In view of the fact that 25 years have elapsed since this MCL became an enforceable standard, EPA believes that is appropriate to consider only the costs and benefits of the changes that are made to the current radium standards as a cost of today's rule. EPA further believes that any costs incurred by facilities that are required to comply with the 1976 rule represent deferred costs that those facilities elected not to expend until now.[14]

b. Cost/Benefit Analysis Requirements: One commenter suggested that the analysis of costs and benefits, as presented in the Notice of Data Availability (USEPA 2000e) omitted some information required under section 1412(b)(4)(C) of the 1996 SDWA. EPA disagrees with this comment. All of the required information relevant to the analysis of costs and benefits for the options considered are found in the draft Health Risk Reduction and Cost Analysis (HRRCA, USEPA 2000f), which was announced by and described in the NODA. In the HRRCA, EPA did meet the requirements of the Safe Drinking Water Act for performing analyses of costs and benefits. For compliance with each regulatory option being considered, EPA updated the analysis supporting the 1991 radionuclides proposal, including estimates of quantifiable and non-quantifiable health risk reduction benefits, quantifiable and non-quantifiable health risk reduction benefits likely to occur from reductions in co-occurring contaminants (excluding those associated with compliance with other proposed or promulgated regulations), quantifiable and non-quantifiable costs, the incremental costs and benefits for the uranium options, the effects of the contaminant on the general population and on sensitive groups within the population (*e.g.*, children), and other relevant factors. In addition to the HRRCA, EPA is supporting today's final actions with a Economic Analysis (USEPA 2000g) that builds on the HRRCA, including some changes made in response to comments received.

c. Cumulative Affordability: Several commenters suggested that EPA consider the cumulative impact of its regulations on the affordability of water service, as opposed to looking at affordability one regulation at a time. EPA agrees that it would be best to look at "cumulative affordability," since this is the only realistic indicator of affordability. For this reason, EPA includes a "water bill baseline" in its affordability assessments, which includes cumulative impacts from existing regulations. When a rule is promulgated, the water bill baseline increases and the estimate of affordability decreases, the details of which depend on the percentages of systems impacted and the estimates of the annual per household costs associated with the regulation. The affordability assessment supporting the uranium small systems compliance

[13] Table 2.4, Uncertainty Categories for Selected Risk Coefficients. Federal Guidance Report 13 (1999).

[14] It is difficult to estimate these costs due to recent efforts by many CWSs to comply with the current radium rule, however, we would expect approximately 200–400 systems would spend in the range of $18–36 million annually to comply with the current standard. (Low estimate in range is based on recent SDWIS data; high estimate is based on 1984 NIRS occurrence database.)

technology list is based on the current baseline, which is described in "Variance Technology Findings for Contaminants Regulated Before 1996", which can be downloaded at "http://www.epa.gov/OGWDW/standard/varfd.pdf." As future rules are promulgated that impact small water systems (including this one), this baseline will be revised.

d. Disposal costs: One commenter suggested that EPA "did not adequately address the disposal of waste stream residuals" in the NODA and that waste disposal costs are a "significant factor" in estimating costs. EPA agrees that waste disposal considerations are very important when considering the implementation of this rule. Since the only MCL that EPA is finalizing today is the uranium MCL (the others are existing regulations), this is the only MCL that could be impacted by this consideration. In estimating the compliance costs for today's actions, EPA did include waste disposal costs in its estimate of treatment costs, including estimated waste-related capital costs, operations and maintenance costs, and residuals disposal. EPA believes that its estimate of residuals disposal are adequate and are based on the best available information.

e. Discounting of Costs and Benefits: One commenter stated that it is "appropriate and standard practice to ensure that costs and benefits be evaluated on the same basis to avoid apples and oranges comparison," further stating that EPA should discount both or neither. EPA agrees that costs and benefits should be evaluated in such a way that they can be compared.

One approach to accomplish this is to annualize the costs and benefits of the regulation. In such instances, the capital costs, paid up front, need to be spread out across the life of the equipment. To do that, one needs to reflect the time value of resources. The analyst must ask the question: What is the annual payment that could finance the capital investment? Such a calculation would reflect the social discount rate. Annual operations and maintenance (O&M) costs would not have to be annualized, since these costs are assumed to be accrued on a continual basis each year.

Ideally, the analysis would also annualize the benefits using the same techniques. As noted previously, we have not made any such adjustments to the benefits associated with today's rule for uranium since the principal benefits are non-quantifiable (avoidance of kidney toxicity due to reductions in exposure to uranium). We do not believe that adjustments to these benefits estimates for either timing or income growth would materially affect our benefits assessment or decisions resulting from overall consideration of the benefits and costs of the regulatory standard.

f. Use of MCLs for Ground Water Protection Needs to be Evaluated as Part of this Rulemaking: One commenter stated that, since linkages are made between drinking water standards and "clean-up standards" for radioactively contaminated sites, the costs and benefits of applying drinking water standards to clean-up efforts should be evaluated as part of this rulemaking. EPA disagrees that clean-up costs and benefits should be used to influence the setting of drinking water MCLs. EPA does, however, agree that cross-program costs and benefits should be considered when appropriate. In this case, it is inappropriate to consider clean-up and ground water protection costs since MCLs are set specifically and solely with drinking water exposures in mind. If another program or Agency applies these MCLs for other purposes (*e.g.*, clean-up standards), then the costs and benefits of that application should be considered when evaluating that application.

## V. Other Required Analyses and Consultations

### *A. Regulatory Flexibility Act (RFA)*

The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 USC 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. sec. 601(3)–(5). In addition to the above, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be CWSs serving fewer than 10,000 persons. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. Because this definition does not correspond to the definitions of "small" for small businesses, governments, and non-profit organizations, EPA requested comment on an alternative definition of "small entity" in the preamble to the proposed Consumer Confidence Report (CCR) regulation (63 FR 7620, February 13, 1998). Comments showed that stakeholders support the proposed alternative definition. EPA also consulted with the Small Business Administration's Office of Advocacy on the definition as it relates to small business analysis. In the preamble to the final CCR regulation (63 FR 4511, August 19, 1998), EPA expressed its intention to use this alternative definition for regulatory flexibility assessments under the RFA for all drinking water regulations and has thus used it in this final rulemaking.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the 1991 proposed rule (see 56 FR 33050). Since the proposed rule (July 18, 1991) pre-dated the 1996 Amendments to the RFA, EPA did not convene a Small Business Advocacy Review Panel for this rule.

We also prepared a final regulatory flexibility analysis (FRFA) for today's final rule. The FRFA addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA is available for review in the docket and is summarized below.

The RFA requires EPA to include the following when completing an FRFA:

(1) A succinct statement of the need for, and objectives of the rule;

(2) A summary of the significant issues raised by the public comments on the IRFA, and a summary of the assessment of those issues, and a statement of any changes made to the proposed rule as a result of those comments;

(3) A description of the types and number of small entities to which the rule will apply and the impact they will experience, or an explanation why no estimate is available;

(4) A description of reporting, record keeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the rule and the type of professional skills necessary for preparation of reports or records; and

(5) A description of the steps the Agency has taken to minimize the significant impact on small entities consistent with the stated objectives of

the applicable statutes, including a statement of the factual, policy, and legal reasons why we selected the chosen alternative in the final rule and why the other significant alternatives to the rule were rejected.

EPA has considered and addressed all of the requirements. The following is a summary of the FRFA. The need for and objectives for the rule are discussed in sections I.A, I.B, I.C and II.A of this preamble. Requirements "2" through "4" are addressed in the subsections that follow. The fifth requirement is discussed in sections I.D and I.J., which provide information about steps EPA has taken that will lessen impacts on small systems, including: (1) The selection of the less stringent uranium MCL, (2) overall reduced monitoring frequencies for systems with radionuclides levels less than the MCL, (3) allowance of grandfathering of data and State monitoring discretion for determining initial monitoring baseline, and (4) exclusion of NTNCWS from the regulation. Sections I.C. and I.B provide the rationale for the retention of the MCLs for radium-226 and -228, gross alpha, and photon/beta emitters.

The significant issues raised in public comments were the high cost of compliance for small systems and high cumulative costs for water contaminant testing. EPA understands these concerns and has made several changes to the proposed rule that will reduce cost impacts to small systems. In addition, commenters disagreed with the proposal to include NTNC water systems in the rule. Based on several factors, including these comments and the analyses of risks faced by NTNC customers, risk reductions, benefits, and costs, EPA has decided that additional future analyses and reevaluation, together with any new data that can be obtained is needed before regulating radionuclides at NTNC drinking water systems (see section I.D.8. for further discussion). This information will be collected and future regulatory action will be assessed under the regulatory review process. A complete summary of comments received and EPA's responses can be obtained from the docket (USEPA 2000a).

For many small entities, today's final rule will reduce long-term monitoring costs because the rule provides for less frequent follow-up monitoring (relative to the 1976 rule) for systems if they have radionuclides levels (e.g., gross alpha and radium-226 and -228) below the MCLs (most small systems). For example, under the 1976 rule, a system with a gross alpha level less than the MCL but greater than ½ MCL is required to monitor four times in a four year period. The revised monitoring scheme will allow this system to reduce the monitoring frequency to one sample every three years or less. In addition, EPA is giving States discretion in using historical monitoring data (grandfathering) to determine the initial monitoring baseline for systems. Therefore, systems with sufficient data may not be required to take four quarterly samples for the initial monitoring period and may immediately begin reduced monitoring (*e.g.*, one sample per three years, six years, or nine years) after the rule is effective (*e.g.*, three years after the rule is promulgated). See sections I.D "How has this new information impacted the regulatory decisions being promulgated today?" and I.J "Where and how often must a water system test for radionuclides?" for additional information about monitoring. A small percentage (<1.5%) of systems are expected to exceed the radium-226 and-228 and uranium MCLs and will be required to take action to come into compliance.

