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Environmental Protection Agency

40 CFR Parts 141 and 142

National Primary Drinking Water Regulations; Radionuclides; Notice of Data Availability; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[FRL–6580–8]

RIN–2040–AC98

National Primary Drinking Water Regulations; Radionuclides; Notice of Data Availability

AGENCY: Environmental Protection Agency.

ACTION: Notice of data availability for proposed rules with request for comments.

SUMMARY: The Environmental Protection Agency (EPA) proposed regulations to limit the amount of radionuclides found in drinking water on July 18, 1991. In general, the proposal revised current National Primary Drinking Water regulations (NPDWR); a NPDWR was proposed for uranium which is unregulated. Since that time, new information has become available which the Agency is considering in finalizing these proposed regulations. In addition, the 1996 Amendments to the Safe Drinking Water Act (SDWA) contained provisions which directly affect the 1991 proposed rule.

This document presents additional information relevant to the Maximum Contaminant Level Goals (MCLGs), the Maximum Contaminant Levels (MCLs), and monitoring requirements contained in the 1991 proposal. EPA is seeking public review and comment on these new data. The Agency is also soliciting comments on several implementation options that are being evaluated for inclusion in the final regulations.

DATES: Written comments should be postmarked or delivered by hand by June 20, 2000.

ADDRESSES: Send written comments to the W–00–12 Radionuclides Rule Comment Clerk, Water Docket (MC–4101), 1200 Pennsylvania Ave., NW, Washington, DC 20460 or by sending electronic mail (e-mail) to ow-docket@epa.gov. Hand deliveries should be delivered to: EPA's Drinking Water Docket at 401 M Street, SW, East Basement (Room EB 57), Washington, DC 20460. Please submit an original and three copies of your comments and enclosures (including references). If you wish to hand-deliver your comments, please call (202) 260–3027 between 9:00 a.m. and 4:00 p.m., Monday through Friday, excluding Federal holidays, to obtain the room number for the Docket. Please see Supplementary Information under the heading ''Additional Information for Commenters'' for detailed filing instructions, including electronic submissions.

The record for the proposal has been established under the docket name: National Primary Drinking Water Regulations for Radionuclides (W–00–12). The record includes supporting documentation as well as printed, paper versions of electronic comments. The record is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays at the Water Docket, 401 M Street SW, East 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), 401 M Street SW, Washington, DC 20460; telephone (202) 260–9566. In addition, 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 1–800–426–4791.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities potentially regulated by the Radionuclides Rule are public water systems that are classified as either community water systems (CWSs) or non-transient non-community water systems (NTNCWSs). Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Privately-owned CWSs and NTNCWSs.
State, Tribal, and Local Governments.	Publicly-owned CWSs and NTNCWSs.

This table lists the types of entities, currently known to EPA, that could potentially be regulated by the Radionuclides Rule. It is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the Radionuclides Rule. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by the Radionuclides Rule, you should carefully examine the applicability criteria in §§ 141.15 and 141.26 of title 40 of the Code of Federal Regulations, and the definitions of Community Water systems and Non-Transient, Non-Community water systems in § 141.2 If you have questions regarding the applicability of the Radionuclides Rule to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Additional Information for Commenters

To ensure that EPA can read, understand and therefore properly respond to your comments, the Agency requests that commenters follow the following format: type or print comments in ink, and cite, where possible, the paragraph(s) in this document to which each comment refers. Please use a separate paragraph for each issue discussed and limit your comments to the issues addressed in today's Document.

If you want EPA to acknowledge receipt of your comments, enclose a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted. Comments also may be submitted electronically to ow-docket@epamail.epa.gov. Electronic comments must be submitted as a WordPerfect 8.0 or ASCII file avoiding the use of special characters and forms of encryption and must be transmitted by midnight June 20, 2000. Electronic comments must be identified by the docket name, number, or title of the **Federal Register**. Comments and data also will be accepted on disks in WordPerfect 8.0 or in ASCII file format. Electronic comments on this document may be filed online at many Federal Depository Libraries.

Abbreviations and Acronyms Used in This Notice

Organizations

APHA—American Public Health Association
ASTM—American Society for Testing and Materials
AWWA—American Water Works Association
ICRP—International Commission on Radiological Protection
NBS—National Bureau of Standards
NSF—National Sanitation Foundation
ANPRM—Advanced Notices of Proposed Rulemaking
ATSDR—Agency for Toxic Substances and Disease Registry
BNL—Brookhaven National Laboratory
CFR—Code of Federal Regulations
EML—Environmental Measurements Laboratory
ERAMS—Environmental Radiation Ambient Monitoring System
ERD—Environmental Radiation Data
ERIC—Educational Resources Information Center
FGR–13—Federal Guidance Report 13
FR—Federal Register
FRC—Federal Radiation Council
NAS—National Academy of Sciences
NCHS—National Center for Health Statistics
NESHAP—National Emissions Standards for Hazardous Air Pollutants
NIRS—National Inorganic and Radionuclide Survey

NIST—National Institute of Standards and Technology
NODA—Notice of Data Availability
NPDES—National Pollutant Discharge Elimination System
NPDWRs—National Primary Drinking Water Regulations
NRC—National Research Council
NRC—Nuclear Regulatory Commission
NTIS—National Technical Information Service
ORNL—Oak Ridge National Laboratory
SAB—Science Advisory Board
RADRISK—a computer code for radiation risk estimation
SWTR—Surface Water Treatment Rule
T&C—Technologies and Cost document
UCMR—Unregulated Contaminant Monitoring Rule
USDOE—United States Department of Energy
USDW—underground source of drinking water
USEPA—United States Environmental Protection Agency
USGS—United States Geological Survey
USSCEAR—United Nations Scientific Committee on the Effects of Atomic Radiation

Units of Measurement

Bq—Becquerel
Ci—Curie
EDE/yr—effective dose equivalent per year
kBq—kiloBecquerels
kBq/m ^{3}—kiloBecquerels per cubic meter
kg—kilogram
kgpd—kilogram per day
Mgkd—milligram per kilogram per day
L—liter
L/day—liter per day
mg—milligram
mg/L—milligram per liter
mg/kg—milligram per kilogram
mg UN/L—milligram uranyl nitrate per liter
mg/kg/day—milligram per kilogram per day
mg U/kg/day—milligram uranium per kilogram per day
mgd—million gallons per day
mL—milliliter
mrem—millirem
mrem/yr—millirem per year
Sv—Sievert
µCi—microCurie
µCi/kg—microCurie per kilogram
µg or ug—microgram
µg/g or ug/g—microgram per gram
µg/L or ug/L—microgram per liter
µg uranium/L—microgram uranium per liter
µg uranium/kg/day—microgram uranium per kilogram per day
µR/hr—micro Roentgen per hour
µSv/cm—micro Sievert per centimeter
NTU—Nephelometric Turbidity Unit
pCi—picoCurie
pCi/day—picoCurie per day
pCi/g—picoCurie per gram
pCi/L—picoCurie per liter
pCi/µg—picoCurie per microgram

Other Terms

ACA—anticentromere antigen
ALP—alkaline phosphatase
AS—alpha spectrometry
BAT—best available treatment
BEIR—biological effects of ionizing radiation
BMG—β_2-microglobulin
CWS—community water systems
DL—detection limit
EDE—effective dose equivalent
FSH—follicle stimulating hormone
GGT—gamma glutamyl transferase
GI—gastrointestinal
IE—ion exchange
LDH—lactate dehydrogenase
LET—low energy transfer
LOAEL—lowest observed adverse effect level
LP—Laser phosphorimetry
MCL—maximum contaminant levels
MCLG—maximum contaminant level goals
MDL—method detection limit
n—number
NAG—N-acetyl-β-D-glucosaminidas
NTNC—non-transient, non-community
NTNCWS—non-transient, non-community water systems
PBMS—performance based measurement system
PE—performance evaluation
POE—point-of-entry
POU—point-of-use
PQL—practical quantitation level
PT—performance testing
PWS—public water systems
RF—risk coefficient
RfD—reference dose
RO—reverse osmosis
RSC—relative source contribution
SM—standard methods
SMF—standardized monitoring framework
SPAARC—Spreadsheet Program to Ascertain Residual Radionuclide Concentration
SSCTL—''Small Systems Compliance Technology List''
Stnd. Dev.—standard deviation
TR—target risk level
UIC—underground injection control

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I. Purpose and Organization of This Document

In 1976, EPA promulgated drinking water regulations for several radionuclides. In 1991 (56 FR 33050, July 18, 1991), EPA proposed revisions to the current radionuclides (i.e. beta and photon emitters, radium-226 and radium-228, and gross alpha radiation) and proposed regulations for uranium which is not currently regulated. EPA is publishing this Notice of Data Availability (NODA) to inform the public and the regulated community of new information concerning radionuclides in drinking water. EPA is evaluating these additional data to determine how they will affect the Agency's decisions relative to final regulations to control radionuclides in public water systems. The Agency is under a court agreement to publish these final regulations by November 2000. Information in today's Document includes data about the occurrence, health effects, and treatment options for radionuclides in drinking water, as well as analytical methods, and monitoring requirements. This Document also presents data concerning the costs and benefits of several regulatory options. EPA is soliciting public comment on a number of issues raised by this new information. This introduction provides an overview of the document, and some of the information available to EPA and to highlight the risk management decisions the Agency is contemplating. Subsequent sections will contain more specific information, with a focus on what is new, relative to each of the topics listed previously. Finally, to further assist the public, the Agency has compiled seven appendices, included with this NODA, with more detailed information on each of these topics in addition to the public docket of reference materials. EPA seeks comment on the data and information presented in today's NODA, particularly where regulatory options or alternatives are discussed. Commenters are asked to provide their rationale and any supporting data or information they wish to submit in support of comments offered.

Table I–1 summarizes the major elements of the 1976 rule, the 1991 proposal and the issues being considered in today's NODA.

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

Provision	1976 Rule (Current Rule)	1991 Proposal	2000 NODA
Affected Systems	CWS	CWS + NTNC	CWS + several NTNC options based on the 1991 proposal.
MCLG	no MCLG	MCLG of zero	MCLG of zero.
Radium MCL	Combined Ra-226 + Ra-228 MCL of 5 pCi/L.	Ra-226 MCL of 20 pCi/L; Ra-228 MCL of 20 pCi/L.	Maintain current MCL based on corrected estimates of risk of current MCL.
Beta/Photon Emitters MCL.	4 mrem: Methodology for deriving individual concentration limits incorporated by reference; MCL = sum of the fractions of dose from one or more contaminants; risks estimated not to exceed 5.6×10^{-5}.	4 mrem ede (Effective Dose Equivalent). Derived concentration limits changed to reflect new dose limit; Current estimate of associated risks for these concentration limits are between 10^{-4} and 10^{-3} for most.	Maintain current MCL based on corrected estimates of risk of current MCL.
Gross alpha MCL	15 pCi/L excluding U and Rn, but including Ra-226.	''Adjusted'' gross alpha MCL of 15 pCi/L, excluding Ra-226, radon, and uranium.	Maintain current MCL based on unacceptable risk level of 1991 proposed MCL.
Polonium-210	Included in gross alpha	Included in gross alpha	No changes to current rule. Monitoring required under the UCMR rule. Future 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. Future action may be proposed at a later date
Uranium MCL	Not Regulated	20 μg/L or 30 pCi/L w/ option for 5–80 μg/L.	Three options being considered: 20, 40, 80 μg/L and pCi/L
Ra-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.	Same as current rule, but Ra-224 may be addressed in a future proposal.
Radium 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).
Beta 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/L. Those drawing water from a contaminated source screen at 15 pCi/L.	Same as 1991 proposal with clarifications.
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. Recommendation to analyze within 48–72 hours to capture Ra-224.
Analytical Methods	Provide methods	Method updates proposed in 1991; Current methods were updated in 1997.	Current methods with clarifications.

II. Statutory Authority and Regulatory Background

A. Safe Drinking Water Act of 1974 and Amendments of 1986 and 1996

Regulations for radionuclides in drinking water were first promulgated in 1976 as interim regulations under the authority of the Safe Drinking Water Act (SDWA) of 1974. The standards were set for three groups of radionuclides: beta and photon emitters, radium (radium-226 and radium-228), and gross alpha radiation. These standards became effective in 1977.

The SDWA Amendments of 1986 required EPA to establish health-based regulatory targets, called Maximum Contaminant Level Goals (MCLGs), for every contaminant ''at 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 enforceable standard, the Maximum Contaminant Level (MCL), was required to be established ''as close to the health-based goal as feasible using the best available technology, taking costs into consideration.'' EPA proposed an MCLG of zero for the radionuclides in 1991.

In 1983 and 1986, EPA published an Advanced Notice of Proposed Rulemaking (ANPRM) requesting additional information and comments on radionuclides and numerous organic and inorganic contaminants in drinking water. The 1986 SDWA Amendments identified 83 contaminants for EPA to regulate, including the currently regulated radionuclides, which lacked an MCLG, and two additional radionuclides, uranium and radon. The Amendments also declared the 1976 interim standards to be final National Primary Drinking Water Regulations.

In 1996, Congress again amended the SDWA. These amendments included new and revised provisions that must be considered when revising drinking water regulations. Among these are the

health protection clause (section 1412(b)(9)) which requires that ''any revision of a national primary drinking water regulation (NPDWR) shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater protection of the health of persons.''

The 1996 Amendments also provide for a cost-benefit analysis when publishing a proposal for new NPDWRs pursuant to section 1412 (b)(6). While the EPA had proposed the radionuclides rule prior to these Amendments, the Agency nevertheless conducted an analysis of the costs and associated benefits of all of the options described in today's Document. These analyses serve to update and revise the costs and benefits estimated for the 1991 proposed rule. For the uranium standard, the Agency solicits comment on the possible use of its new discretionary authority at section 1412(b)(6) of the SDWA, which allow for a proposed regulatory level to be set higher than the feasible level, after the Agency has made a determination that the benefits do not justify the costs at the feasible level. Note that section 1412(b)(6) applies to new standards (uranium), not to the revision of existing standards (combined radium-226 and -228, gross alpha, and beta particle and photon radioactivity). Where we expect to maintain current standards at their existing levels, no additional analysis was undertaken because the rule is already in effect.

B. The 1991 Proposal

In 1991, EPA proposed new regulations for uranium and radon, as well as revisions to the existing regulations. The proposal included the following features: (1) an MCLG of zero for all ionizing radiation; (2) revised MCLs for beta particle and photon radioactivity, radium-226, radium-228, and gross alpha emitters; (3) proposed MCLs for uranium and radon; and (4) revisions to the categories of systems required to monitor, the monitoring frequencies, and the appropriate screening levels. EPA received comments on the new data and regulatory options presented in the 1991 proposal. However, the proposal was never promulgated as a final rule in large part because of controversy surrounding the proposed MCL for radon. The 1996 Amendments to the SDWA directed the Agency to withdraw the proposed MCL for radon, which was subsequently done on August 6, 1997 (62 FR 42221).

Most of the comments EPA received on the proposal related to radon. Approximately 120 comments related to non-radon radionuclides were valuable and most are still germane to the Agency's rulemaking efforts. Those comments are addressed, as appropriate, in today's document.

C. Court Agreement

The SDWA (as amended in 1986) provided a statutory deadline to promulgate a revised radionuclide rule of June 1989, but EPA failed to meet this deadline. An Oregon plaintiff brought suit to require EPA to issue the regulations and EPA entered into a series of consent agreements setting schedules to issue regulations for the radionuclides. EPA issued a proposal in 1991. After the SDWA Amendments in 1996, EPA agreed to publish a final action with respect to the proposed regulation for uranium by November 21, 2000. EPA also agreed to either take final action by the same date with respect to radium, beta/photon emitters, and alpha emitters or publish a notice stating its reasons for not taking final action on the proposal. This latter scenario would leave the current rule in effect.

D. Statutory Requirements for Revisions to Regulations

Both the 1986 and the 1996 Amendments to the SDWA state that revisions be made to existing drinking water regulations periodically. Section 1412(b)(9) of the 1986 SDWA Amendments directed that ''national primary drinking water regulations be amended whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons, but in any event, such regulations shall be revised at least once every 3 years.'' The 1996 SDWA Amendments provide that EPA '' * * * not less than every 6 years review and revise, as appropriate, each national primary drinking water regulation,'' and that ''any revision shall maintain, or provide for greater, protection of the health of persons.''

The radionuclides emit ionizing radiation and, absent data indicating that there is a threshold level at which exposure does not present a risk, EPA uses a linear, non-threshold model to set a zero MCLG for radionuclides. This means that any exposure can potentially cause harm and that risk associated with the exposure increases proportionally to the concentration of the radionculide.

EPA's current estimate of the unit risks posed by many of the radionuclides covered by today's document has generally increased relative to the 1991 estimate. In fact, based on the newest science (Federal Guidance Report 13), the fatal cancer risks associated with the 1991 proposed MCL changes for combined radium, gross alpha, and beta particle and photon radioactivity generally exceed the Agency's risk range of 10^{-6} to 10^{-4}. This document discusses and requests comment on the issues EPA has addressed in determining how to best meet applicable SDWA provisions for each of the radionuclide categories covered by today's document.