The number of small entities subject to today's rule is shown in Table V–1.

TABLE V–1.—SUMMARY OF ANALYSIS RESULTS

From the "Economic Analysis of the Radionuclides NPDWR" (USEPA 2000g)

| Community water system size class (25 to 10,00) | Ground water systems | | | | | | Surface water systems | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Combined radium loop-hole | | Uranium (20µg/L) | | Uranium (40 µg/L) | | Uranium (20 µg/L) | | Uranium (40 µg/L) | |
| | Number of systems | Cost/ Rev-enue [1] | Number of systems | Cost/ Rev-enue [1] | Number of systems | Cost/ Rev-enue [1] | Number of systems | Cost/ Rev-enue [1] | Number of systems | Cost/ Rev-enue [1] |
| Total ..... | 270–310 | [2] 1–2 | 820–900 | [2] 1–3 | 300–400 | [2] 1–3 | < 10–40 | [2] 1–3 | 0–20 | [2] 0–3 |

**Notes:**

[1] As reported in the economic analysis support document (USEPA 2000g), the revenue portion of the cost per revenue estimates are based on data collected the 1992 Census of Governments. The Agency then estimated average revenues for small governments.

The reported ranges represent results using the directly proportional approach followed by results using the lognormal distribution approach.

"0" indicates that no systems in this category are expected to be out of compliance with the MCL.

Revenue estimates are taken from Exhibit 6–3 of the economic analysis support document (USEPA 2000g).

See Appendix G of the economic analysis support document (USEPA 2000g) for information regarding the number of affected for the 25 to 10,000 size class and the associated costs. Detail does not add to totals due to rounding.

[2] Percent.

Small systems are also required to provide information in the Consumer Confidence Report or other public notification if the system exceeds one of the MCLs. As is the case for other contaminants, required information on radionuclides levels must be provided by affected systems and is not considered to be confidential. The professional skills necessary for preparing reports are the same skill level required by small systems for current reporting and monitoring requirements for other drinking water standards.

In addition to the public comments on the proposal, the Agency considered comments received through an outreach process that obtained input from small entities, including a Stakeholders meeting, Tribal consultations, and other consultations. After considering all the input from stakeholders as well as its own analyses, the Agency has included several measures in today's rule that should reduce the burden on small drinking water systems: (1) A revised monitoring scheme with long-term monitoring reduction for most small systems; (2) State discretion for grandfathering existing monitoring data; (3) the decision not to regulate non-transient, non-community water systems, which are generally very small water systems; and (4) the selection of a uranium MCL that is less stringent than the 1991 proposed feasible level. The uranium MCL is still protective of public health with an adequate margin

of safety, but will impact fewer small systems, reducing the number of systems that may face waste disposal issues, and increasing the likelihood that non-treatment options for achieving compliance may be used. These items are discussed in more detail in sections I.D and I.J.

EPA also is preparing a small entity compliance guide to help small entities comply with this rule. Small entities will be able to access a copy of this guide at: *http://www.epa.gov/sbrefa/* (to be available within 60 days of the publication of the rule in the **Federal Register**).

*B. Paperwork Reduction Act*

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number—2040–0228

Under this rule, respondents to the monitoring, reporting, and recordkeeping requirements include the owners and operators of community water systems and State officials that must report data to the Agency. Monitoring for radium-228, uranium, and beta and photon emitters will be required at each entry point to the distribution system under the final radionuclides rule. States will have discretion in grandfathering existing data for determining initial monitoring baselines for the currently regulated contaminants, combined radium-226/-228, gross alpha particle activity, and beta particle and photon radioactivity.

EPA has estimated the burden associated with the specific information collection, record keeping and reporting requirements of the proposed rule in the accompanying Information Collection Request (ICR). The ICR for today's final rule compares the current requirements to the revised requirements for information collection, reporting and record-keeping. There are several activities that the State and the CWSs must perform in preparing to comply with the revised Radionuclides Rule. Start-up activities include reading the final rule to become familiar with the requirements and training staff to perform the required activities.

For PWSs, the number of hours required to perform each activity may vary by system size. This rule only applies to community-water systems. As shown in Table V–2, there are approximately 53,121 CWSs and 56 States and territories considered in this ICR (a total of 53,177 respondents). During the first three years after promulgation of this rule, the average burden hours per respondent per year is estimated to be 6 hours for PWSs and 115 hours for States. During this period, the total burden hour per year for the approximately 53,177 respondents covered by this rule is estimated to be 342,873 hours to prepare to comply with this revised Radionuclide Rule. There are no new monitoring, record-keeping, reporting or equipment costs for CWSs during the first three-year period, hence no responses are expected from the CWSs. The average number of responses for the States is expected to be 37 per year during the first three year period. Total annual labor costs during this first 3 year period are expected to be about $10 million per year for CWS.

TABLE V–2.—AVERAGE BURDEN, RESPONDENTS, AND RESPONSES DURING THE THREE-YEAR ICR APPROVAL PERIOD

| | CWSs | States | Total (each year) |
|---|---|---|---|
| Average Burden Hours per Year | 336,433 | 6,440 | 342,873 |
| Average Respondents per Year | 53,121 | 56 | 53,177 |
| Average Burden Hours per Respondent per Year | 6 | 115 | 121 |
| Average Responses per Year | [1] 0 | 33 | 33 |
| Average Burden Hours per Response per Year | [1] 0 | 17 | 17 |
| Average Responses per Respondent per Year | [1] 0 | [2] .66 | .66 |

[1] Preparation only.
[2] Two over 3-year period.

TABLE V–3.—SUMMARY OF BURDEN AND COSTS FOR THE RADIONUCLIDES RULE FOR THE ICR APPROVAL PERIOD

| Respondent Category | Number of respondents annually | Number of responses annually | Total annual burden (hours) | Total annual labor costs ($ dollars) | Total annual capital cost | Total annual O&M cost |
|---|---|---|---|---|---|---|
| CWSs | 53,121 | ([1]) | 336,433 | $9,925,042 | 0 | 0 |
| States | 56 | [2] 37 (2 per respondent over 3 year period) | 6,440 | 247,905 | 0 | 0 |
| Total | 53,177 | 33 | 342,873 | 10,172,947 | 0 | 0 |

[1] Preparation only.
[2] Two per respondent over 3-year period.

Three years after the promulgation date, community water systems will begin collecting mandatory monitoring data as described earlier in this section. As reported in the ICR (using a 7% discount rate over a 23 year period), EPA estimates that today's revisions to monitoring will result in a national annual monitoring, reporting and record keeping burden of $ 4.85 million (25,197 hours) for all CWSs and an average annual programmatic burden of $63,723 (4,170 hours) for States (total for all 56 jurisdictions) over the first 23 years after promulgation of this rule (see Table V–4).

TABLE V–4.—SUMMARY OF BURDEN AND COSTS FOR THE RADIONUCLIDES RULE FOR THE POST-ICR APPROVAL PERIOD

| Respondent category | Number of respondents annually | Number of responses annually | Total annual burden (hours) | Total annual labor costs | Total annual capital cost | Total annual O&M cost (monitoring) |
|---|---|---|---|---|---|---|
| CWSs | 53,121 | 50,394 | 25,197 | $537,574 | 0 | $4,855,439 |
| States | 56 | 224 | 4,170 | 63,723 | 0 | 63,723 |
| Total | 53,177 | 50,618 | 29,367 | 601,297 | 0 | 4,919,162 |

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing procedures to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. EPA is amending the table in 40 CFR part 9 of the currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule.

*C. Unfunded Mandates Reform Act*

1. Summary of UMRA Requirements

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub.L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under UMRA section 202, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule, for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The estimated total annual compliance costs of the final rule is 83 million (See section IV. Economic Analyses for additional information). Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA. This rule will establish requirements that affect small community water systems. EPA has determined that this rule may contain regulatory requirements that significantly or uniquely affect small governments. As described in part A of this section, EPA has provided all public water systems (including small systems) with opportunities to provide input into the development of this rule and to be informed about the requirements for compliance.

*D. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (Pub. L. 104–113, section 12(d), 15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, material specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide to Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

Today's rule does not establish any technical standards, thus, NTTAA does not apply to this rule. It should be noted, however, that systems complying with this rule need to use previously approved technical standards already included in § 141.25. Currently, a total of 89 radiochemical methods are approved for compliance monitoring of radionuclides in drinking water. Of these methods, twenty-four (24) are approved by the Standard Methods Committee and are described in the "Standard Methods for the Examination of Waste and Wastewater (13th, 17th, 18th, and 19th editions)," which was prepared and published by the American Public Health Association. In addition, twelve of the approved radiochemistry methods are from the American Society for Testing and Materials (ASTM) and are described in the Annual Book of ASTM Standards. These methods and their references are provided in Table I–8 (shown in section I of this preamble).