III. Overview of Today's Document

Additional data since the 1991 proposal suggest a need to retain some portions of the proposal, while retaining much of the current rule. Any changes that are finalized must meet the provisions for public health protection in accordance with the 1996 Amendments. EPA has presented its approach for finalizing the non-radon portions of the 1991 radionuclides proposal at several public meetings.

In December 1997 EPA held a public forum (stakeholder meeting) to discuss the requirements and limitations of the new Amendments pertaining to revisions to the radionuclide regulation. The Agency discussed most of the concepts presented in this document and received valuable feedback from the public, the regulated community, and other Federal Agencies. In this Document, EPA is presenting the current information and options upon which the Agency will make its decisions regarding revisions to the existing standards. At the same time, the Agency is requesting additional data and comments on the approach EPA expects to take in formulating the final rule.

The most significant new information concerns the occurrence, monitoring, and health effects of radionuclides in drinking water. Recent data suggest a more widespread occurrence of certain radionuclides which may point to a need for improved monitoring for these radionuclides in certain areas of the country. Conversely, a better understanding of the occurrence patterns may also indicate the need for less frequent monitoring. The newest health effects models, which are based on improved age-dependent biokinetic and dosimetric models of the effects of ionizing radiation on the body and more recent epidemiological information, reveal that radionuclides generally present a somewhat greater risk than the estimates of previous models, including the 1991 RADRISK model. EPA's publication ''Federal Guidance Report 13'' (FGR–13, EPA 1999b) discusses the newest risk modeling. The resulting risk estimates based on of the new health effects models are largely the reason for the publication of this document. The

following are some aspects of the NODA which the Agency would like to highlight.

A. Health Risk Consistency With Chemical Carcinogens

The risks associated with exposure to chemical carcinogens are usually expressed as the risks of illness. It is EPA policy to issue standards that maintain a risk ceiling in the target risk range of 10^{-6} (one in one million) up to 10^{-4} (one in ten thousand). For consistency between the level of protection between chemical and radiological drinking water contaminants, EPA is considering utilizing whichever risk provides the greater protection for MCL changes, a 1×10^{-4} risk of cancer incidence, or a mortality risk at half the incidence, 5×10^{-5}. The risk of death at 5×10^{-5} is the more protective if the mortality rate from a particular radionuclide is more than 50%, which is true for most of the radionuclides. However, for the thyroid, the mortality rate from thyroid cancer is at 10%. Protecting at 1×10^{-4} incidence corresponds to a mortality at $1\text{x}10^{-5}$. Conversely, protecting at 5×10^{-5} mortality with only a 10% mortality rate allows an incidence, of 5×10^{-4}, a less protective number.

B. Drinking Water Consumption

EPA received comments in 1991 from the American Water Works Association (AWWA), the Colorado Water Quality Commission, the Atlantic Richfield Co., and the Rio Algom Mining Corp. suggesting that consumption of drinking water was actually 1.2 liters per day, thus EPA was being too conservative in using two liters per day.

When establishing an MCL for a carcinogen, the risk which the MCL would represent is considered as well as treatability and costs. Radionuclides will have an MCLG of zero, with MCLs based on standard assumptions of two liters intake per person per day (2 L/day), an average individual weight of 70 kg, and a 70 year life span. EPA now has data to indicate that the average consumption of tap water is 1.1 liters per day per person and that a consumption rate of 2.2 L/day represents the 90th percentile consumption level.[1] Basing the MCL on a consumption rate higher than the average value is justified since MCLs are intended to be protective of the persons that comprise the population and not just ''typical individuals''. Since a consumption value of 2 L/day is less than the 90th percentile consumption rate, EPA believes that its assumption of 2 L/day for MCL determinations is not overly conservative and is justifiable.

When computing the national benefits of a regulation and the estimate of cancer mortality risks or risk reductions, EPA is now using 1.1 liters per person per day (L/day) of water as the estimate of the average daily consumption rate for individuals. In effect, this reduces population risk estimates by approximately one half and reduces the estimate of risk reductions by approximately one half. Since benefits calculations are based on risk reductions, this reduces monetized benefits by approximately one half. It should be noted that it is consistent to set health protection levels based on a subset of individuals that face the highest risks (sensitive subpopulations and/or the substantial minority of the population have higher water consumption levels), while estimating benefits based on average individuals (average consumption and sensitivity). EPA believes this approach leads to protective MCLs and realistic benefits calculations.

C. Risk Modeling and the MCL

The Agency's current radionuclides health effects model is based on Federal Guidance Report 13 (FGR–13, EPA 1999b). The Agency's new health effects model uses state-of-the-art methods, models and data that are based on the most recent scientific knowledge. Compared with the approaches used in 1976 and 1991, the revised methodology includes substantial refinements (described in appendix II, ''Health Effects''). While commenters have pointed out the MCLs in the current rule are based on ''old science'', the newest science indicates that many of the MCLs proposed in 1991 have corresponding risks that are much greater than the upper limit of the Agency's acceptable lifetime excess risk range of approximately 10^{-6} to 10^{-4} (one in one million to one in ten thousand lifetime excess risk of cancer). The risks associated with each existing and proposed MCL are described in sections that follow. The risk models are described in detail in appendix II (Health Effects) and in the Technical Support Document for the Radionuclides Notice of Data Availability (EPA 2000a).

Between 1976 and the present, different scientific models have been used to calculate risks from radiation exposure. Each model derives a different concentration of a particular nuclide for a given level of risk. For example, in 1991, the RADRISK model indicated that consuming drinking water with radium-228 at 26 pCi/L would lead to an excess lifetime cancer risk of 1×10^{-4}. However, using today's model (based on Federal Guidance Report 13), the best estimate of lifetime risk of Ra-228 at 26 pCi/L is 1×10^{-3}, a risk value ten times greater than thought in 1991.

Likewise, the 1991 proposed MCL for Ra-228 at 20 pCi/L was thought to correspond to lifetime excess cancer risk of 7.7×10^{-5}. The most current risk estimate for Ra-228 at 20 pCi/L 7.7×10^{-4}, again ten-fold greater and much higher than the Agency's target risk ceiling of 10^{-4}. For individuals consuming water with 20 pCi/L of both Ra-228 and Ra-226, the risk was thought to be 1.7×10^{-4} in 1991. However, based on the newest science, these individuals would be exposed to lifetime excess risks of 1×10^{-3} risk (one in a thousand), a risk level 10-fold higher than the Agency's target risk ceiling for drinking water MCLs. EPA requests comments on these issues.

D. Sensitive Sub-Population: Children

The age-specific, sex-specific models used by EPA for estimating risk from ionizing radiation implicitly provide for risk differentiation by gender and age. The computer program suite, DCAL (FGR–13), uses age-specific metabolic models to calculate the dose from a unit intake of a radioisotope during each year of life from birth to 120 years of age. Age-specific organ masses are used for all ages up to adult, and for adult males and adult females. Risk coefficients are given by age and sex for each year of life from birth to 120 years of age. The risk is then calculated by combining calculated doses and age-sex-specific risk coefficients with age-sex-specific intake data and age-sex-specific survival data.

A separate risk analysis for children was performed and is described in appendix II (Health Effects), part C. Risks to children are explicitly considered when setting MCLs for radionuclides. In the case of the regulated water systems (currently, community water systems), children are fully protected. In the case of the unregulated systems of potential concern (non-transient non-community water systems, NTNCWSs), the analysis is more complicated. Risks to children served by NTNCWSs are discussed in appendix II, part C, number 3.

[1] If one ranked, from lowest to highest, the average daily water consumption levels for every CWS customer in the U.S., the ''90th percentile'' value of 2.2 L/day is the best estimate of the value for which 90 percent of the population would drink that much or less on an typical day.

E. MCL for Beta Particle and Photon Radioactivity

1. EPA's Plans for Finalizing the 1991 Proposed MCL for Beta and Photon Radioactivity

This section presents the important considerations that have led EPA to consider retaining the current MCL for beta particle and photon radioactivity when the 1991 proposal is finalized in November of 2000. EPA is, however, also considering finalizing the 1991 proposed changes to the monitoring requirements for beta particle and photon radioactivity, as described later in this section. The current MCL is (40 CFR 141.16):

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

(b) Except for the radionuclides listed in Table A, the concentration of man-made radionuclides causing 4 mrem total body or organ dose equivalents shall be calculated on the basis of a 2 liter per day drinking water intake using the 168 hour data listed in ''Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air or Water for Occupational Exposure,'' NBS Handbook 69 as amended August 1963, U.S. Department of Commerce. If two or more radionuclides are present, the sum of their annual equivalent to the total body or to any organ shall not exceed 4 millirem/year.

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

Radionuclide	Critical organ	pCi per liter
Tritium	Total body	20,000
Strontium-90	Bone marrow ..	8

Following these instructions leads to a unique list of concentration limits for 168 other man-made radionuclides. This list is included in today's document in appendix II, ''Health Effects.''

The 1991 proposed MCL for beta emitter and photon radioactivity was 4 mrem-ede (effective dose equivalents), with the footnote:

''**NOTE.** —The unit mrem-ede/yr refers to the dose committed over a period of 50 years to reference man (ICRP 1975) from an annual intake at the rate of 2 liters of drinking water per day.''

Following these instructions leads to a unique list of concentration limits for 230 radionuclides. EPA has determined that there is no way to update the 4 mrem dose basis (1976) for the beta particle and photon radioactivity MCL without the extensive process of a new proposal. While some stakeholders have suggested that reverting to the existing rule for beta particle and photon radioactivity (''beta emitters'') is relying on ''old science,'' it should be pointed out the newest risk estimates, based on the peer-reviewed Federal Guidance Report 13, indicates that the risks associated with the 1991 proposed MCL of 4 mrem-ede (effective dose equivalents) are above the 10^{-4} risk level (10^{-3} to 10^{-4}) for many of the beta emitters. Figure 1 shows the most current risk estimates for the beta emitter concentration limits derived under both the current and proposed MCLs. As the figure shows, the current MCL results in concentration limits with risks that fall within the Agency's risk range goal of 10^{-6} to 10^{-4} (while some are slightly above and some slightly below, all round to values within these orders of magnitude).

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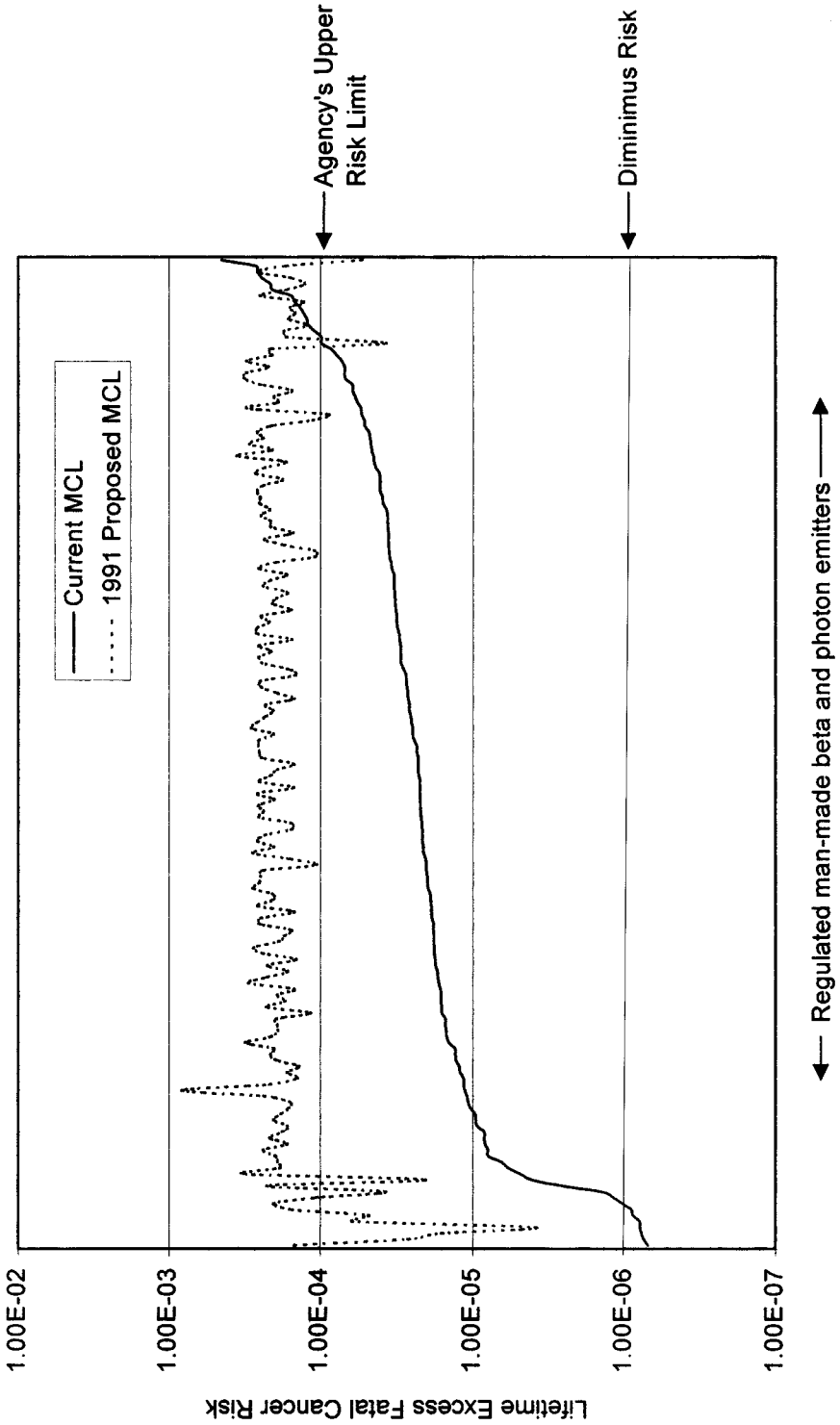
Figure 1. Lifetime Excess Risks for Current and Proposed MCLs for Beta and Photon Radioactivity



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In summary, the Agency fully recognizes that the dose-based MCL of 4 mrem/year is based on older scientific models. However, the Agency has decided to retain the current MCL given that:

- Federal Guidance Report 13 (FGR–13, EPA 1999b) demonstrates that the 1991 proposed MCL of 4 mrem-ede/year results in concentration limits that are outside the 10^{-6} to 10^{-4} range;
- FGR–13 demonstrates that the current MCL of 4 mrem/year results in concentration limits that are within the 10^{-6} to 10^{-4} range;
- the fact that there is no evidence of appreciable occurrence of man-made beta emitters in drinking water;
- the 1996 Safe Drinking Water Act requires EPA to evaluate all NPDWRs every six years (''Six Year Review'').

EPA believes that Six Year Review is the appropriate vehicle for updating the beta particle and photon radioactivity MCL.

2. Beta Particle and Photon Radioactivity Monitoring

Currently, surface water systems serving more than 100,000 persons are required to monitor for beta particle and photon radioactivity using a screening level of 50 pCi/L, while systems that are determined to be vulnerable by the State are required to monitor using a screening level of 15 pCi/L. In 1991, EPA proposed that all ground water and surface water systems within 15 miles of a potential source, as determined by the State, be required to monitor using a screening level of 30 or 50 pCi/L. EPA is considering retaining the current monitoring requirement of a 15 pCi/L screen for water systems drawing water from contaminated sources. EPA solicits comment on these issues. EPA is taking comment on screening levels of 30 or 50 pCi/L for systems within 15 miles of a potential source.

3. Lead-210 and Radium-228

The 1991 proposal included lead-210 (Pb-210) and radium-228 (Ra-228) in the list of regulated beta and photon emitters, both of which are naturally occurring. An 1991 the Agency was considering raising the Ra-228 MCL to 20 pCi/L, which is high enough to significantly contribute to gross beta levels. However, since the Agency is retaining the current combined Ra-226 and Ra-228 standard of 5 pCi/L, Ra-228 will no longer be a significant contributor to gross beta. For the reason, the Agency sees no value in including Ra-228 in the list of beta/photon emitters.

New risk analyses indicate that Pb-210 is of concern well below the current and proposed screening levels for beta and photon emitters. In order to assess the occurrence of Pb-210 to determine if it is present at levels high enough to warrant separate monitoring, EPA has included it on the list published in the Unregulated Contaminant Monitoring Rule (UCMR) (64 FR 50556, Friday, September 14, 1999). USGS also monitored for Pb-210 in its study with EPA of 100 locations. The reader is referred to appendix I and the Technical Support Document (EPA 2000a) for further information regarding this study. Since Pb-210 specific monitoring was not proposed in 1991, EPA cannot address this concern without a new proposal. After occurrence data has been reviewed from the UCMR, EPA may propose appropriate actions.