*E. Executive Order 12866: Regulatory Planning and Review*

Under Executive Order 12866, [58 FR 51735 (October 4, 1993)] the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant

regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order."

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action." As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

*F. Executive Order 12898: Environmental Justice*

Executive Order 12898 "Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations," (59 FR 7629, February 16, 1994) establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice-related issues concerning the potential impacts of this action and has consulted with minority and low-income stakeholders by convening a stakeholder meeting via video conference specifically to address environmental justice issues.

As part of EPA's responsibilities to comply with E.O. 12898, the Agency held a stakeholder meeting via video conference on March 12, 1998, to highlight components of pending drinking water regulations and how they may impact sensitive sub-populations, minority populations, and low-income populations. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants included national, State, tribal, municipal, and individual stakeholders. EPA conducted the meeting by video conference call between eleven cities. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's Drinking Water programs. The major objectives for the 1998 meeting were:

(1) Solicit ideas from Environmental Justice (EJ) stakeholders on known issues concerning current drinking water regulatory efforts;

(2) Identify key issues of concern to EJ stakeholders; and

(3) Receive suggestions from EJ stakeholders concerning ways to increase representation of EJ communities in OGWDW regulatory efforts.

In addition, EPA developed a plain-English guide specifically for this meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulations. A meeting summary for the March 12, 1998 Environmental Justice stakeholders meeting (USEPA 1998J) is available in the public docket for this final rulemaking.

The radionuclides rule applies to all community water systems, which will provide equal health protection for all minority and low-income populations served by systems regulated under this rule from exposure to radionuclides.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Was initiated after April 21, 1997, or for which a Notice of Proposed Rulemaking was published after April 21, 1998; (2) is determined to be "economically significant" as defined under E.O. 12866, and (3) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets all three criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to the Executive Order because EPA published a notice of proposed rulemaking before April 21, 1998. However, EPA's policy since November 1, 1995 is to consistently and explicitly consider risks to infants and children in all risk assessments generated during its decision making process including the setting of standards to protect public health and the environment.

Today's action primarily involves retaining the current MCLs for the regulated radionuclides, rather than adopting the less stringent 1991 proposed MCLs for the regulated radionuclides. In addition, an MCL for uranium, currently unregulated, is promulgated in today's rule. Since today's rule involves the decision to retain the more stringent current MCLs and to adopt a uranium MCL that is protective of both kidney toxicity and radiological carcinogenicity, today's action is consistent with greater protection of children's health.

The cancer risks estimated and presented in today's final rule explicitly account for differential cancer risks to children. In the case of uranium kidney toxicity, there is no information that suggests that children are a sensitive subpopulation. However, as discussed in the Notice of Data Availability (USEPA 2000e), the Agency does have reason to believe that radionuclides in drinking water present higher unit risks to children than to adults, since there is evidence that children are more sensitive to radiation than adults. Because of this, we have explicitly considered the risks to children in evaluating the lifetime risks associated with the current MCLs and 1991 proposed MCLs. In other words, the lifetime risks that are reported for each MCL are integrated over the entire lifetime of the individual and include the risks incurred during childhood.

In more detail, the per unit dose risk coefficients used to estimate lifetime risks are age-specific and organ-specific and are used in a lifetime risk model that applies the appropriate age-specific sensitivities throughout the calculation. The model also includes age-specific changes in organ mass and metabolism, which further incorporates age-specific effects pertinent to age sensitivity. The risk estimate at any age is the best estimate of risk for an individual of that age, so the summation of these age-specific risk estimates over all ages is best estimate of the lifetime risk for an individual. In developing the lifetime risks, the model calculates the risks over an age distribution for a stationary population to simulate the lifetime risk of an individual. The model also accounts for competing causes of death and age-specific survival rates. These adjustments make the lifetime risk estimate more realistic. At the same time, consumption rates of food, water and air are different between adults and children. The lifetime risk estimates for radionuclides in water use age-specific water intake rates derived from average

national consumption rates when calculating the risk per unit intake.

While radiation protection organizations have developed the concept of committed dose, the dose to an organ or tissue from time of intake to end of life, there is no equivalent for risk. If we define "committed risk" as the lifetime risk from a given intake, then it will be easier to compare the risks of intakes at different times of life. In Table V–5, the "committed risk" is given for 5 isotopes and 5 periods of life and continuous lifetime exposure. If the radionuclide concentration in the water is kept constant, the fraction of the lifetime risk committed during any age interval will also remain constant. Unless the intake is restricted in an age-specific manner, the fraction of the lifetime risk contributed by any age interval is a constant.

TABLE V–5.—LIFETIME RISKS AND FRACTIONS OF LIFETIME RISK PER AGE GROUP

| Age (yrs) | 0–6 | 6–18 | 18–30 | 30–70 | 70–110 | 0–110 |
|---|---|---|---|---|---|---|
| **Lifetime risk for intake of water containing 1 Bq/L during several different age intervals** | | | | | | |
| Ra-224 | 2.3e–05 | 3.3e–05 | 1.1e–05 | 1.5e–05 | 9.8e–07 | 8.4e–05 |
| Ra-226 | 2.9e–05 | 8.6e–05 | 5.0e–05 | 5.1e–05 | 2.9e–06 | 2.2e–04 |
| Ra-228 | 1.1e–04 | 2.6e–04 | 1.2e–04 | 1.1e–04 | 5.1e–06 | 6.1e–04 |
| U-238 | 6.7e–06 | 1.2e–05 | 6.1e–06 | 9.8e–06 | 3.7e–07 | 3.4e–05 |
| H-3 | 3.9e–09 | 8.5e–09 | 6.2e–09 | 9.6e–09 | 6.7e–10 | 2.9e–08 |
| **Percentage of lifetime risk committed for water intake during the age interval** | | | | | | |
| Ra-224 | 28 | 40 | 13 | 18 | 1 | 100 |
| Ra-226 | 13 | 39 | 23 | 23 | 1 | 100 |
| Ra-228 | 17 | 43 | 20 | 19 | 1 | 100 |
| U-238 | 19 | 33 | 18 | 28 | 1 | 100 |
| H-3 | 13 | 29 | 21 | 33 | 2 | 100 |

In summary, today's decision to retain the current more stringent MCLs for radionuclides and to establish an MCL for uranium in drinking water is consistent with the protection of children's health. In making this decision, EPA evaluated the lifetime radiogenic cancer risks associated with the current and final MCLs, which are based on age-specific cancer risk models that explicitly consider children's higher per unit dose risks.

*H. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments*

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute if it significantly or uniquely affects the communities of Indian tribal governments and imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments or if EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

EPA does not believe that today's rule significantly or uniquely affect the communities of Indian tribal governments nor does it impose substantial direct compliance costs on these communities. The provisions of today's rules apply to all community water systems. Tribal governments may be owners or operators of such systems, however, nothing in today's provisions uniquely affects them. EPA believes that the final rule will not significantly burdens most Tribal systems, and in some cases, will be less burdensome than the current radionuclides rule. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

Nonetheless, EPA did inform and involve Tribal governments in the rulemaking process. EPA staff attended the 16th Annual Consumer Conference of the National Indian Health Board on October 6–8, 1998 in Anchorage, Alaska. Over nine hundred attendees representing Tribes from across the country were in attendance. During the conference, EPA conducted two workshops for meeting participants. The objectives of the workshops were to present an overview of EPA's drinking water program, solicit comments on key issues of potential interest in upcoming drinking water regulations, and to solicit advice in identifying an effective consultative process with Tribes for the future.

EPA, in conjunction with the Inter Tribal Council of Arizona (ITCA), also convened a Tribal consultation meeting on February 24–25, 1999, in Las Vegas, Nevada to discuss ways to involve Tribal representatives, both Tribal council members and tribal water utility operators, in the stakeholder process. Approximately twenty-five representatives from a diverse group of Tribes attended the two-day meeting. Meeting participants included representatives from the following Tribes: Cherokee Nation, Nezperce Tribe, Jicarilla Apache Tribe, Blackfeet Tribe, Seminole Tribe of Florida, Hopi Tribe, Cheyenne River Sioux Tribe, Menominee Indian Tribe, Tulalip Tribes, Mississippi Band of Choctaw Indians, Narragansett Indian Tribe, and Yakama Nation.

The major meeting objectives were to:

(1) Identify key issues of concern to Tribal representatives;

(2) Solicit input on issues concerning current OGWDW regulatory efforts;

(3) Solicit input and information that should be included in support of future drinking water regulations; and

(4) Provide an effective format for Tribal involvement in EPA's regulatory development process.

EPA staff also provided an overview on the forthcoming radionuclides rule at the meeting. The presentation included the health concerns associated with radionuclides, EPA's current position

on radionuclides in drinking water, and specific issues for Tribes. The following questions were posed to the Tribal representatives to begin discussion on radionuclides in drinking water:

(1) What are the current radionuclides levels in your water systems?

(2) Are you treating for radionuclides if they exceed the MCL? Is it effective and affordable?

(3) What are Tribal water systems affordability issues in regard to radionuclides?

(4) Would in home treatment units be an acceptable alternative to central treatment?

(5) What level of monitoring is reasonable?

The summary for the February 24–25, 1999 meeting was sent to all 565 Federally recognized Tribes in the United States.

EPA also conducted a series of workshops at the Annual Conference of the National Tribal Environmental Council which was held on May 18–20, 1999 in Eureka, California. Representatives from over 50 Tribes attended all, or part, of these sessions. The objectives of the workshops were to provide an overview of forthcoming EPA regulations affecting water systems; discuss changes to operator certification requirements; discuss funding for Tribal water systems; and to discuss innovative approaches to regulatory cost reduction. Meeting summaries for EPA's Tribal consultations are available in the public docket for this rulemaking (USEPA 1999c, USEPA 1999d).

*I. Executive Order 13132*

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications'are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule

Although Executive Order 13132 does not apply to this rule, EPA did consult with representatives of State and local elected officials in the process of developing this final regulation. On May 30, 2000, EPA held a one-day meeting in Washington, DC with representatives of elected State and local officials to discuss how upcoming drinking water regulations may affect State, county, and local governments. The rules discussed were: Arsenic, Radon, Radionuclides, Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule, and the Ground Water Rule. EPA invited associations which represent elected officials, including National Governors' Association (NGA), National League of Cities (NLC), Council of State Governments (CSG), U.S. Conference of Mayors, International City/County Management Association (ICMA), National Association of Counties (NACO), National Association of Towns and Townships, and National Conference of State Legislators (NCSL). EPA also invited the National Association of Attorneys General (NAAG), the Association of State and Territorial Health Officials (ASTHO), the Environmental Council of States (ECOS), and the Southern Govenors' Association (SGO). With the invitation letter, EPA provided an agenda and background information about the five upcoming drinking water rules, including today's rule.

Ten representatives of elected officials participated in the one-day meeting, which included State of Florida—Governor Bush's Office, State of Ohio-Governor Taft's Office, NGA, NACO, NAAG, NLC, ECOS, ICMA, SGO, and ASTHO. The meeting encompassed presentation and discussion about each of the five rules. The purpose of the meeting was to:

- Provide information about the five upcoming drinking water regulations;
- Consult on the expected compliance and implementation costs of these rules for State, county, and local governments; and
- Gain a better understanding of State, county, and local governments' and their elected officials' views.

Following the meeting, EPA sent the materials presented and distributed at the meeting to the organizations that were not able to attend, in order to provide them additional information about the upcoming regulations. EPA has prepared a meeting summary which provides in more detail the participants' concerns and questions regarding each rule. This summary is available in the public docket supporting this rulemaking (USEPA 2000c).

This meeting was not held sooner due to the relatively recently signed Executive Order and the need to consider how to best comply with its terms and conditions. Thus, many of the issues associated with today's rulemaking were in relatively advanced stages of development by the time of the May 30, 2000 meeting. Nevertheless, we endeavored to accommodate each of the comments received from elected officials or their representatives to the maximum extent possible, within the constraints imposed by our statutory mandate to protect public health through the promulgation of drinking water standards.

The principal concerns of these officials were the overall burden of the rule and the potentially high costs of compliance with its provisions. In particular, they expressed concerns about the affordability for the rule for small systems and costs for disposal of treatment residues that may be considered hazardous due to radioactivity. In response, we took several steps to address these particular concerns as well as actions in response to the generalized concern about the overall burden of the rule.

EPA believes that today's regulatory action is necessary to reduce kidney toxicity and cancer health risks from uranium, as well as to maintain public health protection resulting from the current radionuclide National Primary Drinking Water Regulations. The Agency understands the officials' concerns about regulatory burden and have addressed them in several ways. First, EPA selected a less stringent MCL for uranium of 30 μg/L by invoking the discretionary authority for the Administrator to set an MCL less stringent than the feasible level if the benefits of an MCL set at the feasible level would not justify the costs (section 1412(b)(6)). As a result, fewer water systems will be in violation of the uranium MCL, reducing the number of systems that may face radioactive waste disposal issues, and resulting in the ability of a higher percentage of water systems to use non-treatment options for achieving compliance (*e.g.*, new wells, blending of water sources, modifying existing operations, etc.).

To further mitigate impacts on water systems and State drinking water programs, EPA is allowing State discretion in grandfathering data for determining initial monitoring frequency. Since the data grandfathering plan will be a part of a State's primacy package, EPA will have oversight over the data grandfathering process. EPA believes that this approach provides flexibility for States to consider their

particular circumstances, while allowing EPA to ensure that goals are met. Under this approach, many systems will be able to use existing monitoring data to establish initial monitoring baselines, which will be used to determine future monitoring frequency under the Standardized Monitoring Framework. Water systems that do not have adequate data to grandfather will be required to follow the requirements for new monitoring. The details of these requirements can be found in part J of section I, "Where and how often must a water system test for radionuclides?" EPA expects that there will be overall reduced monitoring burden in the long-term, with monitoring relief being targeted towards those water systems that have low radionuclide levels. Today's final rule will not apply to non-transient, non-community water systems (*e.g.*, schools, state parks, nursing homes), which are primarily small ground water systems.

EPA will provide guidance to small water systems on complying with today's rule. This will include information on monitoring, treatment technology and other compliance options, including information on the disposal of water treatment residuals. Regarding the cost of treatment, EPA agrees that treatment technologies can be expensive for small water systems. However, EPA expects that many small water systems will rely on other compliance options, *e.g.*, alternate source, purchasing water, and point-of-use devices. In cases in which small water systems have no other option and cannot afford to install treatment, they may apply to the State for exemptions (see part M of section I, "Can my water system get a variance or an exemption?"), which gives them extra time. An exemption is limited to three years after the otherwise applicable compliance date, although extensions up to a total of six additional years may be available to small systems under certain conditions. If a water system has very high contaminant levels and no compliance options other than treatment, the water system can apply for a variance, under the requirements described in part M of section I. In addition, there are various sources of funding for State and local governments, including the Drinking Water State Revolving Fund, which is described in part M of section I, "What financial assistance is available for complying with the rule?"

*J. Consultation With the Science Advisory Board and the National Drinking Water Advisory Council*

In accordance with section 1412(d) and (e) of SDWA, EPA consulted with the Science Advisory Board and National Drinking Water Advisory Council and considered their comments in developing this rule. See the OW Docket for additional information.

*K. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective December 8, 2003.

## VI. References


NIH 2000a. "Kidney Diseases: Publications On-Line." National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). June 2000. National Institutes of Health.

NIH 2000b. "Proteinuria." National Kidney and Urologic Diseases Information Clearinghouse. June 2000. National Institutes of Health.

NIH 2000c. "Your Kidneys and How They Work." National Kidney and Urologic Diseases Information Clearinghouse. June 2000. National Institutes of Health.

USEPA 1991. "Regulatory Impact Analysis of Proposed National Primary Drinking Water Regulations for Radionuclides (Draft dated June 14, 1991). Prepared by Wade Miller Associates.

USEPA 1994. Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994.

USEPA 1998a. "A Fact Sheet on the Health Effects from Ionizing Radiation." Prepared by the Office of Radiation & Indoor Air, Radiation Protection Division. EPA 402–F–98–010. May 1998.

USEPA 1998b. Announcement of Small System Compliance Technology Lists for Existing National Primary Drinking Water Regulations and Findings Concerning Variance Technologies, 63 FR 42032, August 6, 1998.

USEPA 1998c. "Ionizing Radiation Series No. 1." Prepared by the Office of Radiation & Indoor Air, Radiation Protection Division. EPA 402–F–98–009. May 1998.

USEPA 1998d. National Primary Drinking Water Regulations: Consumer Confidence; Proposed Rule 63 FR 7605, February 13, 1998.

USEPA 1998e. National Primary Drinking Water Regulation: Consumer Confidence Reports; Final Rule, 63 FR 44511, August 19, 1998.

USEPA 1998f. "Small System Compliance Technology List for the Non-Microbial Contaminants Regulated Before 1996." EPA–815–R–98–002. September 1998.

USEPA 1999a. "Small Systems Compliance Technology List for the Radionuclides Rule." Prepared by International Consultants, Inc. Draft. April 1999.

USEPA 1999b. Cancer Risk Coefficients for Environmental Exposure to Radionuclides, Federal Guidance Report No. 13. US Environmental Protection Agency, Washington, DC, 1999.

USEPA 1999c. "Inter Tribal Council of Arizona, Inc.: Ground Water and Drinking Water Tribal Consultation Meeting." Executive Summary. February 24–25, 1999.

USEPA 1999d. "OGWDW Tribal Consultations: Workshops at the Annual Conference of the National Tribal Environmental Council." May 18–20, 1999.

USEPA 2000a. "Comment/Response Document for the Radionuclides Notice of Data Availability and 1991 Proposed Rule." Prepared by Industrial Economics, Inc. for EPA. November 2000.

USEPA 2000b. "Draft Toxicological Review of Uranium." Prepared by the Office of Science and Technology. Draft. June 6, 2000.

USEPA 2000c. Government Dialogue on U.S. EPA's Upcoming Drinking Water Regulations. Meeting Summary. May 30, 2000.

USEPA 2000d. "Information Collection Request for National Primary Drinking Water Regulations: Radionuclides". Prepared by ISSI Consulting Group, for EPA. September 22, 2000.

USEPA 2000e. National Primary Drinking Water Regulations; Radionuclides; Notice of Data Availability; Proposed Rule. 65 FR 21577. April 21, 2000.