F. Combined Ra-226 and Ra-228

1. MCL Considerations

The combined radium-226 and -228 NPDWR has long been a contentious issue. A number of water systems believe the current MCL is too stringent and have not installed treatment or taken other measures to comply. EPA first proposed the possibility of increasing the current 5 pCi/L limit for combined radium-226 and -228 in 1991. The proposal suggested a new level of 20 pCi/L for Ra-226 and Ra-228 separately along with a proposed limit of 300 pCi/L for radon-222 . This combination was proposed in part due to the disproportionate costs of removing radium compared to radon. The proposal was met with opposition, largely due to the controversy surrounding the radon component. In the ensuing deliberations, debates regarding the radon component of the proposal interfered with promulgation of the proposal. In the 1996 Amendments to the SDWA, Congress directed EPA to remove the radon component from the proposal. Consequently, the Agency has once again considered the issues surrounding the allowable concentration of radium-226 plus radium-228 in drinking water.

EPA is considering retaining the current MCL for combined radium-226 and -228 at 5 pCi/L for the following reasons. First, the unit risks for Ra-226 and Ra-228 are believed to be much greater than estimated in 1991, such that raising the combined Ra-226 and Ra-228 MCL up to 20 pCi/L for each radionuclide would result in a lifetime excess cancer risks that are ten-fold higher than the Agency's acceptable risk range of 10^{-6} to 10^{-4}. And second, EPA is required to consider the MCL for Ra-226 and Ra-228 apart from any NPDWR for radon, both by the 1996 SDWA Amendments and the later court stipulated agreement. Both points are discussed further here.

First, in 1976 the estimate of risk from either Ra-226 or Ra-228 at 5 pCi/L was between 5×10^{-5} and 2×10^{-4}, averaging 1×10^{-4}. In 1991 the RADRISK model calculated that a 1×10^{-4} risk corresponded to Ra-228 at 26 pCi/L and Ra-226 at 22 pCi/L.

Table III–1 shows the change in estimated risks from 1976 until the present. ''Current Risk Estimates'' are calculated using the 1999 model, FGR–13 (EPA 1999b). The table allows a comparison between the calculated risk during each phase of the evolution of the radionuclides NPDWRs, including the current best estimate of risk based upon FGR–13 (EPA 1999b). Details of why the models have changed and the additional data taken into consideration are found in the appendix II and the Technical Support Document (EPA 2000a).

TABLE III–1.—CHANGES IN ESTIMATED RISKS FOR VARIOUS RA-226 AND RA-228 LEVELS

Year model used	Radium-228			Radium-226		
	Concentration pCi/L	Previous risk estimate	Current risk estimate	Concentration pCi/L	Previous risk estimate	Current risk estimate
2000 FGR–13	5	2×10^{-4}	2×10^{-4}	5	7.3×10^{-5}	7.3×10^{-5}
2000 FGR–13	2.5	1×10^{-4}	1×10^{-4}	6.85	1×10^{-4}	1×10^{-4}
1994 FGR–11	11	1×10^{-4}	4.5×10^{-4}	10	1×10^{-4}	1.5×10^{-4}
1991 RADRISK	26	1×10^{-4}	1×10^{-3}	22	1×10^{-4}	3.3×10^{-4}
1991 RADRISK proposed MCL	20	7.7×10^{-5}	7.7×10^{-4}	20	9.1×10^{-5}	2.9×10^{-4}
1991 RADRISK	5	1.9×10^{-5}	2×10^{-4}	5	2.3×10^{-5}	7.3×10^{-5}

TABLE III–1.—CHANGES IN ESTIMATED RISKS FOR VARIOUS RA-226 AND RA-228 LEVELS—Continued

Year model used	Radium-228			Radium-226		
	Concentration pCi/L	Previous risk estimate	Current risk estimate	Concentration pCi/L	Previous risk estimate	Current risk estimate
1976*	5	1×10^{-4}	2×10^{-5}	5	1×10^{-4}	7.3×10^{-5}

*The risk of either radium-226 or radium-228 at 5 pCi/L was believed to be between 5×10^{-5} and 2×10^{-4} in 1976. The average would have been 1×10^{-4}.

The 1991 estimated risk corresponding to 20 pCi/l of Ra-226 in addition to 20 pCi/l of Ra-228 was thought to be 1.7×10^{-4}. However, the current risk estimate based on FGR–13 (EPA 1999b) for 20 pCi/l of Ra-226 in addition to 20 pCi/l of Ra-228 is 1×10^{-3} (one in a thousand), an order of magnitude (ten times) above the acceptable risk of 1×10^{-4}.

In contrast, maintaining the current standard would allow a maximum lifetime risk of 2×10^{-4} (within the original risk range of the 1976 regulation). This represents a one in 5,000 lifetime mortality risk and would only be present if 5 pCi/L in the drinking water were all radium-228, a relatively rare occurrence situation. If the radium present were all radium-226, the risk would be 7×10^{-5}, just below EPA's risk ceiling. Since:

- the risks associated with the current MCL of 5 pCi/L are already at the upper end of the Agency's allowable risk range of 10^{-5}; and
- the 1991 proposed MCLs for Ra-226 and Ra-228 have risks as high as 1×10^{-3}, ten-fold higher than the Agency's allowable risk, the Agency believes that maintaining the current MCL for combined Ra-226 and Ra-228 is the appropriate action.

Regarding treatment feasibility, EPA's determination that water systems can feasibility treat and quantify combined radium at 5 pCi/L is supported by case studies of systems that had combined radium levels in excess of the MCL and that later came into compliance through treatment. In addition, EPA has case studies of systems that have come into compliance through purchasing water, blending, and developing new wells (EPA 2000a).

Since risk estimates for Ra-228 are significantly higher than thought in 1991, EPA has evaluated the risk reductions, costs, and benefits of decreasing the allowable level of radium-228 to 3 pCi/L and has discussed the results in the Technical Support Document (EPA 2000a). The concern is that a system with 5 pCi/L of Ra-228 with insignificant levels of Ra-226 would be in compliance with the combined radium MCL, but would have an associated lifetime excess cancer morbidity risk of 2×10^{-4}, which exceeds the risk ceiling on 1×10^{-4}. While this is true, the occurrence data reported in appendix I suggest that this situation should be rare. Since EPA did not propose this action in the 1991 proposal, EPA cannot address this concern in the finalization of this proposal. However, EPA will consider this situation further and will later determine if a regulatory action is appropriate.

An unintended effect in the 1991 proposal was that the costs and benefits were not evenly distributed to all affected persons (individuals). In the 1991 proposal, an MCL was proposed for radon at 300 pCi/L and a revised MCL for radium from 5 pCi/L combined for both radium-226 and radium-228 to 20 pCi/L each. Benefits and costs were considered together for both radon and radium on a national basis. Compared to radium, radon is easier and cheaper to remove from water due to its air strippability. Since the risks avoided were higher and the treatment costs lower for the radon MCL, it was reasoned that the radon rule was much more cost-effective than the combined radium rule. However, since radium and radon do not tend to co-occur, individuals that would have benefitted from the radon rule were not the same individuals that would have faced higher risks under the proposed radium MCLs. EPA believes that such a trade-off is no longer appropriate. Among other considerations, the 1996 Amendments to SDWA explicitly separated the radon rule from the rule for the other radionuclides.

In summary, EPA based its proposed increase in the radium standard on the risk models that existed at that time and on a population risk trade-off with radon. The models in use in 1991 indicated that radium posed less of a risk than originally believed in 1976. However, current risk models (FGR–13, EPA 1999b) suggest that the combined radium standard of 5 pCi/L presents an even greater health risk than thought in 1976. Given the much higher current estimate of risks associated with the proposed Ra-226 and Ra-228 MCLs of 20 pCi/L and the statutorily required withdrawal of radon-222 from the proposal, the Agency believes that the MCLs for radium proposed in 1991 are no longer appropriate. EPA requests public comment on retaining the current radium standard of 5 pCi/L for combined Ra-226 and Ra-228.

2. Separate Radium Analysis

The 1991 proposal recommended decoupling the monitoring of radium-228 from radium-226. The current radionuclides rule requires analysis of Ra-228 only when Ra-226 levels are above 3 pCi/L. The rule recommends analysis of Ra-226 and/or Ra-228 when gross alpha exceeds 2 pCi/L where Ra-228 may be present, and requires analysis of Ra-226 when gross alpha exceeds 3pCi.L.

Ra-228 may be present with minor amounts of Ra-226 or in the absence of Ra-226. In general, the mobility of a parent radionuclide may be very different from that of a daughter element, depending on the geochemistry of the elements involved. However, the occurrence of a radionuclide may still be governed by the occurrence and distribution of its parent (see EPA 2000a). Since radium-226 arises from the uranium decay series and radium-228 arises from the thorium series, it is logical to expect them to occur independently of one another. Also, the parents of Ra-226 (uranium isotopes) and Ra-228 (thorium isotopes) have very different geochemical behaviors. Uranium is fairly mobile in oxidizing ground waters, while thorium is rather insoluble. In contrast, the daughter radium isotopes are more mobile in reducing waters and are relatively immobile in oxidizing waters. Since Ra-226 is part of the uranium series (relatively mobile parent) and Ra-228 is part of the thorium series (immobile parent), Ra-226 can and does mobilize in waters containing Ra-228 more frequently than the reverse situation. These observations indicate that Ra-226 and Ra-228 may be expected to significantly co-occur, but that the correlation will not be strong enough to use the occurrence of one to predict the other with acceptable certainty. Recent

studies support this conclusion (EPA 2000a).

This conclusion indicates that the current monitoring screen for Ra-228 based on Ra-226 is not reliable. Therefore as proposed in 1991, EPA is considering requiring separate monitoring and analysis of both radium-226 and radium-228 in the final rule. The Ra-228 and Ra-226 results would be summed to determine compliance with the radium MCL. This will provide a more accurate assessment of systems containing little or no radium-226, but possessing a significant enough concentration of radium-228 to exceed the standard.

G. Gross Alpha MCL

The gross alpha standard promulgated in 1976 considered natural and man-made alpha emitters as a group rather than individually. At the time, the analytical costs made it impractical to identify each alpha-emitting nuclide in a given water sample. The existing gross alpha MCL includes radium-226, but excludes radon-222 and uranium (because these latter nuclides were to be regulated at a later date). The 1991 risk estimates indicated that the inclusion of Ra-226 was not warranted. However, today's risk estimates, based on FGR–13 (EPA 1999b), suggest that the Ra-226 unit risk is large enough to warrant to include it in gross alpha, as in the current standard. In today's Document, the Agency is considering maintaining the current MCL for gross alpha, believing it to be protective. EPA will consider proposing changes to the rule in the future.

EPA believes that the term ''gross alpha'' may be confusing. ''Gross alpha'' implies counting the total alpha emissions and is the appropriate name for that particular analytical method. The standard excludes uranium and radon from the total or gross count. Just as the proposal suggested the term ''adjusted gross alpha'' with the exclusion of radium-226, EPA believes the term ''net alpha'' or ''the alpha standard'' might better describes the current standard which excludes such alpha emitters as radon, uranium. EPA requests public comment on the name change.

The gross alpha MCL was originally established at 15 pCi/L to account for the risk from radium-226 at 5 pCi/L (the radium regulatory limit) plus the risk from polonium-210, the next most radiotoxic element in the uranium decay chain. In 1976, the risk resulting from exposure to 10 pCi/L of polonium-210 was thought to be equivalent to the risk resulting from exposure to 1 pCi/L of radium-226. Looked at another way, the 1976 gross alpha standard equated to 6 pCi/L of radium-226 (5 pCi/L of radium-226, plus the10 pCi/L of polonium-210 which itself was equal to 1 pCi/L of radium-226). Since the risk associated with the combined radium standard was believed to be in the range of 5×10^{-5} to 2×10^{-4}, this assumption placed the gross alpha standard reasonably within that range as well.

The gross alpha standard proposed in 1991 remained at 15 pCi/L, but excluded radium-226 (because it was proposed at 20 pCi/L). The new limit was termed ''adjusted gross alpha.'' In effect, it allowed an increase of 5 pCi/L of non-radium alpha emitters in drinking water from 10 to 15 pCi/L by occupying the 5 pCi/L originally represented by the radium. In the 1991 proposal, the allowable non-radium gross alpha contribution in that same water sample i.e. Po-210, would be 15 pCi/L. Because this latter scenario represents more risk than the scenario evaluated for the current regulation, EPA no longer supports an ''adjusted gross alpha'' limit of 15 pCi/L.

In the future, EPA may consider a proposal to exclude radium-226 from the gross alpha MCL as proposed in 1991 (because of the existence of a separate standard for radium-226), but to maintain protection, limiting the gross alpha standard to 10 pCi/L. Reducing the limit has the advantage of effectively reducing exposure to polonium-210 and radium-224. In addition, excluding radium-226 from being in both the gross alpha and radium standards may avoid confusion. EPA examined the possibility of this change in the context of the potential for added treatment costs versus the marginal benefits to be derived. However it appears that retaining the standard at 15 pCi/L is protective of public health at a reasonable cost. A picoCurie cap of 15 represents different risks for various nuclides, but this is not unlike other regulated carcinogens or the other radionuclides. The risks represented by two components, namely radium-224 and Polonium-210, are discussed next.

1. Polonium-210

Current risk estimates suggest that the risk resulting from exposure to polonium-210 is ten times greater than originally believed in 1976 compared to radium. However, existing occurrence data indicates that its presence in drinking water is relatively rare. To gain a better understanding of the public health risk posed by polonium-210 in drinking water, EPA included this radionuclide in the Agency's Unregulated Contaminants Monitoring Rule (64 FR 50556, Friday, September 17, 1999). The Agency may consider a future proposal to develop a separate limit for polonium-210 within (or separate from) a potentially revised gross alpha standard.

EPA believes that current technology can limit polonium-210 to 4 pCi/L or below, although precise quantification at this level may present a challenge. Because of its energetic alpha emissions, a gross alpha measurement may overestimate the actual concentration of polonium-210 in the sample by a factor of two. With current gross alpha measurement, if the total alpha were 15 pCi/l contributed by polonium, the actual concentration of polonium could be much less, depending on the calibration standard. At present, since there is no specific drinking water regulation for polonium-210, there is no EPA-approved method for measuring polonium to determine compliance with a drinking water standard. Should EPA decide to develop a separate limit for polonium-210, the Agency will ensure that the approved analytical method for demonstrating compliance is in place and includes a calibration standard appropriate for polonium's energetic alpha, thereby reducing the possibility of overestimating its presence. EPA requests information relative to any known occurrence of polonium and the need for a proposal of a separate limit. Recently, USGS co-operated with EPA and the American Water Works Association in monitoring for radionuclides, including Po-210 (103 wells in 27 States). The study and findings are described in EPA 2000a). USGS will publish the study in the near future. In this study, Po-210 levels were found above 1 pCi/L in less than two percent of the wells. Since the wells were targeted for high radium occurrence, this may not be typical. The reader is referred to appendix I (Occurrence) and the Technical Support Document (EPA 2000a) for further information.

2. The Occurrence of Radium-224 and its Impact on Alpha

Recently, the short lived isotope of radium has been found in some drinking water supplies. Extensive monitoring in the State of New Jersey over the past several years and follow-on survey by EPA and the USGS has demonstrated that radium-224 may be present in significant quantities in ground water, especially where its decay chain ancestor radium-228 is present. Although it is included in the (gross) alpha MCL, it was not targeted specifically for several reasons: (1) It was not believed to be a health risk, (2)

it was not known to be prevalent and (3) sampling it at a representative point within the distribution system rather than the entry point to the system allowed decay. However, newer FGR–13 risk estimates (EPA 1999b), coupled with the greater occurrence, and the 1991 proposal to sample at the entry point to the distribution system, now make radium-224 a concern.

Radium-224 is a naturally occurring radioisotope, which is part of the thorium decay chain. It emits alpha particles and has a half-life of 3.66 days. The decay of its progeny via alpha and beta decay also happens very quickly. In approximately 4.1 days, an original radium-224 atom has decayed to stable lead-208 by emission of an equivalent of 4 alpha and 2 beta particles. A gross alpha analysis will detect 3 alpha particle emissions including daughters in equilibrium with the parent Ra-224. If a sample analysis is done within 72 hours, preferably 48 hours, an appropriate back-calculation can be performed of the gross alpha count of the sample water. Otherwise the laboratory will significantly underestimate the radium-224 and other alpha emitters that may have been originally present in the sample.

Under the current rule, utilities are allowed to collect quarterly samples, composite and analyze at the end of the year. In 1991, EPA proposed a holding time of 6 months for gross alpha. However, neither the annual composite under the current rule or the proposed holding time of 6 months can appropriately capture the presence of alpha-emitting radium-224, or its progeny in a gross alpha analysis. The Agency intends therefore, to issue a separate proposal to change the holding time for gross alpha analysis to account for the presence of radium-224 in the sample.