USEPA 2000f. "Preliminary Health Risk Reduction and Cost Analysis: Revised National Primary Drinking Water Standards for Radionuclides." Prepared by Industrial Economics, Inc. for EPA. Draft. January 2000.

USEPA 2000g. "Economic Analysis of the Radionuclides National Primary Drinking Water Regulations." Prepared by Industrial Economics, Inc. for EPA. November 2000.

USEPA 2000h. "Technical Support Document for the Radionuclides Notice of Data Availability." Draft. March, 2000.

USEPA 2000i. "Technologies and Costs for the Removal of Radionuclides from Potable Water Supplies." Draft. Prepared by Malcolm Pirnie, Inc. June, 2000.


## List of Subjects

*40 CFR Part 9*

Reporting and recordkeeping requirements.

8150

*40 CFR Part 141*

Environmental protection, Chemicals, Indians-lands, Incorporation by reference, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

*40 CFR Part 142*

Environmental protection, Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: November 21, 2000.

**Carol M. Browner,**

*Administrator.*

For reasons set out in the preamble, 40 CFR parts 9, 141, and 142 are amended as follows:

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326–1330, 1324, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended by:

(a) Removing the entry for 141.25–141.30 and adding new entries for 141.25(a)–(e), 141.26 (a)–(b), and 141.27–141.30;

(b) Removing the entry for 142.14(a)–(d)(7) and adding new entries for 142.14(a)–(d)(3), 142.14(d)(4)–(5), and 142.14(d)(6)–(7); and

(c) Removing the entry for 142.15(c)(5)–(d) and adding new entries for 142.15(c)(5), 142.15(c)(6)–(7), and 142.15(d).

The additions read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

* * * * *

| 40 CFR citation | OMB control No. |
|---|---|
| * * * * * | |
| **National Primary Drinking Water Regulations** | |
| * * * * * | |
| 141.25(a)–(e) | 2040–0090 |
| 141.26(a)–(b) | 2040–0228 |
| 141.27–141.30 | 2040–0090 |
| 142.14(a)–(d)(3) | 2040–0090 |
| 142.14(d)(4)–(5) | 2040–0228 |
| 142.14(d)(6)–(7) | 2040–0090 |
| * * * * * | |
| 142.15(c)(5) | 2040–0090 |
| 142.15(c)(6)–(7) | 2040–0228 |
| 142.15(d) | 2040–0090 |

* * * * *

## PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

**Authority:** 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

### Subpart B—[Amended]

**§§ 141.15 and 141.16 [Removed]**

2. Sections 141.15 and 141.16 are removed.

### Subpart C—[Amended]

3. Section 141.25 is amended by:

a. Revising paragraph (a) introductory text (the table remains unchanged),

b. Revising paragraph (c)(1),

c. Revising paragraph (c)(2) and redisgnating Table B in paragraph (c)(2) as Table C and

d. Revising paragraph (d).

The revisions read as follows:

**§ 141.25 Analytical methods for radioactivity.**

(a) Analysis for the following contaminants shall be conducted to determine compliance with § 141.66 (radioactivity) in accordance with the methods in the following table, or their equivalent determined by EPA in accordance with § 141.27.

* * * * *

(c) * * *

(1) To determine compliance with § 141.66(b), (c), and (e) the detection limit shall not exceed the concentrations in Table B to this paragraph.

TABLE B.—DETECTION LIMITS FOR GROSS ALPHA PARTICLE ACTIVITY, RADIUM 226, RADIUM 228, AND URANIUM

| Contaminant | Detection limit |
|---|---|
| Gross alpha particle activity | 3 pCi/L |
| Radium 226 | 1 pCi/L |
| Radium 228 | 1 pCi/L |
| Uranium | Reserve |

(2) To determine compliance with § 141.66(d) the detection limits shall not exceed the concentrations listed in Table C to this paragraph.

* * * * *

(d) To judge compliance with the maximum contaminant levels listed in § 141.66, averages of data shall be used and shall be rounded to the same number of significant figures as the maximum contaminant level for the substance in question.

* * * * *

4. Section 141.26 is revised to read as follows:

**§ 141.26 Monitoring frequency and compliance requirements for radionuclides in community water systems**

(a) Monitoring and compliance requirements for gross alpha particle activity, radium-226, radium-228, and uranium.

(1) Community water systems (CWSs) must conduct initial monitoring to determine compliance with § 141.66(b), (c), and (e) by December 31, 2007. For the purposes of monitoring for gross alpha particle activity, radium-226, radium-228, uranium, and beta particle and photon radioactivity in drinking water, "detection limit" is defined as in § 141.25(c).

(i) Applicability and sampling location for existing community water systems or sources. All existing CWSs using ground water, surface water or systems using both ground and surface water (for the purpose of this section hereafter referred to as systems) must sample at every entry point to the distribution system that is representative of all sources being used (hereafter called a sampling point) under normal operating conditions. The system must take each sample at the same sampling point unless conditions make another sampling point more representative of each source or the State has designated a distribution system location, in accordance with paragraph (a)(2)(ii)(C) of this section.

(ii) Applicability and sampling location for new community water systems or sources. All new CWSs or CWSs that use a new source of water

must begin to conduct initial monitoring for the new source within the first quarter after initiating use of the source. CWSs must conduct more frequent monitoring when ordered by the State in the event of possible contamination or when changes in the distribution system or treatment processes occur which may increase the concentration of radioactivity in finished water.

(2) Initial monitoring: Systems must conduct initial monitoring for gross alpha particle activity, radium-226, radium-228, and uranium as follows:

(i) Systems without acceptable historical data, as defined below, must collect four consecutive quarterly samples at all sampling points before December 31, 2007.

(ii) Grandfathering of data: States may allow historical monitoring data collected at a sampling point to satisfy the initial monitoring requirements for that sampling point, for the following situations.

(A) To satisfy initial monitoring requirements, a community water system having only one entry point to the distribution system may use the monitoring data from the last compliance monitoring period that began between June 2000 and December 8, 2003.

(B) To satisfy initial monitoring requirements, a community water system with multiple entry points and having appropriate historical monitoring data for each entry point to the distribution system may use the monitoring data from the last compliance monitoring period that began between June 2000 and December 8, 2003.

(C) To satisfy initial monitoring requirements, a community water system with appropriate historical data for a representative point in the distribution system may use the monitoring data from the last compliance monitoring period that began between June 2000 and December 8, 2003, provided that the State finds that the historical data satisfactorily demonstrate that each entry point to the distribution system is expected to be in compliance based upon the historical data and reasonable assumptions about the variability of contaminant levels between entry points. The State must make a written finding indicating how the data conforms to the these requirements.

(iii) For gross alpha particle activity, uranium, radium-226, and radium-228 monitoring, the State may waive the final two quarters of initial monitoring for a sampling point if the results of the samples from the previous two quarters are below the detection limit.

(iv) If the average of the initial monitoring results for a sampling point is above the MCL, the system must collect and analyze quarterly samples at that sampling point until the system has results from four consecutive quarters that are at or below the MCL, unless the system enters into another schedule as part of a formal compliance agreement with the State.

(3) Reduced monitoring: States may allow community water systems to reduce the future frequency of monitoring from once every three years to once every six or nine years at each sampling point, based on the following criteria.

(i) If the average of the initial monitoring results for each contaminant (*i.e.*, gross alpha particle activity, uranium, radium-226, or radium-228) is below the detection limit specified in Table B, in § 141.25(c)(1), the system must collect and analyze for that contaminant using at least one sample at that sampling point every nine years.

(ii) For gross alpha particle activity and uranium, if the average of the initial monitoring results for each contaminant is at or above the detection limit but at or below ½ the MCL, the system must collect and analyze for that contaminant using at least one sample at that sampling point every six years. For combined radium-226 and radium-228, the analytical results must be combined. If the average of the combined initial monitoring results for radium-226 and radium-228 is at or above the detection limit but at or below ½ the MCL, the system must collect and analyze for that contaminant using at least one sample at that sampling point every six years.

(iii) For gross alpha particle activity and uranium, if the average of the initial monitoring results for each contaminant is above ½ the MCL but at or below the MCL, the system must collect and analyze at least one sample at that sampling point every three years. For combined radium-226 and radium-228, the analytical results must be combined. If the average of the combined initial monitoring results for radium-226 and radium-228 is above ½ the MCL but at or below the MCL, the system must collect and analyze at least one sample at that sampling point every three years.

(iv) Systems must use the samples collected during the reduced monitoring period to determine the monitoring frequency for subsequent monitoring periods (*e.g.*, if a system's sampling point is on a nine year monitoring period, and the sample result is above ½ MCL, then the next monitoring period for that sampling point is three years).

(v) If a system has a monitoring result that exceeds the MCL while on reduced monitoring, the system must collect and analyze quarterly samples at that sampling point until the system has results from four consecutive quarters that are below the MCL, unless the system enters into another schedule as part of a formal compliance agreement with the State.

(4) Compositing: To fulfill quarterly monitoring requirements for gross alpha particle activity, radium-226, radium-228, or uranium, a system may composite up to four consecutive quarterly samples from a single entry point if analysis is done within a year of the first sample. States will treat analytical results from the composited as the average analytical result to determine compliance with the MCLs and the future monitoring frequency. If the analytical result from the composited sample is greater than ½ MCL, the State may direct the system to take additional quarterly samples before allowing the system to sample under a reduced monitoring schedule.

(5) A gross alpha particle activity measurement may be substituted for the required radium-226 measurement provided that the measured gross alpha particle activity does not exceed 5 pCi/l. A gross alpha particle activity measurement may be substituted for the required uranium measurement provided that the measured gross alpha particle activity does not exceed 15 pCi/l.

The gross alpha measurement shall have a confidence interval of 95% (1.65$\sigma$, where $\sigma$ is the standard deviation of the net counting rate of the sample) for radium-226 and uranium. When a system uses a gross alpha particle activity measurement in lieu of a radium-226 and/or uranium measurement, the gross alpha particle activity analytical result will be used to determine the future monitoring frequency for radium-226 and/or uranium. If the gross alpha particle activity result is less than detection, ½ the detection limit will be used to determine compliance and the future monitoring frequency.

(b) *Monitoring and compliance requirements for beta particle and photon radioactivity.*

To determine compliance with the maximum contaminant levels in § 141.66(d) for beta particle and photon radioactivity, a system must monitor at a frequency as follows:

(1) Community water systems (both surface and ground water) designated by the State as vulnerable must sample for beta particle and photon radioactivity. Systems must collect quarterly samples

for beta emitters and annual samples for tritium and strontium-90 at each entry point to the distribution system (hereafter called a sampling point), beginning within one quarter after being notified by the State. Systems already designated by the State must continue to sample until the State reviews and either reaffirms or removes the designation.

(i) If the gross beta particle activity minus the naturally occurring potassium-40 beta particle activity at a sampling point has a running annual average (computed quarterly) less than or equal to 50 pCi/L (screening level), the State may reduce the frequency of monitoring at that sampling point to once every 3 years. Systems must collect all samples required in paragraph (b)(1) of this section during the reduced monitoring period.

(ii) For systems in the vicinity of a nuclear facility, the State may allow the CWS to utilize environmental surveillance data collected by the nuclear facility in lieu of monitoring at the system's entry point(s), where the State determines if such data is applicable to a particular water system. In the event that there is a release from a nuclear facility, systems which are using surveillance data must begin monitoring at the community water system's entry point(s) in accordance with paragraph (b)(1) of this section.

(2) Community water systems (both surface and ground water) designated by the State as utilizing waters contaminated by effluents from nuclear facilities must sample for beta particle and photon radioactivity. Systems must collect quarterly samples for beta emitters and iodine-131 and annual samples for tritium and strontium-90 at each entry point to the distribution system (hereafter called a sampling point), beginning within one quarter after being notified by the State. Systems already designated by the State as systems using waters contaminated by effluents from nuclear facilities must continue to sample until the State reviews and either reaffirms or removes the designation.

(i) Quarterly monitoring for gross beta particle activity shall be based on the analysis of monthly samples or the analysis of a composite of three monthly samples. The former is recommended.

(ii) For iodine-131, a composite of five consecutive daily samples shall be analyzed once each quarter. As ordered by the State, more frequent monitoring shall be conducted when iodine-131 is identified in the finished water.

(iii) Annual monitoring for strontium-90 and tritium shall be conducted by means of the analysis of a composite of four consecutive quarterly samples or analysis of four quarterly samples. The latter procedure is recommended.

(iv) If the gross beta particle activity beta minus the naturally occurring potassium-40 beta particle activity at a sampling point has a running annual average (computed quarterly) less than or equal to 15 pCi/L, the State may reduce the frequency of monitoring at that sampling point to every 3 years. Systems must collect all samples required in paragraph (b)(2) of this section during the reduced monitoring period.

(v) For systems in the vicinity of a nuclear facility, the State may allow the CWS to utilize environmental surveillance data collected by the nuclear facility in lieu of monitoring at the system's entry point(s), where the State determines if such data is applicable to a particular water system. In the event that there is a release from a nuclear facility, systems which are using surveillance data must begin monitoring at the community water system's entry point(s) in accordance with paragraph (b)(2) of this section.

(3) Community water systems designated by the State to monitor for beta particle and photon radioactivity can not apply to the State for a waiver from the monitoring frequencies specified in paragraph (b)(1) or (b)(2) of this section.

(4) Community water systems may analyze for naturally occurring potassium-40 beta particle activity from the same or equivalent sample used for the gross beta particle activity analysis. Systems are allowed to subtract the potassium-40 beta particle activity value from the total gross beta particle activity value to determine if the screening level is exceeded. The potassium-40 beta particle activity must be calculated by multiplying elemental potassium concentrations (in mg/L) by a factor of 0.82.

(5) If the gross beta particle activity minus the naturally occurring potassium-40 beta particle activity exceeds the screening level, an analysis of the sample must be performed to identify the major radioactive constituents present in the sample and the appropriate doses must be calculated and summed to determine compliance with § 141.66(d)(1), using the formula in § 141.66(d)(2). Doses must also be calculated and combined for measured levels of tritium and strontium to determine compliance.

(6) Systems must monitor monthly at the sampling point(s) which exceed the maximum contaminant level in § 141.66(d) beginning the month after the exceedance occurs. Systems must continue monthly monitoring until the system has established, by a rolling average of 3 monthly samples, that the MCL is being met. Systems who establish that the MCL is being met must return to quarterly monitoring until they meet the requirements set forth in paragraph (b)(1)(ii) or (b)(2)(i) of this section.

(c) General monitoring and compliance requirements for radionuclides.

(1) The State may require more frequent monitoring than specified in paragraphs (a) and (b) of this section, or may require confirmation samples at its discretion. The results of the initial and confirmation samples will be averaged for use in compliance determinations.

(2) Each public water systems shall monitor at the time designated by the State during each compliance period.

(3) Compliance: Compliance with § 141.66 (b) through (e) will be determined based on the analytical result(s) obtained at each sampling point. If one sampling point is in violation of an MCL, the system is in violation of the MCL.

(i) For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. If the average of any sampling point is greater than the MCL, then the system is out of compliance with the MCL.

(ii) For systems monitoring more than once per year, if any sample result will cause the running average to exceed the MCL at any sample point, the system is out of compliance with the MCL immediately.

(iii) Systems must include all samples taken and analyzed under the provisions of this section in determining compliance, even if that number is greater than the minimum required.

(iv) If a system does not collect all required samples when compliance is based on a running annual average of quarterly samples, compliance will be based on the running average of the samples collected.

(v) If a sample result is less than the detection limit, zero will be used to calculate the annual average, unless a gross alpha particle activity is being used in lieu of radium-226 and/or uranium. If the gross alpha particle activity result is less than detection, ½ the detection limit will be used to calculate the annual average.

(4) States have the discretion to delete results of obvious sampling or analytic errors.

(5) If the MCL for radioactivity set forth in § 141.66 (b) through (e) is exceeded, the operator of a community water system must give notice to the

State pursuant to § 141.31 and to the public as required by subpart Q of this part.

**Subpart F—[Amended]**

5. A new § 141.55 is added to subpart F to read as follows:

**§ 141.55 Maximum contaminant level goals for radionuclides.**

MCLGs for radionuclides are as indicated in the following table:

| Contaminant | MCLG |
|---|---|
| 1. Combined radium-226 and radium-228. | Zero. |
| 2. Gross alpha particle activity (excluding radon and uranium). | Zero. |
| 3. Beta particle and photon radioactivity. | Zero. |
| 4. Uranium | Zero. |

**Subpart G—National Primary Drinking Water Regulations: Maximum Contaminant Levels and Maximum Residual Disinfectant Levels**

6. The heading of subpart G is revised as set out above.

7. A new § 141.66 is added to subpart G to read as follows:

**§ 141.66 Maximum contaminant levels for radionuclides.**

(a) [Reserved]

(b) *MCL for combined radium-226 and -228.* The maximum contaminant level for combined radium-226 and radium-228 is 5 pCi/L. The combined radium-226 and radium-228 value is determined by the addition of the results of the analysis for radium-226 and the analysis for radium-228.

(c) *MCL for gross alpha particle activity (excluding radon and uranium).* The maximum contaminant level for gross alpha particle activity (including radium-226 but excluding radon and uranium) is 15 pCi/L.

(d) *MCL for beta particle and photon radioactivity.* (1) The average annual concentration of beta particle and photon radioactivity from man-made radionuclides in drinking water must not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem/year (mrem/year).

(2) Except for the radionuclides listed in table A, the concentration of man-made radionuclides causing 4 mrem total body or organ dose equivalents must be calculated on the basis of 2 liter per day drinking water intake using the 168 hour data list in "Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air and in Water for Occupational Exposure," NBS (National Bureau of Standards) Handbook 69 as amended August 1963, U.S. Department of Commerce. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this document are available from the National Technical Information Service, NTIS ADA 280 282, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800–553–6847. Copies may be inspected at EPA's Drinking Water Docket, 401 M Street, SW., Washington, DC 20460; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. If two or more radionuclides are present, the sum of their annual dose equivalent to the total body or to any organ shall not exceed 4 mrem/year.

TABLE A.—AVERAGE ANNUAL CONCENTRATIONS ASSUMED TO PRODUCE: A TOTAL BODY OR ORGAN DOSE OF 4 MREM/YR

| | | |
|---|---|---|
| 1. Radionuclide | Critical organ | pCi per liter |
| 2. Tritium | Total body | 20,000 |
| 3. Strontium-90 | Bone Marrow | 8 |

(e) *MCL for uranium.* The maximum contaminant level for uranium is 30 µg/L.