At this point in time, the Agency strongly recommends to States and utilities that an alpha analysis be performed within 48 to 72 hour after sample collection to capture the contribution of the alpha particles arising from radium-224. In this NODA, the Agency is reiterating and underscoring its recommendation to that effect as outlined in a memorandum of January 27, 1999 from Cynthia Dougherty, Director of the Office of Ground Water and Drinking Water (EPA 1999a). For systems to whom a rapid analysis might be a burden, a reasonable screening tool for the presence of Ra-224 under many geochemical circumstances is the presence of its radiological ancestor, Ra-228. Since systems will monitor for Ra-228, the result can serve as a general proxy for the presence or Ra-224 for the purposes of prioritization. It is not definitive and would not be an acceptable substitute for a rapid analysis of gross alpha or Ra-224. In the absence of Ra-228, a system may not need to place as high a priority on rapid gross alpha or specific Ra-224 analysis. Since, as explained earlier, each Ra-224 atom contributes approximately three daughter alpha particles to the gross alpha count, a simple first approximation of Ra-224's contribution to gross alpha would be three times the Ra-228 concentration in pCi/L. For the purposes of prioritizing monitoring for Ra-224, grandfathered gross alpha data added to three times the result of the Ra-228 measurement would be a reasonable first approximation of the gross alpha including Ra-224 and its daughters available from a rapid gross alpha test. However, EPA reiterates that this approximation is not a substitute for rapid analysis of gross alpha or Ra-224.

EPA is not considering requiring a separate MCL or analysis for radium-224 when the rule is finalized in November of 2000. The definition of gross alpha will continue to include Ra-224. EPA is willing to consider comments on the need to apply sub-limits to Po-210 or Ra-224 within the MCL of 15 or as separate standards. Proposing a separate limit for radium-224 at 10 pCi/L within the alpha MCL of 15 pCi/L is a future possibility, as is a separate MCL for radium-224. The latter would require a separate, specific, rapid analysis specifically for radium-224, rather than relying on the gross alpha test and alpha MCL. Such actions would require a new proposal or proposals.

As part of the alpha standard, the Agency does not consider Ra-224 a significant risk. The lifetime mortality risk associated with exposure to 10 pCi/L of radium-224 is approximately 5×10^{-5} or one in 20,000. Because radium-224 and its progeny have very short half-lives, the total alpha count represents the radium-224 and its progeny. Consequently, there are effectively three alpha particle counts for every atom of radium-224 present. The health risk of radium-224 already includes the impact of these progeny in the body (the committed dose). Therefore while the gross alpha count may be at 15, the impact of the emissions is approximately related to Ra-224 at 5 pCi/L and the risk of 2.5×10^{-5} or excess mortality of one in 40,000.

H. Uranium

Uranium is not currently regulated by the 1976 radionuclides drinking water standards. The 1986 SDWA Amendments included uranium as one of the 83 contaminants listed to be regulated in drinking water. Two health effects are associated with exposure to uranium: cancer, resulting from the radioactive emissions, and kidney toxicity, resulting from the exposure to the uranium itself. The mass of the uranium is measured in micrograms (μg) while the radiation activity is measured in picoCuries. In 1991, EPA proposed a limit on uranium of 20 μg per liter (μg/L) to protect against kidney toxicity. The corresponding radioactivity limit was assumed to be 30 pCi/L. At that time, the Agency also proposed an MCLG of zero, based on absence of an identifiable dose-response threshold. EPA has reevaluated both the health impact level for kidney toxicity and the cancer risks from radiation and costs of regulation. As discussed briefly next, the best estimate of the cost per cancer case or cancer death avoided at 20 μg/L is relatively large. However, it should also be noted that this cost per case avoided excludes the reduction in kidney toxicity risk. At the present time, kidney toxicity for uranium must be treated as a non-quantifiable benefit (see appendix II, ''Health Effects'' and the Technical Support Document, EPA 2000a).

Today's NODA presents new information which supports a regulatory level of 20 μg/L, based upon protection from kidney toxicity. The derivation of this number is based on newer, more complete studies which have also resulted in a lower uncertainty factor, now 100-fold. In addition, the contribution to ingestion from drinking water relative to food or inhalation, the relative source contribution (RSC), has been recalculated. Drinking water is now considered to contribute 80 percent of a person's total daily uranium intake. This has the effect of permitting 80% of the reference dose (RfD) to be occupied by the drinking water component of diet. Both a lower uncertainty factor coupled with a lower food intake and higher proportional contribution from drinking water to total intake, might suggest the allowance of a higher regulatory limit; however, the more recent studies have offset this by revealing a lower observed effect level for kidney toxicity. The recalculated ''safe level'' for kidney toxicity remains 20 ug/L. The derivation of the uncertainty factor is based on the types of uranium health data available. EPA's policy for uncertainty factors for estimating LOAELs is summarized in 63 *FR* 43756 (August 14, 1998, ''Draft Water Quality Criteria Methodology Revisions: Human Health''). The derivation is described in appendix II.

Uranium is also classified as a carcinogen because of its radioactivity, and resulting emissions of ionizing radiation. The two most prevalent isotopes of uranium, uranium-234 and uranium-238, have very different half-lives which result in different amounts of radiation emitted per unit mass. Uranium-234 emits far more radioactivity than U–238, but is much less abundant in aquifer materials. Uranium-238 emits less radioactivity, but is far more prevalent than U–234. The average ratio of uranium activity to mass in rock is 0.68 picoCuries per μg. Issues involving the activity to mass ration follow later in this section.

Complicating the Agency's decision making about a uranium standard is the fact that the monetized benefit of kidney toxicity cannot be calculated at low concentrations because data are lacking in terms of the level at which kidney disease is actually manifested. The calculated 20 μg/L level represents an intake which would result in no effect over 70 years by drinking two liters per day. Conclusions based on the toxicity of uranium to the kidney are based primarily on observed adverse effects at the cellular level, but which have not necessarily resulted in a recognized disease. It is difficult to monetize the benefits derived in such a situation, and EPA does not currently have a methodology for estimating benefits for kidney toxicity from uranium. In the case of reducing the risk of non-fatal cancer resulting from uranium, EPA can monetize these benefits based on avoided ''cost of illness.'' This methodology is discussed in some detail in the Technical Support Document (EPA 2000a) and elsewhere (EPA 2000b).

Thus, for kidney toxicity, the benefit to society are considered as ''non-quantifiable benefits.'' Kidney toxicity avoidance benefits can be expressed in terms of ''avoidance of exposure,'' but cannot be quantified in terms of avoidance of a specified number of cases of disease or fatalities (and the associated monetized benefits), as with cancer. In addition, it appears that excess uranium concentrations tend to be found in small water systems. This suggests that while many systems will be impacted, the affected populations will be small. In terms of cancer risk, the number of statistical cases avoided for MCLs of 20 and 40 μg/L are low (0.2 to 2 cases for 20 μg/L and 0.04 to 1.5 cases for 40 μg/L). In terms of exposure avoided for kidney toxicity, around 500 thousand to two million persons are exposed above 20 μg/L and 50 thousand to 900 thousand persons are exposed above 40 μg/L. See appendix V and the Technical Support Document (EPA 2000a) for details.

Although uranium is treatable to levels well below the 1991 proposed MCL of 20 μg/L (5 pCi/L was evaluated), EPA determined that levels below 20 pCi/l were not feasible under the SDWA, after taking the costs of treatment into consideration. Section 1412(b)(6) of the 1996 SDWA permits the Agency to evaluate whether the benefits of regulating at various MCLs justify the costs. Possible exercise of this authority is discussed in more detail later in this section.

The MCLG that was proposed for uranium in 1991 was zero because of concerns about the lack of a known threshold for the carcinogenicity of ionizing radiation. The MCL that was proposed in 1991 (20 μg/L) was based on uranium kidney toxicity, as previously described. The corresponding risk of cancer at a concentration of 20 μg/l is now estimated to be approximately 5×10^{-5}. In terms of the cost per cancer case avoided and kidney toxicity reduced, the cost of regulation is still relatively high (see Table V–2 in appendix V).

In its current benefit-cost analysis, EPA also evaluated regulatory options of uranium MCLs of 40 μg/L and 80 μg/L. EPA estimates that a level of 40 μg/L would correspond to a cancer risk of approximately a 1×10^{-4}, thus providing cancer risk protection within the Agency's traditional risk range. A level of 40 μg/L would represent a slightly higher risk of kidney toxicity. At a level of 80 μg/L, the cancer mortality risk is approximately 2×10^{-4}, which is above the Agency's acceptable risk range. At 80 μg/L, the projected total national costs decrease significantly, but the estimates of cancer cases avoided drops to values close to zero (*i.e.,* benefits diminish considerably), indicating that the cost per cancer case avoided may not be signficantly lower at an MCL of 80 μg/L than at an MCL of 40 μg/L. From a health effects perspective, the toxic health effects on the kidneys or other organs or systems in the body at exposure levels of 80 μg/L is unknown and is four times EPA's best estimate of the ''safe level'' with respect to kidney toxicity.

In terms of benefits and costs, Table V–2 (appendix V) shows the range of compliance costs and net benefits for the uranium MCL options of 20 μg/L, 40 μg/L, and 80 μg/L. While annual compliance costs drop significantly as the MCL increases from 20 up to 80, the estimate of cancer cases avoided drops considerably also. In fact, it is not clear whether the cost per case avoided increases or decreases with increasing MCL because of the uncertainties involved. The corresponding estimate of cases avoided for MCLs of 20, 40, and 80 pCi/L are 2.1, 1.5, and 1.0 cases annually. Based solely on cancer incidence, it may be appropriate for EPA to consider using an MCL higher than 20 μg/L for uranium, since it is arguable that the benefits do not justify the costs at this level. However, in terms of kidney toxicity, 20 μg/L may be justified. EPA solicits comment on this issue.

Health effects from uranium also need to be evaluated in the context of the effects of various uranium species and their activity levels. A mortality risk level of 5×10^{-5} translates to 23 pCi/L of U–238, 22 pCi/L of U–235, and 21 pCi/L of U–234 in drinking water. An ''alpha spec'' analysis of the water would determine the fractions of each present and a sum of the fractions below 100% would meet the MCL. However, this level is costly to obtain. Doubling the radioactivity limit to 46, 44 and 42 pCi/L for U–238, U–235, and U–234 respectively corresponds to a mortality risk level of 1×10^{-4}, which may be more acceptable, considering the costs. Likewise, a doubling of risk to 2×10^{-4} would again double the picoCurie limits of each isotope to 92, 88, and 84 pCi/L respectively. However, at these higher risk levels, the calculated protective limit for toxicity to the kidney may be exceeded, depending upon the uncertainty factor used.

By contrast, the relative dissolved concentration of the various isotopes of uranium will differ markedly from one locale to another. The 1991 proposal utilized a conversion factor of 1.3 picoCuries per microgram of uranium to convert a 20 μg/L proposed MCL in mass units to activity units in picoCuries (however, 1991 cost estimates were based on the more accurate conversion ratio of 0.9). Analysis of NIRS data suggest that it would have been more appropriate to use the 1.3 pCi/μg conversion factor for total uranium where concentrations are less than 3.5 pCi/L and a 0.9 conversion factor for concentrations above 3.5 pCi/L (Telofsky 1999). Converting the derived MCL option of 20 μg/L from mass to activity using a ratio of 0.9 for levels above 3.5 μg/L yields approximately 18 pCi/L . A statistical evaluation of uranium data reveals that, based on a linear regression of the data, the appropriate activity based MCL for 20 μg/L would be 17.3 pCi/L rounded to 17 pCi/L. Coupled with the knowledge that the concentration of uranium isotopes varies from place to place, the Agency is led to consider an MCL that

is protective in any location against both toxicity (μg/L) and cancer (pCi/L), whichever presents the greatest risk. This can be determined by conducting isotopic analysis to determine the relative amounts of each isotope in any one water system. Once the concentration ratio is known, a regulated entity may choose to measure mass or activity and select whichever analytical method or methods is most cost effective.

For example, if the uranium standard were 20 μg/L or pCi/L, a gross alpha measurement screen for uranium could be used in the following way (EPA 2000c and 2000d). The analysis breaks out as follows: if the result is below the detection limit for gross alpha, neither uranium measurements by mass or activity would be necessary since neither 20 pCi/L nor 20 μg/L could be exceeded. If the gross alpha test is between 3 and 5.5 pCi/L, the mass of 20 μg/L could be exceeded if all the activity were coming from uranium-238. Therefore a fluroimetric test for uranium mass concentration (μg/L) or an alpha spectrometry test for the activities (pCi/L, converted to μg/L using standard isotopic conversion factors) of the various isotopes present would be necessary to determine the uranium concentration in μg/L. Because gross alpha tests may underestimate uranium by a factor of as much as 3.62, if the gross alpha test exceeded 5.5 pCi/L (20÷3.62), it is indicative that the 20 pCi/L limit may be exceeded, and an isotopic analysis must be done. EPA solicits comment on these issues.

EPA is soliciting information and comment on the data and the appropriate course of action the Agency should pursue, given the factors of risk levels, national cost, number of cancers avoided, cost per case, cost per death, and kidney toxicity. EPA is currently evaluating three regulatory options:

- Regulate at 20 μg/L and 20 pCi/L (protective of kidney toxicity using the Agency standard 100-fold uncertainty factor for this type of LOAEL with an associated cancer risk of approximately 5×10^{-5} or five in one hundred thousand);
- Regulate at 40 μg/L and 40 pCi/L (this is twice the safe level with respect to kidney toxicity and would reduce the margin of exposure between the effect level and the proposed regulatory standard; with an associated cancer risk level of 1×10^{-4} or one in ten thousand, which is the Agency's usual upper cancer risk target);
- Regulate at 80 μg/L and 80 pCi/L (this is four times the safe level with respect to kidney toxicity and would further reduce the margin of exposure between the effect level and the proposed regulatory standard; with an associated cancer risk level of 2×10^{-4} or two in ten thousand, which is above the Agency's usual upper cancer risk target).

In summary, EPA believes that 20 μg/L is feasible and is the Agency's preferred option, but may not have benefits that justify the costs. Were a higher level to be chosen, EPA would be exercising its discretionary authority under section 1412(b)(6) to select a level above the feasible level. It should be noted, however, that there may be considerable non-quantifiable benefits of avoiding exposure to cancer and kidney toxicity. Also, as discussed previously, there is little available data or information about the effects of kidney toxicity at relatively high exposures and thus, the benefits attributable to avoided illness cannot be quantified. Thus, the costs may be justified at a more stringent level than would be suggested in light of the currently quantifiable benefits alone. In addition, the Agency generally does not establish regulatory levels outside of its target risk range and, in fact, prefers to set levels at the more protective end of that range (1×10^{-6}), wherever possible. Further, we usually follow Agency guidelines on use of uncertainty factors. For these reasons, the Agency does not favor an MCL option of 80 μg/L, but solicits comment on this and the previously-described regulatory options, together with any supporting rationale or data commenters wish to provide.

I. Inclusion of Non-Transient Non-Community Water Systems

Today's document is soliciting comment on several approaches for covering Non-Transient Non-Community (NTNC) water systems. Although current radionuclide regulations do not apply to NTNC water systems, in 1991 EPA proposed extending the radionuclides NPDWRs to include them. Several approaches representing varying degrees of control are being currently considered for finalization because, although much more has been learned about NTNC water systems and their customers since 1991, there is still very little known about the distribution of the highest levels of radionuclides in their water supplies. Based on the Agency's occurrence estimates, control of some radionuclides in NTNC water systems may not present a meaningful opportunity for health risk reduction. This issue arises as a consequence of the 1996 Amendments to SDWA which allow the Agency to consider whether the benefits of extending coverage to this category of water systems would justify the costs (section 1412(b)(6)(A)) and whether such regulation would provide a meaningful opportunity for health risk reduction (section 1412(b)(1)(A)(iii)). The Technical Support Document (EPA 2000a) presents a ''what if'' analysis for costs and benefits for NTNCWSs.

While it is feasible to control radionuclides in NTNC water systems, extending regulation to these systems needs to be considered in light of the new SDWA requirements. This analysis requires a balancing of both quantitative and non-quantitative factors. Based on the risk modeling discussed in the Technical Support Document (EPA 2000a), the ninetieth (90th) percentile lifetime risk of cancer incidence in an individual consuming water from a NTNC water system in the absence of a regulation is not expected to exceed three in 100,000 [2]. The cost per cancer case avoided to achieve reductions in these risks would considerably exceed the hundred million dollar mark if coverage of the rule were extended to NTNCs. The associated cost per case avoided ranges are well above the range of historical environmental risk management decisions.

Relative to community water systems, NTNC systems have much lower associated risk levels because most individuals served by these systems are expected to receive only a small portion of their lifetime drinking water exposure from this source [3]. This conclusion holds even using very conservative assumptions for modeling the NTNC exposure scenarios. For example, in the case of school children exposure, the Agency has conservatively assumed all impacted children would attend only schools served by NTNC water systems, have twelve years of perfect attendance, and get half of their daily water consumption at school. For the average thirteen year old, this scenario implies half of a liter (over sixteen ounces) every school day. Even under this very conservative set of assumptions, the water consumed by an individual student is estimated to represent less

[2] Throughout this discussion, exposures and risks were only considered for populations potentially addressable by regulation, i.e. systems with radionuclides present in excess of the proposed MCLs for community water systems.

[3] It is important to remember that the risk assessment for NTNC water systems does not consider exposure risk from private wells which may serve some customers at home. EPA recognizes that the radionuclide levels in some private wells may exceed the MCLs for CWSs, but this is a non-controllable factor since private wells are not regulated by the Safe Drinking Water Act.

than five percent of lifetime consumption [4].