(f) *Compliance dates.* (1) Compliance dates for combined radium-226 and -228, gross alpha particle activity, gross beta particle and photon radioactivity, and uranium: Community water systems must comply with the MCLs listed in paragraphs (b), (c), (d), and (e) of this section beginning December 8, 2003 and compliance shall be determined in accordance with the requirements of §§ 141.25 and 141.26. Compliance with reporting requirements for the radionuclides under appendix A to subpart O and appendices A and B to subpart Q is required on December 8, 2003.

(g) *Best available technologies (BATs) for radionuclides.* The Administrator, pursuant to section 1412 of the Act, hereby identifies as indicated in the following table the best technology available for achieving compliance with the maximum contaminant levels for combined radium-226 and -228, uranium, gross alpha particle activity, and beta particle and photon radioactivity.

TABLE B.—BAT FOR COMBINED RADIUM-226 AND RADIUM-228, URANIUM, GROSS ALPHA PARTICLE ACTIVITY, AND BETA PARTICLE AND PHOTON RADIOACTIVITY

| Contaminant | BAT |
|---|---|
| 1. Combined radium-226 and radium-228 | Ion exchange, reverse osmosis, lime softening. |
| 2. Uranium | Ion exchange, reverse osmosis, lime softening, coagulation/filtration. |
| 3. Gross alpha particle activity (excluding Radon and Uranium) | Reverse osmosis. |
| 4. Beta particle and photon radioactivity | Ion exchange, reverse osmosis. |

(h) *Small systems compliance technologies list for radionuclides.*

TABLE C.—LIST OF SMALL SYSTEMS COMPLIANCE TECHNOLOGIES FOR RADIONUCLIDES AND LIMITATIONS TO USE

| Unit technologies | Limitations (see footnotes) | Operator skill level required [1] | Raw water quality range and considerations.[1] |
|---|---|---|---|
| 1. Ion exchange (IE) | (a) | Intermediate | All ground waters. |
| 2. Point of use (POU [2]) IE | (b) | Basic | All ground waters. |
| 3. Reverse osmosis (RO) | (c) | Advanced | Surface waters usually require pre-filtration. |
| 4. POU[2] RO | (b) | Basic | Surface waters usually require pre-filtration. |
| 5. Lime softening | (d) | Advanced | All waters. |
| 6. Green sand filtration | (e) | Basic. | |
| 7. Co-precipitation with Barium sulfate | (f) | Intermediate to Advanced | Ground waters with suitable water quality. |
| 8. Electrodialysis/electrodialysis reversal | | Basic to Intermediate | All ground waters. |
| 9. Pre-formed hydrous Manganese oxide filtration. | (g) | Intermediate | All ground waters. |
| 10. Activated alumina | (a), (h) | Advanced | All ground waters; competing anion concentrations may affect regeneration frequency. |
| 11. Enhanced coagulation/filtration | (i) | Advanced | Can treat a wide range of water qualities. |

[1] National Research Council (NRC). Safe Water from Every Tap: Improving Water Service to Small Communities. National Academy Press. Washington, D.C. 1997.

[2] A POU, or "point-of-use" technology is a treatment device installed at a single tap used for the purpose of reducing contaminants in drinking water at that one tap. POU devices are typically installed at the kitchen tap. See the April 21, 2000 NODA for more details.

Limitations Footnotes: Technologies for Radionuclides:

[a] The regeneration solution contains high concentrations of the contaminant ions. Disposal options should be carefully considered before choosing this technology.

[b] When POU devices are used for compliance, programs for long-term operation, maintenance, and monitoring must be provided by water utility to ensure proper performance.

[c] Reject water disposal options should be carefully considered before choosing this technology. See other RO limitations described in the SWTR Compliance Technologies Table.

[d] The combination of variable source water quality and the complexity of the water chemistry involved may make this technology too complex for small surface water systems.

[e] Removal efficiencies can vary depending on water quality.

[f] This technology may be very limited in application to small systems. Since the process requires static mixing, detention basins, and filtration, it is most applicable to systems with sufficiently high sulfate levels that already have a suitable filtration treatment train in place.

[g] This technology is most applicable to small systems that already have filtration in place.

[h] Handling of chemicals required during regeneration and pH adjustment may be too difficult for small systems without an adequately trained operator.

[i] Assumes modification to a coagulation/filtration process already in place.

TABLE D.—COMPLIANCE TECHNOLOGIES BY SYSTEM SIZE CATEGORY FOR RADIONUCLIDE NPDWR'S

| Contaminant | Compliance technologies [1] for system size categories (population served) | | 3,300–10,000 |
|---|---|---|---|
| | 25–500 | 501–3,300 | |
| 1. Combined radium-226 and radium-228 | 1, 2, 3, 4, 5, 6, 7, 8, 9 | 1, 2, 3, 4, 5, 6, 7, 8, 9 | 1, 2, 3, 4, 5, 6, 7. 8, 9. |
| 2. Gross alpha particle activity | 3, 4 | 3, 4 | 3, 4. |
| 3. Beta particle activity and photon activity | 1, 2, 3, 4 | 1, 2, 3, 4 | 1, 2, 3, 4. |
| 4. Uranium | 1, 2, 4, 10, 11 | 1, 2, 3, 4, 5, 10, 11 | 1, 2, 3, 4, 5, 10, 11. |

**Note:** [1] Numbers correspond to those technologies found listed in the table C of 141.66(h).

**Subpart O—[Amended]**

8. The table in appendix A to subpart O is amended under the heading "Radioactive contaminants" by revising the entries for "Beta/photon emitters (mrem/yr)", "Alpha emitters (pCi/l)", and "Combined radium (pCi/l)" and adding a new entry for "Uranium (pCi/L)" to read as follows:

**Appendix A to Subpart O—Regulated Contaminants**

| Contaminant units | Traditional MCL in mg/L | To convert for CCR, multiply by | MCL in CCR units | MCLG | Major sources in drinking-water | Health effects language |
|---|---|---|---|---|---|---|
| * | * | * | * | * | * | * |
| Radioactive contaminants: | | | | | | |
| Beta/photon emitters (mrem/yr). | 4 mrem/yr | – | 4 | 0 | Decay of natural and man-made deposits. | Certain minerals are radioactive and may emit forms of radiation known as photons and beta radiation. Some people who drink water containing beta particle and photon radioactivity in excess of the MCL over many years may have an increased risk of getting cancer. |
| Alpha emitters (pCi/L). | 15 pCi/L | – | 15 | 0 | Erosion of natural deposits. | Certain minerals are radioactive and may emit a form of radiation known as alpha radiation. Some people who drink water containing alpha emitters in excess of the MCL over many years may have an increased risk of getting cancer. |
| Combined radium (pCi/L). | 5 pCi/L | – | 5 | 0 | Erosion of natural deposits. | Some people who drink water containing radium-226 or -228 in excess of the MCL over many years may have an increased risk of getting cancer. |
| Uranium (pCi/L) | 30 µg/L | – | 30 | 0 | Erosion of natural deposits. | Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk of getting cancer and kidney toxicity. |
| * | * | * | * | * | * | * |

**Subpart Q—[Amended]**

9. Appendix A to subpart Q under I.F. "Radioactive contaminants" is amended by:

a. Revising entries 1, 2, and 3;

b. Adding entry 4;

c. Redesignating endnotes 9 through 17 as endnotes 11 through 19; and

d. Adding new endnotes 9 and 10.

**Appendix A to Subpart Q—NPDWR Violations and Other Situations Requiring Public Notice [1]**

| Contaminant | MCL/MRDL/TT Violations [2] | | Monitoring and testing procedure violations | |
|---|---|---|---|---|
| | Tier of public notice required | Citation | Tier of public notice required | Citation |
| **I. Violations of National Primary Drinking Water Regulations (NPDWR) [3]** | | | | |
| * | * | * | * | * |
| **F. Radioactive contaminants** | | | | |
| 1. Beta/photon emitters | 2 | 141.66(d) | 3 | 141.25(a)<br>141.26(b) |
| 2. Alpha emitters | 2 | 141.66(c) | 3 | 141.25(a)<br>141.26(a) |
| 3. Combined radium (226 and 228) | 2 | 141.66(b) | 3 | 141.25(a)<br>141.26(a) |
| 4. Uranium | [9] 2 | 141.66(e) | [10] 3 | 141.25(a)<br>141.26(a) |
| * | * | * | * | * |

Appendix A—Endnotes

* * * * *

1. Violations and other situations not listed in this table (e.g., reporting violations and failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primary agency. Primacy agencies may, at their option, also

require a more stringent public notice tier (*e.g.*, Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under Sec. 141.202(a) and Sec. 141.203(a).

2. MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique.

3. The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.

* * * * *

9. The uranium MCL Tier 2 violation citations are effective December 8, 2003 for all community water systems.

10. The uranium Tier 3 violation citations are effective December 8, 2000 for all community water systems.

* * * * *

10. Appendix B to Subpart Q is amended by:

a. Redesignating entries 79 through 84 and 86 through 88 as 80 through 85 and 87 through 89, respectively, and entries 85a and 85b as 86a and 86b, respectively;

b. Adding a new entry 79 for uranium under "G. Radioactive contaminants";

c. Redesignating endnote entries 16 through 21 as 17 through 22; and

d. adding a new endnote 16.

**Appendix B to Subpart Q—Standard Health Effects Language for Public Notification**

| Contaminant | MCLG[1] mg/L | MCL[2] mg/L | Standard health effects language for public notification |
|---|---|---|---|
| **National Primary Drinking Water Regulations (NPDWR)** | | | |
| * * * | * | * | * * * * |
| **G. Radioactive contaminants** | | | |
| * * * | * | * | * * * * |
| 79. Uranium[16] | Zero | 30 µg/L | Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk of getting cancer and kidney toxicity. |
| * * * | * | * | * * * * |

**Appendix B—Endnotes**

1. MCLG—Maximum contaminant level goal

2. MCL—Maximum contaminant level

* * * * *

16. The uranium MCL is effective December 8, 2003 for all community water systems.

* * * * *

## PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 continues to read as follows:

**Authority:** 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

### Subpart B—Primary Enforcement Responsibility

2. Section 142.16 is amended by adding and reserving paragraphs (i), (j), and (k) and adding a new paragraph (l) to read as follows:

**§ 142.16 Special primacy requirements.**

* * * * *

(i)–(k) [Reserved]

(l) An application for approval of a State program revision for radionuclides which adopts the requirements specified in § 141.26(a)(2)(ii)(C) of this chapter must contain the following (in addition to the general primacy requirements enumerated in this part, including that State regulations be at least as stringent as the Federal requirements):

(1) If a State chooses to use grandfathered data in the manner described in § 141.26(a)(2)(ii)(C) of this chapter, then the State must describe the procedures and criteria which it will use to make these determinations (whether distribution system or entry point sampling points are used).

(i) The decision criteria that the State will use to determine that data collected in the distribution system are representative of the drinking water supplied from each entry point to the distribution system. These determinations must consider:

(A) All previous monitoring data.

(B) The variation in reported activity levels.

(C) Other factors affecting the representativeness of the data (*e.g.* geology).

(ii) [Reserved]

(2) A monitoring plan by which the State will assure all systems complete the required monitoring within the regulatory deadlines. States may update their existing monitoring plan or use the same monitoring plan submitted for the requirements in § 142.16(e)(5) under the national primary drinking water regulations for the inorganic and organic contaminants (*i.e.* the phase II/V rules). States may note in their application any revision to an existing monitoring plan or note that the same monitoring plan will be used. The State must demonstrate that the monitoring plan is enforceable under State law.

### Subpart G—[Amended]

3. Section 142.65 is added to read as follows.

**§ 142.65 Variances and exemptions from the maximum contaminant levels for radionuclides.**

(a)(1) Variances and exemptions from the maximum contaminant levels for combined radium-226 and radium-228, uranium, gross alpha particle activity (excluding Radon and Uranium), and beta particle and photon radioactivity.

(i) The Administrator, pursuant to section 1415(a)(1)(A) of the Act, hereby identifies the following as the best available technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for the radionuclides listed in § 141.66(b), (c), (d), and (e) of this chapter, for the purposes of issuing variances and exemptions, as shown in Table A to this paragraph.

TABLE A.—BAT FOR RADIONUCLIDES LISTED IN § 141.66

| Contaminant | BAT |
|---|---|
| Combined radium-226 and radium-228 | Ion exchange, reverse osmosis, lime softening. |
| Uranium | Ion exchange, reverse osmosis, lime softening, coagulation/filtration. |
| Gross alpha particle activity (excluding radon and uranium) | Reverse osmosis. |
| Beta particle and photon radioactivity | Ion exchange, reverse osmosis. |

(ii) In addition, the Administrator hereby identifies the following as the best available technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for the radionuclides listed in § 141.66(b), (c), (d), and (e) of this chapter, for the purposes of issuing variances and exemptions to small drinking water systems, defined here as those serving 10,000 persons or fewer, as shown in Table C to this paragraph.

TABLE B.—LIST OF SMALL SYSTEMS COMPLIANCE TECHNOLOGIES FOR RADIONUCLIDES AND LIMITATIONS TO USE

| Unit technologies | Limitations (see footnotes) | Operator skill level required [1] | Raw water quality range & considerations [1] |
|---|---|---|---|
| 1. Ion exchange (IE) | (a) | Intermediate | All ground waters. |
| 2. Point of use (POU [2]) IE | (b) | Basic | All ground waters. |
| 3. Reverse osmosis (RO) | (c) | Advanced | Surface waters usually require pre-filtration. |
| 4. POU [2] RO | (b) | Basic | Surface waters usually require pre-filtration. |
| 5. Lime softening | (d) | Advanced | All waters. |
| 6. Green sand filtration | (e) | Basic. | |
| 7. Co-precipitation with barium sulfate | (f) | Intermediate to Advanced | Ground waters with suitable water quality. |
| 8. Electrodialysis/electrodialysis reversal | | Basic to Intermediate | All ground waters. |
| 9. Pre-formed hydrous manganese oxide filtration. | (g) | Intermediate | All ground waters. |
| 10. Activated alumina | (a), (h) | Advanced | All ground waters; competing anion concentrations may affect regeneration frequency. |
| 11. Enhanced coagulation/filtration | (i) | Advanced | Can treat a wide range of water qualities. |

[1] National Research Council (NRC). Safe Water from Every Tap: Improving Water Service to Small Communities. National Academy Press. Washington, D.C. 1997.

[2] A POU, or "point-of-use" technology is a treatment device installed at a single tap used for the purpose of reducing contaminants in drinking water at that one tap. POU devices are typically installed at the kitchen tap. See the April 21, 2000 NODA for more details.

Limitations Footnotes: Technologies for Radionuclides:

[a] The regeneration solution contains high concentrations of the contaminant ions. Disposal options should be carefully considered before choosing this technology.

[b] When POU devices are used for compliance, programs for long-term operation, maintenance, and monitoring must be provided by water utility to ensure proper performance.

[c] Reject water disposal options should be carefully considered before choosing this technology. See other RO limitations described in the SWTR compliance technologies table.

[d] The combination of variable source water quality and the complexity of the water chemistry involved may make this technology too complex for small surface water systems.

[e] Removal efficiencies can vary depending on water quality.

[f] This technology may be very limited in application to small systems. Since the process requires static mixing, detention basins, and filtration, it is most applicable to systems with sufficiently high sulfate levels that already have a suitable filtration treatment train in place.

[g] This technology is most applicable to small systems that already have filtration in place.

[h] Handling of chemicals required during regeneration and pH adjustment may be too difficult for small systems without an adequately trained operator.

[i] Assumes modification to a coagulation/filtration process already in place.

TABLE C.—BAT FOR SMALL COMMUNITY WATER SYSTEMS FOR THE RADIONUCLIDES LISTED IN § 141.66

| Contaminant | Compliance technologies [1] for system size categories (population served) | | |
|---|---|---|---|
| | 25–500 | 501–3,300 | 3,300–10,000 |
| Combined radium-226 and radium-228 | 1, 2, 3, 4, 5, 6, 7, 8, 9 | 1, 2, 3, 4, 5, 6, 7, 8, 9 | 1, 2, 3, 4, 5, 6, 7, 8, 9. |
| Gross alpha particle activity | 3, 4 | 3, 4 | 3, 4. |
| Beta particle activity and photon activity | 1, 2, 3, 4 | 1, 2, 3, 4 | 1, 2, 3, 4. |
| Uranium | 1, 2, 4, 10, 11 | 1, 2, 3, 4, 5, 10, 11 | 1, 2, 3, 4, 5, 10, 11. |

[1] **Note:** Numbers correspond to those technologies found listed in the table B to this paragraph.

(2) A State shall require community water systems to install and/or use any treatment technology identified in Table A to this section, or in the case of small water systems (those serving 10,000 persons or fewer), Table B and Table C

of this section, as a condition for granting a variance except as provided in paragraph (a)(3) of this section. If, after the system's installation of the treatment technology, the system cannot meet the MCL, that system shall be eligible for a variance under the provisions of section 1415(a)(1)(A) of the Act.

(3) If a community water system can demonstrate through comprehensive engineering assessments, which may include pilot plant studies, that the treatment technologies identified in this section would only achieve a de minimus reduction in the contaminant level, the State may issue a schedule of compliance that requires the system being granted the variance to examine other treatment technologies as a condition of obtaining the variance.

(4) If the State determines that a treatment technology identified under paragraph (a)(3) of this section is technically feasible, the Administrator or primacy State may require the system to install and/or use that treatment technology in connection with a compliance schedule issued under the provisions of section 1415(a)(1)(A) of the Act. The State's determination shall be based upon studies by the system and other relevant information.

(5) The State may require a community water system to use bottled water, point-of-use devices, point-of-entry devices or other means as a condition of granting a variance or an exemption from the requirements of § 141.66 of this chapter, to avoid an unreasonable risk to health.

(6) Community water systems that use bottled water as a condition for receiving a variance or an exemption from the requirements of § 141.66 of this chapter must meet the requirements specified in either § 142.62(g)(1) or § 142.62(g)(2) and (g)(3).

(7) Community water systems that use point-of-use or point-of-entry devices as a condition for obtaining a variance or an exemption from the radionuclides NPDWRs must meet the conditions in § 142.62(h)(1) through (h)(6).

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