On the other hand, much remains to be learned about the NTNC water systems. Little is known about the extent to which users of the different NTNC water systems use other water systems. It is conceivable that some areas in the country exist where individuals are subjected to exposure at a number of different non-community systems (e.g., day care center plus school plus factory, etc.). In such circumstances, individuals would be exposed to proportionately higher risks if the water systems all had elevated levels. For some individuals, the exposures could approach levels observed in corresponding community water systems.

This concern is somewhat alleviated by the fact that NTNC systems generally serve only a very small portion of the total population. For example, over ninety-five percent (95%) of all school children are served by community water systems, not NTNC systems. Only a small percentage of children are served by NTNC water systems and, of that group, less than one percent (or less than one in 2000 of the overall student population) would be expected to have individual radionuclides in their water above the proposed regulatory levels. Likewise, less than 0.1 percent of the work force population receive water from an NTNC water system. With such low portions of the total population exposed to any particular type of NTNC system, the overall likelihood of multiple exposure cases in the NTNC population should also be small.

Nevertheless, because children are more sensitive to radionuclides exposure [5], multiple water system exposure scenarios were considered in the modeling effort [6]. Tables III–2 and III–3 present individual risk estimates for average and most sensitive populations among the NTNC water systems. All of these factors contributed to the Agency's evaluation of whether or not to extend regulation to NTNC water systems and are discussed further in the appendix.

Review of Table III–3 shows that 90th percentile individual risk patterns for NTNC water system users exposed to uranium or radium-226 are relatively low. These 90th percentile figures represent risks estimated using the previously described conservative exposure scenarios, maximum water consumption patterns, and what are effectively 99.9th percentile occurrence estimates [7] from the NIRS data. Even with these conservative factors, lifetime cancer risks do not exceed the one in 10,000 level which has traditionally formed the upper bound of allowable risk in Agency decision-making.

TABLE III–2.—SELECTED SECTOR AND OVERALL NTNC, INDIVIDUAL RISK PATTERNS

[Lifetime cancer risk for individuals using average consumption levels]

Sector	Alpha	Radium 226	Radium 228	Uranium
School Students	2×10^{-5}	$0.9–1.1\times10^{-5}$	$2–3\times10^{-5}$	$0.7–0.9\times10^{-5}$
Day Care Children	$2–3\times10^{-5}$	$0.6–0.7\times10^{-5}$	$2–3\times10^{-5}$	$0.8–1\times10^{-5}$
Factory Worker	$1–2\times10^{-5}$	1×10^{-5}	$2–3\times10^{-5}$	1×10^{-5}
All NTNC Water Systems	$0.3–0.4\times10^{-5}$	$0.2–0.3\times10^{-5}$	$0.5–0.7\times10^{-5}$	0.2×10^{-5}

Note that Radium 224 is being used as a surrogate for alpha emitters.

TABLE III–3.—SELECTED SECTOR AND OVERALL NTNC, INDIVIDUAL RISK PATTERNS

[Lifetime cancer risk for individuals using 90th percentile consumption levels]

Sector	Alpha	Radium 226	Radium 228	Uranium
School Students	$0.5–0.6\times10^{-4}$	0.3×10^{-4}	$0.6–0.7\times10^{-4}$	0.3×10^{-4}
Day Care Children	$0.7–0.8\times10^{-4}$	0.2×10^{-4}	0.6×10^{-4}	$0.3–0.4\times10^{-4}$
Factory Worker	$0.5–0.6\times10^{-4}$	$0.3–0.4\times10^{-4}$	$0.7–0.8\times10^{-4}$	$0.5–0.6\times10^{-4}$
All NTNC Water Systems	0.2×10^{-4}	0.1×10^{-4}	$0.2–0.3\times10^{-4}$	$0.1–0.2\times10^{-4}$

Radium-228 and gross alpha pose approximately twice the threat of the other two radionuclides. While sensitive individual estimates still fall below the one in ten thousand range, they may not in a scenario in which other drinking water sources are similarly high. However, as stated previously, the Agency views it as somewhat improbable that this system overlap occurs to a significant extent. Nevertheless, it could be an issue in some rural communities. While such infrequent and highly site-specific conditions are very difficult to address efficiently in a National-level regulation, the Agency believes that exempting NTNC water systems from the radionuclide NPDWRs, given the degree uncertainty about the occurrence levels and extent of system customer overlap, may be inappropriate. For these reasons, the Agency believes it may be appropriate to take a somewhat different approach with respect to NTNC water systems than previously practiced.

EPA is considering extending partial coverage of the radionuclide NPDWRs to NTNC water systems under several possible scenarios. Under the first three options, NTNC systems would be subject to targeted radionuclide monitoring requirements, in which selected NTNC systems would follow the radionuclides monitoring requirements for community water systems. The targeting strategy would be based on small community water system occurrence for the same radionuclides.

[4] Day care exposure is similarly conservatively estimated by assuming five years of perfect attendance, fifty weeks per year and five days per week. Factory workers are assumed to perfectly attend and work at the same facility for forty-five years. All of these assumptions are under continuing investigation and will likely be revised downward in the future as the Agency is able to gather further information.

[5] As an example, the lifetime risk per pCi/L of Ra–228 to a child whose exposure begins under the age of five is more than ten times greater than the lifetime risk of an individual whose exposure begins between the ages of 25 and 30.

[6] For example, the possibility that a child spent five years in a day care center, then twelve years in schools, and then forty-five years working in a factory served only by NTNC water systems with high radionuclide levels.

[7] In other words, the expected number of NTNC systems nationwide would be less than twenty. It is because these levels are so rare that the level is fairly speculative. As discussed in the appendix, the Agency believes its estimates of occurrence are reasonable, based on levels observed in small ground water community water systems.

The States (or primacy agency) would determine which NTNC systems are likely to be using contaminated water systems, based on CWS monitoring results. These systems may then be required to monitor and meet CWS MCLs for gross alpha and combined radium and other relevant radionuclides. EPA is considering:

- Requiring targeted NTNC systems to monitor and meet the CWS MCLs for all or selected radionuclides, where targeting is determined by the State based on whether the NTNC system is using source water for which CWSs have reported MCL violations for radionuclide in question;
- Requiring targeted NTNC systems to monitor and post notice if the system exceeds the CWS MCL, using the same definition of targeting as in the first option;
- Issuing guidance that recommends that targeted NTNC systems monitor and meet the CWS MCLs, using the same definition of targeting as in the first option.

The Agency requests comments on these options and any supporting rationale for such a decision. The Agency is also interested in receiving comments on other options such as extending full coverage of the rule to NTNCs and not extending any aspect of the radionuclides NPDWRs to NTNC systems. The Agency will decide, as part of the upcoming finalization of the 1991 proposal, to incorporate what it considers to be the most appropriate option in view of available the data and information.

J. Analytical Methods

Today's NODA provides a brief update of the methods-related items which have occurred since the 1991 proposed rule. For a more thorough discussion of the analytical methods updates, the public is referred to appendix III of this NODA and to the Analytical Methods section of the Technical Support Document for the Radionuclides Notice of Data Availability (EPA 2000a).

1. Radionuclides Methods Updates

On July 18, 1991 (56 FR 33050; EPA 1991), 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 approved in the March 5, 1997 final methods rule (62 FR 10168; EPA 1997a). In addition to these fifty-four, EPA also approved 12 radiochemical methods, which were submitted by commenters after the 1991 proposed rule. Currently, an overall total of 89 radiochemical methods are approved for compliance monitoring of radionuclides in drinking water. These methods are currently listed in 40 CFR 141.25.

The March 5, 1997 **Federal Register** also approved suitable calibration standards for the analysis of gross alpha-emitting particles and gross beta-emitting particles. These specific methods-related items are addressed in some detail in the Technical Support Document for the Radionuclides Notice of Data Availability (EPA 2000a) and in even greater detail in the 1997 final methods rule (62 FR 10168, EPA 1997a) and the 1991 proposed rule (56 FR 33050; EPA 1991).

This NODA also notifies the public about the use of the gross beta method for the screening of radium-228. In the 1991 proposed rule (56 FR 33050; EPA 1991), the Agency would have allowed the use of the gross beta-particle activity method to screen for the presence of radium-228 at the proposed radium-228 MCL of 20 pCi/L. For the combined radium-226 and 228 standard of 5 pCi/L (the current standard), the Agency can not recommend the use of the gross beta-particle activity method for screening of radium-228. Instead, a specific analysis for radium-228 would be necessary. Although several methods are currently approved for the analysis of radium-228 in drinking water, the Agency requests comments from the public and supporting documentation regarding other radium-228 methods or method variations which may be able to reach greater sensitivity at the 2 pCi/L level.

2. The Updated 1997 Laboratory Certification Manual

In the 1991 proposed rule (56 FR 33050; EPA 1991), EPA cited the 1990 laboratory certification manual's guidance for sample handling, preservation, holding time and instrumentation. In response to the 1991 proposed rule, a commenter questioned why the holding time for radioactive iodine was six months, when the half-life of iodine-131 is eight days. The Agency recognized this typographical error and changed the holding time to eight days in the updated 1997 certification manual (EPA 815–B–97–001; EPA 1997d). Table III–2 in the appendix shows the updated guidance for sample handling, preservation, holding times, and instrumentation that appeared in this manual. Table III–2 in the appendix also includes additional recommendations for radiochemical instrumentation (footnoted by the number 6). The Agency is seeking comment about the additional recommendations found in Table III–2.

3. Recommendations for Determining the Presence of Radium-224

To determine the presence of the short-lived radium-224 isotope (half life ~3.66 days), the Agency recommends using one of the several options discussed in the appendix III. Although these measurement options are only recommendations, the Agency strongly urges water systems to check for the presence of radium-224 in their drinking water supplies. Comments are solicited from the public about the options listed in appendix III or any other appropriate methods of detection.

4. Cost for Radiochemical Analysis

Revised Cost Estimates for Radiochemical Analysis.

In the 1991 proposed rule (56 FR 33050; EPA 1991), EPA cited cost estimates for radiochemical analyses. The Agency updated these costs estimates by surveying a small number of radiochemical laboratories (no more than 9 laboratories) (EPA 2000a). The revised cost estimates are shown in Table III–3 (appendix III). Because this information is based on a limited number of laboratories, the slight increase in costs from 1991 to 1999 may be due to either statistical uncertainty or possibly others factors such as inflation.

After the 1991 proposed rule, there were several comments regarding analytical costs. One commenter stated the costs of analysis for radium-226, radium-228, radioactive strontium and total strontium were unrealistically low. The Agency can neither agree nor disagree. As noted earlier, EPA revised the cost estimates for radiochemical analysis. Both the 1991 costs estimates and the revised cost estimates were from small surveys and may not be truly representative of the actual costs for some radiochemical analyses. Comparison of the estimated costs from 1991 with the revised cost estimates indicate the costs for some analyses to similar, while for other analyses, cost do appear to be higher. The Agency solicits comments and factual data that would clarify this matter.

Several commenters stated that small systems, which are likely to need only a few analyses, cannot take advantage of rates for volume sample analyses. The Agency agrees that individual small systems may not be able to take advantage of lower bulk analysis costs. To alleviate cost burdens, small systems may want to consider pooling their analytical needs with other small systems to negotiate for bulk rates.

5. Externalization of the Performance Evaluation Program

Due to resource limitations, on July 18, 1996 (61 FR 37464; EPA 1996b), EPA proposed options for the externalization of the PE studies program (now referred to as the Proficiency Testing or PT program). After evaluating public comment, in the June 12, 1997 final notice EPA (62 FR 32112; EPA 1997b):

> decided on a program where EPA would issue standards for the operation of the program, the National Institute of Standards and Technology (NIST) would develop standards for private sector PE (PT) suppliers and would evaluate and accredit PE suppliers, and the private sector would develop and manufacture PE (PT) materials and conduct PE (PT) studies. In addition, as part of the program, the PE (PT) providers would report the results of the studies to the study participants and to those organizations that have responsibility for administering programs supported by the studies.

EPA has addressed this topic in public stakeholders meetings and in some recent publications. For more information, readers are referred to the aforementioned Federal Register notices. More information about laboratory certification and PT (PE) externalization can be accessed at the OGWDW laboratory certification website under the drinking water standards heading (www.epa.gov/safewater). At this time, 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 cost estimates, the Agency solicits public comments on this subject.

6. The Detection Limits as the Required Measures of Sensitivity

In 1976, the National Primary Drinking Water Regulations 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).'' Table III–4 in the appendix cites the detection limits or the required sensitivity for the specific radioanalyses that were listed in the 1976 rule and are also cited in 40 CFR 141.25. In the 1991 proposal (56 FR 33050; EPA 1991), EPA proposed using the method detection limit (MDL) and the practical quantitation level (PQL) as measures of performance for specific radioanalytical methods. Acceptance limits based on the PQLs, which were derived from performance evaluation studies, were also proposed in the 1991 rule. Some commenters found the use of acceptance limits confusing and the relationship to the actual method performance was not clear. With perhaps the exception of uranium, the Agency will not go forward with the proposed acceptance limits, PQL, or MDL. Because uranium has never been regulated, it did not have a detection limit in the CFR and one has never been proposed. In 1991, EPA did propose a PQL of 5 pCi/L with an acceptance limit of +/− 30%. Although it is believed that a detection limit for uranium would be very similar to the PQL, because a detection limit has never been proposed, the Agency may have to adopt the PQL for uranium until a detection limit is proposed. For the other radionuclides, which are regulated, the Agency believes the current 1976 detection limit requirements are most appropriate. The existing definition of the detection limit takes into account the influence of various factors (efficiency, volume, recovery yield, background, counting time) that typically vary from sample to sample. Furthermore, the detection limit is computed for each individual sample and does not represent an idealized set of measurement parameters. Therefore, the detection limit reflects the expected random uncertainty for a given sample analysis.

7. Performance Based Measurement System

On October 6, 1997, EPA published a Notice of the Agency's intent to implement a Performance Based Measurement System (PBMS) in all of its programs to the extent feasible (62 FR 52098; EPA 1997c). EPA is currently determining how to adopt PBMS into its drinking water program, but has not yet made final decisions. When PBMS is adopted into the drinking water program, its intended purpose will be to increase flexibility in laboratories in selecting suitable analytical methods for compliance monitoring, significantly reducing the need for prior EPA approval of drinking water analytical methods. Under PBMS, EPA will modify the regulations that require exclusive use of Agency-approved methods for compliance monitoring of regulated contaminants in drinking water regulatory programs. EPA will probably specify ''performance standards'' for methods, which the Agency would derive from the existing approved methods and supporting documentation. A laboratory would be free to use any method or method variant for compliance monitoring that performed acceptably according to these criteria. EPA is currently evaluating which relevant performance characteristics under PBMS should be specified to ensure adequate data quality for drinking water compliance purposes. After PBMS is implemented, EPA may continue to approve and publish compliance methods for laboratories that choose not to use PBMS. After EPA makes final determinations about the implementation of PBMS in programs under the Safe Drinking Water Act, the Agency would then provide specific instruction on the specified performance criteria and how these criteria would be used by laboratories for compliance monitoring of SDWA analytes.

K. Monitoring

1. Features of Today's NODAA

EPA's 1976 regulations for radionuclides in drinking water contained separate monitoring requirements for radiums, alpha emitters, and man-made beta and photon emitters. In 1991, EPA proposed to make modifications to the 1976 regulations to expand the scope of coverage to include non-transient non-community water systems, to change the monitoring location and monitoring frequencies, and to incorporate monitoring requirements for radon and uranium. A summary of the 1976 requirements and proposed changes in 1991 are presented in this section.

In today's document EPA is suggesting merging the current requirements and the 1991 proposed requirements into a unified system which is consistent with the Standardized Monitoring Framework (SMF), the current rule, and the proposed changes which are still germane. EPA is soliciting comment on monitoring at the entry points to the distribution system, as proposed in 1991, to ensure equal protection for all customers, under the sampling schedule of the SMF. EPA believes that this will increase consistency between monitoring requirements for radionuclides and the other regulated contaminants. As described in section III, part I (''Inclusion of Non-Transient Non-Community Water Systems''), EPA is considering several options for NTNC water systems, some of which would require monitoring. Because some monitoring provisions of the 1991 proposal were based on the proposed MCLs and not the current MCLs, their application to the current levels may entail a slightly different construct than in 1991. To the extent comments reveal aspects of the framework which need to be addressed separately from the 1976 rule or 1991 proposal, EPA will return

to the current rule's framework and propose to correct deficiencies via a proposal which will address analytical method issues as well, such as methods for Ra-224, Po-210 and Pb-210.

2. Standardized Monitoring Framework

Per the current rule, once the contaminant concentration in the water is established by the average results for four consecutive quarterly samples or by suitable grandfathered data, a system would be categorized as to whether it was above or below 50% of the MCL for that contaminant. In accordance with the SMF, as proposed in 1991, EPA is suggesting a tiered frequency for alpha emitters, combined radium, and uranium. This would entail one sample every three years for compliant systems with annual average contaminant levels above 50% of the MCL. For compliant systems with annual average levels below 50% of the MCL for these contaminants, one sample would be required every 6 years; non-detects, one sample every 9 years. EPA believes this system would align with the standardized monitoring framework, and would provide regulatory relief for systems with low to very low levels (without needing a waiver as called for in 1991). It would also provide more careful screening for systems with multiple sources of water entering the distribution system, by requiring a sample at each of these points to be protective of all of the customers within each water system. For beta particle and photon radioactivity, EPA is considering requiring four consecutive quarters every four years, the requirement under the current rule, for vulnerable systems because of their proximity to contamination sources.

EPA believes this monitoring scheme is less burdensome on systems in the long term than either the existing or proposed regulations. It provides slightly more protection than the current rules by more frequent monitoring for contaminants above half the MCL, and less frequent monitoring for the vast majority of systems below half the MCL. EPA believes this is more realistic and less burdensome, while recognizing the potential for variability of naturally occurring radionuclide levels in ground water over time. Such variability (*e.g.,* a change in pH by nitrogen fertilizer application leading to a higher solubility of radium) was seen in New Jersey and is further discussed in appendix I.

Small ground water systems comprise the vast majority of systems with radionuclide contamination problems. Since most small systems have only one entry point, an entry point monitoring requirement will not have an impact. For systems with radium above 50% of the MCL, with three or fewer entry points to the distribution system, monitoring at each entry point once every three years would have an equal or smaller impact (in terms of the number of samples analyzed) than the 1976 requirement of monitoring four times every four years.

3. Entry Point Monitoring

EPA recognizes that sampling conducted at the monitoring location specified in the current rule may under-represent the risk to some consumers. Results can vary depending on the usage of each water source and changes in the monitoring location within the distribution systems. For systems with more than one water source, monitoring within the distribution system may yield different results. In the current rule, sampling is conducted ''at a free flowing tap'' within the distribution system. The current rule also recognizes the potential problems by providing that systems with two or more sources of water with different concentrations of radionuclides monitor the source water, as well as water from a free flowing tap, when ordered by the State. Entry point monitoring, a feature of more recent NPDWRs, provides a better measure of water quality for residents near the start of the distribution system than monitoring within the distribution system (e.g., the middle of the system) where water is subject to blending if there are other sources. Therefore, EPA proposed in 1991 to change the location for compliance monitoring to the entry points to the distribution system, consistent with other NPDWRs.

4. Grandfathering Data

In the implementation guidance, which will be available on OGWDW's home page (http://www.epa.gov/ogwdw), EPA is suggesting that samples within the latest compliance period, beginning June, 1996, be eligible for use in determining the baseline for monitoring frequency. While EPA prefers this approach, others may be possible. Please provide data and supporting rationale if you comment on this issue. The application of this provision would extend to all classes of radionuclides for which data are available.

The Agency solicits comment on two different approaches for the beta monitoring requirements. The first option is to not allow any reduced monitoring and the second would be to allow reduced monitoring similar to the alpha emitters. If systems must collect samples on a quarterly basis (no reduced monitoring) then grandfathering of data is not necessary. If the Agency decides to allow reduced monitoring, the Agency believes that States may use historical data to supplement their vulnerability assessments but should not use grandfathered data to satisfy the initial monitoring requirements because a sufficient baseline needs to be established in those systems considered vulnerable to man-made radioactivity.

Grandfathered data would be used to comply with the initial monitoring requirements for gross alpha, radium-226/228, and uranium, under some circumstances. Data collected after June 1996, during the most recent compliance period, would be considered for grandfathering. It would be the State's responsibility to determine if grandfathered data is sufficient to satisfy the initial monitoring requirements established by this rule. At the State's discretion, systems with one entry point to the distribution system (EPTDS) could use grandfathered data to satisfy the initial monitoring requirements. Systems that have multiple entry points to the distribution system could use grandfathered data collected after June 1996 to satisfy the initial monitoring requirements, provided that the data were collected at the EPTDS.

EPA is also considering that, at the State's discretion, systems with up to three entry points to the distribution system could also use grandfathered data to satisfy initial monitoring requirements, even if not collected from EPTDS, if the State makes a written finding that the circumstances of the system and their review of historic data justify such action. While the Agency cannot prescribe every possible scenario that a State may encounter, an example of circumstances that might support such a finding could be: a system that has three wells (and EPTDS), that are simply from different parts of a well-field, using the same aquifer, with good historical data showing uniform, low to no radionuclide occurrence from all wells, perhaps from the raw water as well as distribution system samples.

5. Sample Compositing

In general, compositing of samples is an effective means of decreasing analytical costs to systems. Compositing is permitted for alpha emitters and beta and photon emitters in the current rule. It is also allowed for radium-226 and -228 to the extent gross alpha was used as a screen for Ra-226 and, in turn, Ra-228. In the 1991 proposal, gross beta compositing was prohibited. Compositing for other nuclides was

allowed for up to five sampling points within one system; if the result for the composite was more than 3 pCi/l for any nuclide, individual non-composited samples were to be analyzed. This provision stemmed from the lowest MCL in the 1991 proposal, adjusted gross alpha at 15 pCi/l. Because of the possibility that one of the five samples taken might be at 15 pCi/L even if the other four were at zero, the rule envisioned one fifth (3 pCi/L) of the MCL as the maximum allowed result to assure no single well could exceed the MCL. The principle of limiting the result of five composited samples from separate entry points to one fifth of the MCL (or four composites to one fourth the MCL etc.) is still valid as a general matter, and should be followed whenever compositing is done.

A 3 picoCurie limit in the proposal would have been conservatively protective for a five sample composited for the proposed separate MCLs radium-226 and radium-228 at 20 pCi/L each, since ⅕ of each MCL is greater than 3 pCi/L. However, because EPA is considering retaining the current radium standard at 5 pCi/L combined, adding the results of five composited entry points samples for Ra-228 to the results of 5 composited entry point samples of Ra-226 must yield a result of one tenth (1/10) of the MCL to be assured that the combined Ra-226 and Ra-228 concentration could not exceed the MCL at any one entry point. Because one tenth of the MCL (0.5 pCi/L) is below the detection limit for Ra-226 and Ra-228, compositing of separate entry points cannot apply in case of Ra-226 or Ra228. However, annual compositing of samples from the same entry point may apply.

EPA requests comment on the feasibility and practical utility of compositing separate entry points (spatial compositing) versus compositing samples over time from the same entry point (temporal compositing). EPA believes that the use of one or the other (but never both simultaneously) may be appropriate under some circumstances. Greater certainty in the analytical result is obtained by taking the average of four separate (non-composited) results from one sampling location than by using a single result of composited samples. However, where an MCL is sufficiently above the detection limit such that analytical results are not subject to significant error near the MCL, compositing may be a cost saving measure. Additionally, when historical data indicate that contaminant levels are negligible (e.g., non-detects) for a water system, compositing among wells in a system or between systems having one point of entry may be advisable at State discretion. However, because of the costs of re-sampling and re-analysis of all points to confirm an MCL violation, or to qualify for decreased monitoring, it may not be in the systems best interest to initially composite in the absence of historical data.

6. Increased and Decreased Monitoring

Additionally, the Agency is considering having the final rule allow systems that are currently on a reduced monitoring schedule to remain on that reduced schedule as long as the system qualifies for reduced monitoring based on the most current analytical result. Systems for which the most current analytical result indicates a higher level than allowed for that monitoring schedule would resume monitoring at a frequency consistent with the most recent result. For example, a system with an annual average below half of the MCL could reduce monitoring to one sample every 6 years. If, while on this reduced frequency, the system collects a sample with an analytical result above half the MCL, the system would have to increase monitoring again to once every 3 years. It could revert to its previous reduced frequency of once every six years if the subsequent analytical result (of the sample taken three years later) was less than half the MCL. EPA also believes it is prudent to require quarterly samples to be collected at least 60 days apart, to capture seasonal variations. EPA solicits comment on this and other monitoring provisions.

7. Compliance Determinations

Compliance would be determined based on the annual average of quarterly samples collected at each entry point for all classes of radionuclides. If the annual average of any entry point exceeds an MCL, the CWS would be in violation. If NTNC systems are subject to MCLs, the same situation would apply to them. An immediate violation would occur for any sample analytical result or combination of sample analytical results that would place the system in violation before four quarters of data are collected (e.g., the first sample is greater than 4 times the MCL or the average of the first two samples is greater than twice the MCL). If a system has a sample that exceeds the MCL while on reduced monitoring, it would need to begin quarterly monitoring the following quarter. Compliance would be based on the average of the four consecutive quarters of data beginning with the initial result that exceeded the MCL. If a system fails to collect all samples required during any year, compliance would be calculated based on available data. Under the current rule, quarterly monitoring is continued until the annual average concentration no longer exceeds the MCL or until a monitoring schedule as a condition to a variance, exemption, or enforcement action becomes effective.

The following is a summary of certain features of the monitoring requirements for each regulated radionuclide or radionuclide group.

8. Combined Radium-226 and -228

Standardized monitoring: EPA contemplates application of the standardized 3, 6, 9 year cycles to the combined radium standard depending on whether analytical results for compliant systems are greater than (3) or less than (6) half the MCL or are a non-detect (9), as previously discussed. Decreased and increased monitoring would be based on the result of the analysis of the most recent required sample(s).

Entry point monitoring: Monitoring at entry points to the distribution system would be a requirement per the 1991 proposal unless EPA receives comments with compelling reasons for not doing so.

Sample Compositing: To decrease the burden of monitoring at distribution entry points, EPA is contemplating allowance of sample compositing for radium-226 or radium-228, but only when results will be indicative of the true level at a single entry point (temporal compositing). According to the proposal, systems would be required to analyze for Ra-228 separately from gross alpha or Ra-226. The Agency sees no reason why four separate samples from a single entry point (collected 60 days apart) could not be either analyzed and averaged or composited in the laboratory and analyzed, to determine future monitoring frequency. Therefore, EPA is suggesting for public comment that systems take the average analytical results from four individual samples, or the composite of four samples from each entry point, in order to determine future frequency.

As discussed previously, EPA does not contemplate allowing compositing of multiple entry points for derivation of combined radium results. EPA requests comment on any element of the foregoing discussion.

9. Alpha Emitters

Standardized monitoring: Same as for combined radium (see previous discussion).

Decreased and increased monitoring: Same as for combined radium (see previous discussion).

Entry point monitoring: Same as for combined radium (see previous discussion).

Sample Compositing: The current rule allows compositing of four samples in a laboratory or the averaging of four separate analyses. Under the 1991 proposal and the current rule, systems would be allowed to composite annually for samples taken from single entry points (temporal compositing) and, under the 1991 proposal, to composite samples representing up to five entry points with a six month holding time (spatial compositing).

10. Uranium

Standardized monitoring, monitoring frequency, and entry point monitoring: Same as for combined radium (see previous discussion).

Sample Compositing: For systems with gross alpha levels that are high enough to warrant uranium monitoring, annual composites for a single entry point would be allowed. Compositing of five samples representing five entry points would be permitted. If the result was greater than one fifth of the MCL, the individual samples would have to be analyzed or re-sampling and analysis of the new individual samples would have to occur.

11. Beta and Photon Emitters

Standardized monitoring framework, decreased monitoring: Monitoring for beta and photon emitters would follow the same schedule as in the current rule. Decreased monitoring is not envisioned for beta and photon emitters since only vulnerable systems would monitor, although EPA is taking comment on the possibility of decreased monitoring according to the standardized monitoring framework as outlined previously.

Screening levels: EPA recognizes certain problems with the current and proposed system. The proposed requirement of a 30 pCi/L screen for gross beta and photon emitters had the effect of no longer requiring Sr-90 monitoring because the proposed limit was above the screen of 30 pCi/L. Under the current MCL, there is only one contaminant that has a concentration limit near the 50 pCi/L screening level (Ni-63). There are five contaminants with concentration limits at or near 30 pCi/L and seven with limits below thirty. A screen level of 50 pCi/L would potentially miss the 12 contaminants with concentration limits below 50 pCi/L and a screening level of 30 pCi/L would potentially miss the 7 contaminants with concentration limits below 30 pCi/L. Systems that are drawing water from sources with known beta particle and photon radioactivity are required to use a screening level of 15 pCi/L under the current rule. The 1991 proposal retained this feature.

EPA thinks it is advisable to retain the proposed monitoring for sites within 15 miles of a source of beta photon emitters. The screening level in the original rule only affected surface water systems serving over 100,000, or other systems at State discretion, and the screening level for gross beta reflected this limited regulation. However, a known source of particular beta and photon emitters should be monitored for the specific radionuclides present at that source which may be a health concern below the screen, but would not be triggered by the screen. EPA would give States discretion on requiring specific monitoring for contaminants from specific sources.

In addition, a 15 pCi/l screening level is currently required for systems using water contaminated by effluents from nuclear facilities. These systems may also be required by the State to monitor for individual nuclides on a case by case basis. Since both screens may miss radionuclides of concern, EPA believes this issue is important and may need to be addressed in a future proposal. In addition, since many beta particle and photon emitters have half-lives that are too short to be detected under the current holding time, the issue of sample holding time may have to be re-visited in a future proposal.

Holding time: Another issue has a bearing on the screening level for which EPA is requesting comment. There are a significant number of beta and photon emitting radionuclides with short half lives, including those 13 nuclides of concern below the screening levels being considered. Because annual sample compositing is allowed under the current rule for beta and photon emitters, a screen above 30 pCi/L would detect a greater number of nuclides which (due to decay) may have been above a screen of 50 at the time of sampling, but are now between 30 and 50 pCi/L by the time of analysis. A screen level at 30 pCi/L would be more sensitive a screen for beta particle and photon radioactivity. The Agency requests comment on the selection of screening levels.

Sample Compositing: Annual compositing is permitted for beta and photon emitters in the current rule. In addition, for systems utilizing water contaminated by effluents from nuclear facilities, a quarterly compositing of five consecutive daily samples was to be analyzed for iodine-131, with more frequent monitoring at State discretion if it was detected in the finished water. EPA believes this compositing for single nuclide determinations is still valid. However, the 1991 proposed rule excluded compositing for beta and photon emitter samples. It also limited holding times to 6 months for single samples or 12 months for composites per the lab cert manual. A screen above 50 pCi/L , but with a sample holding time of 6 months without compositing may be a reasonable approach, considering screening options, holding times, and compositing issues. EPA solicits comment on these beta and photon emitter monitoring issues.

Entry point monitoring: EPA solicits opinion on requiring beta photon monitoring at entry points to the distribution system for vulnerable systems. EPA believes this is appropriate as it is for other nuclides, especially as an early warning of contamination from a localized source of man-made beta photon emitters.

12. Monitoring for Non-Transient Non-Community (NTNC) Systems

If EPA finalizes an option that requires monitoring for some or all NTNC systems, EPA wishes to make the monitoring requirements consistent between CWSs and those NTNC systems required to monitor. See the previous discussion for CWS monitoring for details. As with CWSs, monitoring under the SMF would be required at entry points to the distribution system, based on a nine-year cycle, consisting of three, 3-year monitoring periods, with provisions for reduced monitoring as appropriate. If the radionuclides NPDWRs for CWSs are fully extended to NTNCWSs, the monitoring frameworks would be the same.

Table III–4 summarizes the monitoring frequencies for CWSs and NTNC systems, under the options that require monitoring:

TABLE III–4. COMPARISON OF THE MONITORING FRAMEWORKS: THE EXISTING RULE, THE 1991 PROPOSAL, AND THE APPROACH DESCRIBED IN THE NODA

Current rule (1976)	1991 proposal	2000 NODA
Radium Alpha Emitters and Uranium		
Initial baseline: 4 consecutive quarterly samples	Initial baseline: one sample per year for 3 years.	Initial baseline: 4 consecutive quarterly samples taken within 3 years from effective date or grandfathered data in previous compliance period.
If average > MCL=treat, etc	Same as 1976	Same as 1976.
If one or more samples >MCL, do quarterly sampling until average < MCL.	Same as 1976	Same as 1976.
If >50% of MCL, 4 Quarters every 4 years	If >50% of MCL, one sample every 3 yrs or waiver to every 9 yrs.	Same as 1991 with no waiver.
If < 50% of MCL, 1 sample every 4 years	If <50% of MCL, one sample every 3 yrs or waiver to every 9 years.	If < 50% of MCL, one sample every 6 years.
If no detect, 1 sample every 4 years	If no detect, one sample every 3 yrs or waiver to every 9 yrs.	If no detect, one sample every 9 years.
Beta and Photon Emitters		
Quarterly gross beta monitoring. Vulnerable systems and surface water systems > 100,000 pop. Screen of 50; screen of 15 for contaminated water I–131 quarterly, Sr–90 and H–3 annual Sr–89 and Cs134 if above 15.	Vulnerable systems (surface and ground water) within 15 miles of source of man made emitters do gross beta screen proposed at 30.	Same as 1991:Vulnerable systems within 15 miles of source of man made emitters will monitor with screen of 50 or 30. Same as 1976: Screen of 15pCi/L for systems using contaminated waters. Same contaminants as 1976 with corrections per NBS HB–69.

13. Polonium-210 and Lead-210

Risk estimates based on Federal Guidance Report No. 13 indicate that current screening levels for gross alpha and gross beta may not be adequate to capture all contaminants of concern. Specifically, based on the new health-effects information contained in FGR–13 (EPA 1999b), EPA believes it may be appropriate to require systems to perform isotopic analyses for additional radionuclides that may present a significant threat to human health. As a result of this information, EPA is requiring some systems to do analyses for polonium-210 (a naturally occurring alpha emitter) and lead-210 (a naturally occurring beta emitter) under the Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR) (64 FR 50556, Friday, September 17, 1999), to be implemented after analytical methods for these contaminants have been approved.

14. Reporting Requirements

On May 13, 1999, EPA proposed subpart Q (64 FR 25964) to revise the minimum requirements public water systems must meet for public notification of violations of NPDWRs and other situations that pose a risk to public health from the drinking water. EPA anticipates the final Public Notification Rule (PNR), under part 141, subpart Q to be published in early 2000. After the final PNR is published, subsequent EPA drinking water regulations that affect public notification requirements will amend the PNR as part of each individual rulemaking.

The proposed PNR divides the public notice requirements into three (3) tiers, based on the type of violation. ''Tier 1'' applies to violations and situations with significant potential to have serious adverse effects on human health as a result of short-term exposure. Notice is required within 24 hours of the violation. ''Tier 2'' applies to other violations and situations with potential to have serious adverse effects on human health. Notice is required within 30 days, with extensions up to three months at the discretion of the State or primacy agency. ''Tier 3'' applies to all other violations and situations requiring a public notice not included in Tier 1 and Tier 2. Notice is required within 12 months of the violation, and may be included in the consumer confidence report at the option of the water system.

Today's NODA requests comment on whether community water systems (CWS) should provide a Tier 2 public notice for MCL violations under the radionuclide NPDWRs and to provide a tier 3 public notice for violations of the monitoring and testing procedure requirements. If NTNC water systems are required to monitor and notify, then they would be required to provide a Tier 2 notice if the systems exceed the MCLs. EPA requests comment on the implementation of public notification requirements by the effective date of the MCL and on the Tier 2 public notice requirement for quarterly repeat notices for NTNC systems that continue to exceed the CWS MCL(s) under the ''monitoring and notification-only'' option. EPA believes States will phase in monitoring of NTNC systems based on results of CWS systems in the same proximity. The agency requests comment on whether or not the same increase or decreased monitoring requirements which pertain to CWSs should apply to NTNC water systems i.e. the 3, 6 and 9 year monitoring based on being above 50% of the MCL, below 50%, or non-detect.

As in the current rules, an analytical result that exceeds the MCL would trigger additional confirmation samples, which in turn could trigger quarterly monitoring. For man-made beta and photon emitters, EPA is suggesting to finalize the proposal regarding a screening level of 30 or 50 pCi/L for ''vulnerable systems,'' which are defined as being within a 15 mile radius of a source of this class of radionuclides. For Pb-210, EPA will be collecting data to make a future determination regarding additional monitoring for this natural beta emitter.

Tables III–5 and III–6 summarize the current and proposed monitoring requirements and those suggested by today's document.

TABLE III–5.—INITIAL (ROUTINE) MONITORING REQUIREMENTS

1976	1991 proposal	2000 NODA
GROSS ALPHA		
CWSs: Four consecutive quarters at representative point(s) within the distribution system every four years.	CWSs and NTNCWSs: Annual monitoring at each entry point for first three years.	CWSs and NTNCWSs [1]: Four consecutive quarters of monitoring at each entry point, anytime during first 3 years.
RADIUM		
CWSs: Four consecutive quarters at representative point(s) within the distribution system every four years. Initial monitoring is for radium-226. If radium-226 exceeds 3 pCi/L, analysis for radium-228 is required. A gross alpha measurement can be substituted for radium 226 and/or uranium monitoring if the gross alpha measurement is below the applicable MCL(s).	CWSs and NTNCWSs: Annual monitoring for each radium isotope (radium-226 and radium-228) at each entry point, for three years.	CWSs and NTNCWSs: Four consecutive quarters of monitoring for each radium isotope (radium-226 and radium-228) at each entry point, any time during first 3 years.[2]
URANIUM		
None	CWSs and NTNCWSs: Annual monitoring at each entry point for three years.	CWSs and NTNCWSs: Four consecutive quarters of monitoring for uranium to determine compliance with both mass and activity either by gross alpha or specific mass or activity analysis at each entry point, every three years.[2]
BETA AND PHOTON EMITTERS		
CWSs serving > 100,000 persons and using surface water (and other systems designated by the State): Four consecutive quarters for gross beta, tritium and strontium-90 at representative point(s) within the distribution system. Determine major constituents if exceed screen of 50pCi/L Systems using water contaminated with effluent from nuclear facilities: Quarterly monitoring [1] for gross beta and iodine-131, strontium-90 and tritium. If gross beta level is above 15 pCi/L, the same or equivalent samples must be analyzed for strontium-89 and cesium-134.	Vulnerable systems only CWSs and NTNCWSs: (as designated by State): Two gross beta screening levels were discussed in the 1991 Proposal. Using a screen of 30 pCi/L, quarterly monitoring for gross beta is required, along with annual tritium monitoring. Using a screen of 50 pCi/L, quarterly monitoring for gross beta is required, along with annual tritium and strontium-90 monitoring.	Vulnerable systems only CWSs and NTNCWSs: (as designated by the State): Two gross beta [14] screening levels are being considered. Using a screen of 50 or 30 pCi/L, quarterly monitoring for gross beta is required, along with annual monitoring for tritium and strontium-90 as in 1976. Vulnerability based on proximity (15 miles) to source per 1991. Screen of 15 for contaminated waters as in 1976.[3]

NOTE: [1] This assumes that monitoring will be required at NTNC systems. If this is not the case, these requirements would not apply to NTNC systems.

[2] A gross alpha measurement can be substituted for radium-226 and/or uranium monitoring if the gross alpha measurement is below the applicable MCL(s).

[3] Quarterly monitoring for gross beta would be based on the analysis of monthly samples or the analysis of a composite of three monthly samples. For iodine 131, a composite of five consecutive daily samples shall be analyzed once per quarter. Additional monitoring may be required to identify specific isotopes if gross beta measurement exceeds the screening level.

TABLE III–6.—REDUCED MONITORING REQUIREMENTS

1976	1991 proposal	2000 NODA
GROSS ALPHA		
CWSs: One sample every four years if annual average from previous results (four consecutive quarterly samples) is less than ½ MCL.	CWSs and NTNCWSs: One sample every three years, if previous monitoring results (from three years of annual monitoring) are below MCL. If system is reliably and consistently below MCL, the system could receive a waiver, and monitor once every nine years.	CWSs and NTNCWSs: One sample every three years if previous monitoring results (''previous results'') are reliably and consistently at or below MCL; one sample every six years if previous results are reliably and consistently at or below ½ MCL; or one sample every nine years if previous results are reliably and consistently at or below the MDL.

TABLE III–6.—REDUCED MONITORING REQUIREMENTS—Continued

1976	1991 proposal	2000 NODA
RADIUM		
CWSs: One sample every four years if annual average from previous results (four consecutive quarterly samples) is less than ½ MCL.	CWSs and NTNCWSs using ground water: One sample every three years, if previous monitoring results (from three years of annual monitoring) are below MCL. If system is reliably and consistently below MCL, the system could receive a waiver, and monitor once every nine years.	CWSs and NTNCWSs: One sample every three years if previous results are reliably and consistently at or below MCL; one sample every six years if previous results are reliably and consistently at or below ½ MCL; or one sample every nine years if previous results are reliably and consistently at or below the MDL.
URANIUM		
None	CWSs and NTNCWSs: One sample every three years, if previous monitoring results (from three years of annual monitoring) are below MCL. If system is reliably and consistently below MCL, the system could receive a waiver, and monitor once every nine years.	CWSs and NTNCWSs: One sample every three years if previous results average below MCL; one sample every six years if previous results average at or below ½ MCL; or one sample every nine years if previous results average below the MDL.
BETA AND PHOTON EMITTERS		
CWSs serving > 100,000 persons and using surface water (and other systems designated by the State): Every four years, systems must collect samples from four consecutive quarters for gross beta at representative point(s) within the distribution system. Systems using water contaminated with effluent from nuclear facilities: No reduced monitoring is allowed.	Vulnerable systems only (as designated by State): Since only vulnerable systems are required to monitor, no reduced monitoring is allowed.	Vulnerable systems only (as designated by the State): Since only vulnerable systems are required to monitor, no reduced monitoring is allowed.

15. Laboratory Capacity Issue ‘‘ Possible Extension of Initial Monitoring Period

As discussed earlier in the analytical methods section (III.J), the Performance Evaluation Program (now known as the Proficiency Testing Program) has been externalized. Although the Agency is unsure at this time how externalization may affect laboratory capacity, EPA recognizes that it may be an implementation issue for at least three reasons:

- The recent externalization of the radionuclides Performance Evaluation (PE) 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 simultaneously with the radionuclides rule.

NIST is in the process of approving a provider for PT samples for radionuclides. States also have the option of approving their own PT sample providers. Should laboratory capacity issues related to externalization present implementation problems for the initial monitoring period (three years), EPA will consider allowing an additional year (four years total) for the initial monitoring period. During the specified time period, systems would be required to analyze four consecutive quarterly samples to determine compliance. If the final rule is promulgated in November of 2000, the new monitoring requirements would begin to be enforced in November of 2003. If EPA implements a one year extension, water systems would have until December 31 of 2007 to complete the required initial monitoring. This scenario would allow the ‘‘one third of systems per year’’ strategy inherent in the Standard Monitoring Framework to be applied, while allowing one additional year, if necessary, to address any laboratory capacity issues. EPA solicits public comment on this matter.

L. Effective Dates

Much of the rule that will be finalized in November 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 enforcement actions that put systems on compliance schedules as expeditiously as possible.

Under the Safe Drinking Water Act, final rules become effective three years after promulgation (November of 2003, assuming that the rule becomes final in November of 2000). The following discussion assumes a promulgation date of November 2000. For reasons described in the monitoring section of the NODA (section III, part K) and the Appendices (appendix V), initial monitoring will be required to completed by December 31, 2007. Under the Standard Monitoring Framework, systems have three years to complete the initial monitoring cycle of four consecutive quarterly samples. However, for reasons described in the monitoring section of the NODA (section III, part K) , systems will have an additional year to complete the initial monitoring cycle, which will correspond to an end date of December

31, 2007. This includes initial monitoring for uranium, the new monitoring requirements for radium-228, and new initial monitoring under the requirements for entry points. Compliance determinations and future monitoring cycle schedules are also discussed in the monitoring sections cited. MCL violations resulting from the new requirement for separate Ra-228 monitoring will be treated as ''new violations'' and will be on the same schedule as other new violations (e.g. uranium).

M. Costs and Benefits

The Safe Drinking Water Act provides for EPA to consider both public health and the feasibility (taking costs into consideration) in establishing drinking water MCLs. In addition the new Amendments require EPA to evaluate the costs and benefits of potential revisions to the current standards. As noted earlier, the Agency conducted an analysis of the costs and associated benefits of each of the options described in today's document. These analyses were performed consistent with the requirements for a Health Risk Reduction and Cost Analysis set forth in the 1996 Amendments to the SDWA (section 1412(b)(3)(C)).

First, all public water systems that are currently treating and are in compliance with the 1976 standards will have no additional cost if the rule remains the same as it is now. At the same time, EPA recognizes that it may be costly to systems which have delayed compliance. However, to the extent the rule remains the same, costs necessary to comply with the existing rule, as well as public health benefits associated with it, have accrued to that 1976 rule. If EPA changes nothing, the existing 1976 requirements must be met. EPA considers only those costs associated with accommodating revisions to the current regulations to be new costs. Costs incurred, or those that should have been incurred to comply with a previous regulation, are not factored into current considerations.

Second, EPA has reexamined the costs of the 1991 proposal regarding monitoring for any changes which may be warranted based on new data. EPA is contemplating several changes which were part of the 1991 proposed regulation and which may increase costs. These include: (1) Promulgating an NPDWR for uranium; (2) applying the radionuclide NPDWRs to non-transient, non-community (NTNC) systems; (3) requiring monitoring at the point of entry to distribution systems, and ; (4) requiring separate monitoring for radium-226 and radium-228.

EPA is also recommending rapid sample analysis for alpha emitters to detect the presence of short lived radionuclides such as radium-224, but is not contemplating requiring it as part of the revision to the radionuclides rule. The Agency will pursue the issue of a timely analysis of gross alpha to reflect short half lived Ra-224 in a separate proposal.

Costs and benefits for the various options are presented in appendix V of today's document, in the Technical Support Document (EPA 2000a), and in the draft Health Risk Reduction and Cost Analysis (EPA 2000b). Today's NODA solicits comment on whether the incremental risk reduction may justify the costs for certain of the revisions described in the NODA. EPA requests public comment on such questions and on the extent to which its discretionary authority provided by section 1412(b)(6) of the SDWA should be used. This NODA also requests public input regarding the need for further adjustments to the limits based on the cost and risk data presented in today's NODA.

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Appendix I—Occurrence

In order to estimate the total national costs and benefits of revising the MCLs it is necessary to develop updated national estimates of the occurrence and exposure to these radionuclide contaminants in drinking water. Occurrence data and associated analyses provide indications of the number of public water supply systems with concentration of radionuclides above the revised MCL as well as the population served by these systems. Monitoring and treatment costs can be estimated from the occurrence data.

A. Background

EPA conducted a nationwide occurrence study of naturally occurring radionuclides in

public water supplies called the National Inorganic and Radionuclides Survey (NIRS) (see EPA 1991, proposed rule). The objective of NIRS was to characterize the occurrence of a variety of constituents, including radium-226, radium-228, uranium (mass analysis), gross alpha-particle activity, and gross beta-particle activity, present in community ground-water supplies (finished water) in the United States, and its territories. The survey included a random sample from 990 collection sites. The public water supplies were stratified into four size categories, and the samples were chosen to best represent the same stratification present in the total population of community water supply in existence at the time, as shown in ———Table I–1.

TABLE I–1.—COMPARISON OF NIRS TARGET SAMPLE WITH FEDERAL REPORTING DATA SYSTEM (FRDS) INVENTORY

Population category (population range)	Number of FRDS sites*	Percentage of FRDS sites	Number of NIRS sites	Percentage of NIRS sites
Very small (25–500)	34,040	71.4	716	71.6
Small (501–3,300)	10,155	21.3	211	21.1
Medium (3,301–10,000)	2,278	4.8	47	4.7
Large and very large (10,001–>100,000)	1,227	2.6	26	2.5
Total	47,700	100.1	1,000	100.0

*Based in FRDS inventory for fiscal year 1985 from Longtin, 1988.

Results of NIRS were used to develop the proposed radionuclide rule in 1991 (56 FR 33050; EPA 1991). There has not been a comparable national survey for radionuclides since. Since the publication of the proposed 1991 revision to the MCLs, the United States Geological Survey has collected additional data on various radionuclides in groundwater to augment the data of the NIRS. These studies are summarized subsequently, and in greater detail in the Technical Support Document (EPA 2000a).

Szabo and Zapecza (1991) detail the differences in the occurrence of uranium and radium-226 in oxygen-rich and oxygen-poor areas of aquifers. Because the chemical behavior of uranium and radium are vastly different, the degree of mobilization of the parent and product are different in most chemical environments.

Recently, high concentrations of radium were found to be associated with ground water that was geochemically affected by agricultural practices in the recharge areas by strongly enriching the water with competing ions such as hydrogen, calcium, and magnesium (Szabo and dePaul, 1998). Radium-228 was detected in about equivalent concentrations as radium-226 in the aquifer study in New Jersey (Szabo and dePaul, 1998).

B. USGS Radium Survey

A 1998 USGS survey (see EPA 2000a) was designed to target areas of known, or suspected, high concentrations of radium-224 as inferred by associated radium occurrence data, geologic maps, and other geochemical considerations. Thus, the survey is likely biased toward the extreme high end of the occurrence distribution for radium-224 and co-occurring contaminants such as radium-228. Approximately half of the samples were below the minimum detectable concentration of radium-226 and radium-228 in spite of the fact that public water systems were targeted in areas where high concentrations of radium were expected. Table I–2 shows that, of the 104 samples, 21 exceeded the MCL for combined radium, and about 5 percent exceeded 10 pCi/L of radium-224, though several of these samples with pH less than 4.0 also contained detectable concentrations of thorium isotopes as well. Concentrations exceeded 1 pCi/L in about 10 percent of the samples analyzed for lead-210 and 3 percent for polonium-210.

TABLE I–2.—PERCENT OF SAMPLES EXCEEDING SPECIFIED CONCENTRATION

Radionuclide	Total number of samples	Percent of samples exceeding given concentration (pCi/L)					
		1	2	3	5	7	10
Ra-224	104	30	26	20	15	9	5
Ra-226	104	33	22	17	10	5	2
Po-210	95	3	1	1	1	0	0
Pb-210	96	10	3	1	1	0	0

Radium-224 occurs in many of the wells sampled at concentrations that highlight the limitations of the present monitoring scheme for the gross alpha-particle standard. In addition, the contribution of radium-224 and its short-lived daughter products to gross alpha emissions was estimated with data from a concurrent study of ground-water supplies by the USGS in cooperation with the state of New Jersey (Szabo et al., 1998). In that study, gross alpha emissions were measured before the decay of radium-224 and after sufficient time had elapsed for radium-224 decay (about 18–22 days). In this way, the difference between the initial gross-alpha measurement and the final measurement is indicative of the contribution of radium-224 and all other alpha emitting isotopes that would decay within this time frame. The results indicate that the contribution of radium-224 and its short-lived daughter products is approximately three times the concentration of radium-224. While this analysis was developed with a small data set in a restricted geographic range, it is based on a physical process and has important implications for such things as projections of radium-224 occurrence in association with gross-alpha concentrations. These results are also important in light of both the costliness and difficulty of the radium-224 analysis.

Concentrations of radium-228 were highly correlated with radium-224. Although this correlation was based on a limited number of data points, there is a physical basis to the correlation since both nuclides originate from the same decay chain. Therefore, there is potential for using radium-228 as a proxy indicator for the much shorter lived and infrequently sampled radium-224. In addition, the isotopic ratios of radium-226 to radium-228 were below 3:2 in many samples indicating that the gross alpha-particle screen that is currently used for combined radium (radium-226 + radium-228) compliance would be inadequate in many situations.

Polonium-210 and lead-210 are derived from the uranium-238 decay series; the decay series that produces radium-226. However, the survey was designed to assess radium-224; therefore results are possibly biased to areas that would more likely have isotopes in the thorium-232 decay series. In addition, the correlations of radium-226 with radium-224 and radium-228 are only 0.51 and 0.61 respectively; consequently, the wells that were sampled may not be located in areas expected to have polonium-210 or lead-210. Within these constraints, the new data help to fill the gap in occurrence information that existed for these isotopes. Polonium-210 was found in concentrations exceeding 1 pCi/L in only two wells. At this time, these

observations could not be associated with unique geochemical controls (as has been accomplished in a previous study in Florida; Harada et al., 1989) and further investigations would be necessary to infer anything more about the national distribution and occurrence of polonium-210.

Approximately 12 percent of the samples exceeded a lead-210 concentration of 1 pCi/L; however only one sample was greater than 3 pCi/L. The greatest frequency of detection was in the Appalachian Physiographic Province of the northeastern United States, especially in of Connecticut and Pennsylvania. The geochemical mechanism that controls lead-210 dissolution is also not well established and needs further study, though lead is less soluble than radium. In addition, lead-210, like polonium-210, is derived from a different decay chain than radium-224 and it was therefore not considered in designing the study. One possible explanation for the frequent detection of lead-210 in concentrations greater than 1 pCi/L in the Appalachian region may be the high concentrations of radon-222 in ground water in this region (Zapecza and Szabo, 1986). As the radon in solution decays through a series of very short half-lived products to Lead-210, a small fraction of the lead-210 may not be sorbed onto the aquifer matrix; thus, the higher the initial radon-222 concentration, the more likely measurable amounts of lead-210 would be found in the ground water. This hypothesis could not be tested however because radon-222 was not analyzed in this study.

C. USGS Beta/Photon Data Collection Effort

The major source of data for man-made radionuclides is the Environmental Radiation Ambient Monitoring System (ERAMS) which is published quarterly in the Environmental Radiation Data (ERD) reports. The ERD reports provide concentration data on gross beta-particle activity, tritium, strontium-90, and iodine-131 for 78 surface-water sites that are either near major population centers or near selected nuclear facility environs.

An additional data collection effort was completed by the U.S. Geological Survey in the summer of 1999 (see EPA 2000a) to analyze targeted beta-particle emitting radionuclides from a small number of public water systems that had shown relatively high levels of beta/photon emitters during the original NIRS survey. Of the 26 public water systems contacted for this effort none could ascertain which wells in their systems were originally sampled as part of NIRS. Consequently, although all efforts were made to include as many of the original systems as possible, it is presently unknown if the wells sampled match those in NIRS. The radionuclide analyses for this data collection effort included; short-term (48 hour) gross beta-particle and gross alpha-particle activities, long-term (30 days) gross beta-particle and gross alpha-particle activities, tritium, strontium-89, strontium-90, cesium-134, cesium-137, iodine-131, uranium-234, uranium-235, uranium-238, radium-228, radium-226, lead-210, and cobalt-60.

Gross beta-particle activities were all below 50 pCi/L in water collected from public water systems that were sampled previously during the National Inorganics and Radionuclide Survey (NIRS) and had been found to contain gross beta-particle activity in excess of 20 pCi/L. To the extent possible, all samples were collected from the original public water systems surveyed for NIRS where gross beta-particle activities were 20 pCi/L or greater. However due to the amount of time that had elapsed since the NIRS samples were collected, correlation with the original sampling point could not be verified for every water supply sampled.

Though the number of samples was limited (26 samples), a few conclusions can be reached. Concentrations of gross beta-particle activities will rarely exceed 50 pCi/L in water collected from public water systems (and did not do so in this study). A significant percentage (15% or 4 samples) of the 26 samples analyzed, however, contained gross alpha-particle activities at or in excess of the 15 pCi/L MCL indicating that concern over the presence of elevated concentration of gross alpha-particle activity in ground water is justified. Long-term (30-day) gross beta-particle activity analyses did not indicate significant ingrowth of beta-particles in any of the samples, though this result is qualified by the absence of significant quantities of uranium-238 in any of the samples collected. Naturally occurring potassium-40 and radium-228 are a significant source of gross beta-particle activity to many of the samples in agreement with results of Welch et al., 1995., Minor concentrations of naturally-occurring lead-210 are also detected occasionally. No manmade radionuclide was detected in concentration above the maximum detectible concentration (MDC) in any of the samples. The presence of naturally occurring beta-particle emitting radionuclides must be taken into account when evaluating the source of high gross beta-particle activity in ground water as first suggested by Welch et al., 1995.

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Appendix II—Health Effects

The following information summarizes the salient changes in risk assessment information and risk characterization methodology during the past two decades. The Technical Support Document (EPA 2000a) also provides additional information.

A. Use of Linear Non-Threshold Assumption

In estimating the health effects from radionuclides in drinking water, EPA subscribes to the linear, non-threshold model which assumes that any exposure to ionizing radiation has a potential to produce deleterious effects on human health, and that the magnitude of the effects are directly proportional to the exposure level. The Agency further believes that the extent of such harm can be estimated by extrapolating effects on human health that have been observed at higher doses and dose rates to those likely to be encountered from environmental sources of radiation. The risks associated with radiation exposure are extrapolated from a large base of human data. EPA recognizes the inherent uncertainties that exist in estimating health impact at the low levels of exposure and exposure rates expected to be present in the environment. EPA also recognizes that, at these levels, the actual health impact from ingested radionuclides will be difficult, if not impossible, to distinguish from natural disease incidences, even using very large epidemiological studies employing sophisticated statistical analyses. However, in the absence of other data, the Agency continues to support the use of the linear, non-threshold model in assessing risks associated with all carcinogens.

B. Continuous Improvements in Models, Data Base

As various scientific institutions have continued to collect data on the observed effects of radiation from the cohort of bomb survivors, patients with medical exposure, and workers with occupational exposure; continuous improvements have been possible in models to extrapolate effects and to estimate the risks of small exposures to radiation from the natural environment or man-made sources. The data have led to

changes in risk estimates as summarized here.

1. Basis of 1976 Estimates of Risk

- Risk of bone cancer from radium dial painters.
- Autopsy radioassay (see EPA 2000a). Body burden from natural intake or radium, about 1 pCi/day.
- Estimate annual dose rate in several organs from natural radium in rad/year.
- BEIR I risk numbers for radium dial painters yields risk/year per rad/year.
- Calculate risk over lifetime.

a. 1976 Estimates of the Risks from Radium-226 and Radium-228. In general, EPA followed the Federal Radiation Council (FRC) recommendation that radium ingestion limits for the general population should be based on environmental studies and not the models used to establish occupational dose limits (see EPA 2000a). In setting the MCL, EPA considered bone cancer and other soft tissue cancers to be the principal health effects associated with radium ingestion. To calculate body burdens, doses, and risks from ingestion of radium-226 and radium-228, in 1976, EPA relied on data from the 1972 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (see EPA 2000a) and the 1972 the National Academy of Sciences (NAS) Committee on the Biological Effects of Ionizing Radiation, BEIR I Report (see EPA 1991, proposed rule). Additional information and support were found in the International Commission on Radiological Protection, Publication 20 (see EPA 2000a). The literature suggests that radium-228 was as toxic as radium-226, and possibly twice as toxic for bone cancers in dogs. Given this, EPA believed that it was prudent to assume that the adverse health effects due to chronically ingested radium-228 were at least as great as those from radium-226.

Assuming equal toxicity with radium-226, EPA reasoned that lifetime ingestion of only radium-228 at 5 pCi/L would yield lifetime total cancer risks equal to those for a lifetime ingestion of only radium-226 at the same concentration, i.e., between 0.5 to 2×10^{-4}. By setting the MCL at 5 pCi/L for radium-226 and radium-228 combined, rather than individually, EPA sought to limit the lifetime total cancer risk from the ingestion of both isotopes in drinking water to 2×10^{-4} or less.

b. Basis for the 1976 MCL for Gross Alpha Particle Activity. One of the main intentions of the 15 pCi/L MCL for gross alpha particle activity, which includes radium-226 but excludes uranium and radon, was to limit the concentration of other naturally-occurring and man-made alpha emitters relative to radium-226. Specifically, this limit was based on the fact that EPA estimated that continuous consumption of drinking water containing polonium-210, the next most radiotoxic alpha particle emitter in the radium-226 decay chain, at a concentration of 10 pCi/L might cause the total dose to bone to be equivalent to less than 6 pCi/L of radium-226.

The 15 pCi/L limit, which includes radium-226 but excludes uranium and radon, was based on the conservative assumption that if the radium concentration is limited to 5 pCi/L and the balance of the alpha particle activity (i.e., 10 pCi/L) is due to polonium-210, the total dose to bone would be less than that dose associated with an intake of 6 pCi/L of radium-226.

c. Basis for the 1976 MCL for Beta Particle and Photon Radioactivity. In 1976, EPA estimated that continuous consumption of drinking water containing beta and photon emitting radioactivity yielding a 4 mrem/yr total body dose may cause an individual fatal cancer risk of 0.8×10^{-6} per year, or a lifetime cancer risk of 5.6×10^{-5}, assuming a 70-year lifetime. In setting the MCL for man-made beta and photon emitters, EPA used cancer risk estimates from the BEIR I report for the U.S. population in the year 1967 (see EPA 1991, proposed rule). For an exposed group having the same age distribution as the U.S. 1967 population, the BEIR I report indicated that the individual risk of a fatal cancer from a lifetime total body dose rate of 4 mrem per year ranged from about 0.4 to 2×10^{-6} per year depending on whether an absolute or relative risk model was used. Using best estimates from both models for fatal cancer, EPA believed that an individual risk of 0.8×10^{-6} per year resulting from a 4 mrem annual total body dose was a reasonable estimate of the annual risk from a lifetime ingestion of drinking water. Over a 70-year period, the corresponding lifetime fatal cancer risk would be 5.6×10^{-5}, with the risk from the ingestion of water containing less amounts of radioactivity being proportionately smaller.

Based on 1967 U.S. Vital Statistics (see EPA 1991 and EPA 2000a), the probability that an individual would die of cancer was about 0.19, and was thought to be increased by 0.1 percent from a lifetime dose equivalent rate of 15 mrem per year. Therefore, EPA calculated that the 4 mrem/yr MCL for man-made beta and photon emitters corresponded to a lifetime risk increase of 0.025 percent to exposed groups.

EPA knew that partial body irradiation was common for ingested radionuclides since they are, like radium, largely deposited in a particular organ, or in a few organs. In such cases, EPA acknowledged that the risk per millirem varies depending on the radiosensitivity of the organs at risk. For example, EPA estimated that cancers due to the thyroid gland receiving 4 mrem per year continuously ranged from about 0.2 to 0.5 per year per million exposed persons (averaged over all age groups). Considering the sum of the deposited fallout radioactivity and the additional amounts due to releases from other sources existing at that time, EPA believed that the total dose equivalent from man-made radioactivity was not likely to result in a total body or organ dose to any individual that exceeded 4 mrem/yr. Consequently, EPA did not believe that the 4 mrem/yr standard would affect many public water systems, if any. At the same time, the Agency believed that an MCL set at this level would provide adequate public health protection.

2. 1991 Proposal: Basis of Health Risk Estimates

During the years since the publication of the 1976 regulations, the Agency obtained a great deal of additional data and a better understanding of the risks posed to human health by ingested radionuclides. Many of these new studies were presented and discussed in the Advance Notice of Proposed Rulemaking announcing EPA's intent to revise the MCLs (51 FR 34836, Sept. 20, 1986) and the supporting health criteria documents (see EPA 2000a and EPA 1991, the proposed rule).

Among the most important changes made by EPA in developing the 1991 revisions was the adoption of a common calculational framework, the RADRISK computer code (see EPA 1991, proposed rule), to estimate the risks posed by ingestion of radionuclides in drinking water. The RADRISK code consisted of intake, metabolic, dosimetric, and risk models that integrated the results of a large number of studies on a variety of radioactive compounds and radiation exposure situations into an overall model to estimate risks for many different radionuclides. Radionuclide-specific parameters were based on the results of individual scientific studies of a specific radionuclide, such as radium; human epidemiological studies; or experimental animal studies of groups of chemically-similar radionuclides. To summarize, the following are some of the salient changes.

- Used RADRISK metabolic model instead of natural uptake equilibrium model. Based on known intakes.
- Used ICRP report 20 (see EPA 2000a) on alkaline earth elements with Oak Ridge modeled exponential fit to that model.
- BEIR IV risks for alpha emitters.
- Ra–224 data from ankylosing spondylitis, tuberculosis.
- Change in results from Ra–228 calculations (Oak Ridge model of '84) and ICRP 30 (see EPA 2000a) yielded different results based on retention and distribution of each member of decay chain.

a. Basis for the 1991 MCL for Radium-226 and Radium-228. In 1991, EPA proposed revised MCLs for radium-226 and radium-228 individually at 20 pCi/L each. The Agency thought at that time that the limit for each of these radium isotopes was within the Agency's acceptable risk range of 10^{-6} to 10^{-4}. The Agency no longer believes the MCLs proposed in 1991 for radium-226 and radium-228 are within the Agency's acceptable risk range.

i. Human and Animal Health Effects Data Considered. In 1991, EPA based its risk estimates for radium using information from two epidemiological study groups. The first group consisted of radium dial painters who had ingested considerable amounts of radium paint (containing various proportions of radium-226 and radium-228) by sharpening the point of their paint brush with the lips. The second group consisted of patients in Europe injected with a short-lived isotope of radium, radium-224, for treatment of spinal arthritis and tuberculous infection of the bone (see EPA 2000a). The results of these studies are described briefly next.

At high levels of exposure to radium, several non-cancer health effects were observed in radium dial painters, such as benign bone growths, osteoporosis, severe growth retardation, tooth breakage, kidney disease, liver disease, tissue necrosis, cataracts, anemia, immunological suppression and death (see EPA 2000a).

Exposed radium dial painters also exhibited significantly elevated rates of two rare types of cancer, bone sarcomas (osteosarcomas, fibrosarcomas and chondrosarcomas) and carcinomas of head sinuses and mastoids (see EPA 2000a and EPA 1991, the proposed rule). The incidence of head carcinomas was associated with exposure to radium-226, but not radium-228 (see EPA 2000a). This is because these latter cancers were due to an accumulation of radon gas (radon-222) in the mastoid air cells and paranasal sinuses caused by the escape of radon-222 into the air spaces.

ii. Body Burden, Dose, and Risk Calculations. Risk calculations for ingested radium were made using RADRISK (see EPA 1991, proposed rule) based on annual dose rates. For this purpose, EPA computed dose rates for specific organs and tissues at specific ages for an annual unit intake of each radium isotope (see EPA 2000a). Calculation of body burdens was based on metabolic models derived from the radium dial painter studies. Calculations of absorbed doses in specific organs or tissues included cross irradiation from radium in all other organs. RADRISK included lifetime cancer risk estimates for high- and low-LET (linear energy transfer) radiation separately for leukemia, osteosarcomas, sinus tumors, and other solid tumors. These estimates were taken from the BEIR III and BEIR IV (see EPA 1991, proposed rule) reports.

Table II–1 compares the methods used by EPA in 1976 and 1991 to calculate organ burdens, doses, and risks from radium ingestion. Bone doses calculated for radium-226 in 1991 were about 33 percent lower than those assumed in 1976, and the soft tissue doses were about 40 percent lower. Risk estimates for bone per unit dose were about 65 percent lower in 1991 than in 1976, and the soft tissue risk estimates were about 9 percent lower.

TABLE II–1.—COMPARISON OF DERIVATION OF 1976 AND 1991 MCLS FOR RADIUM

Model	1976	1991
Organ and Tissue Burdens	Calculation of body burdens based on environmental studies and ratio of intakes.	Calculation of body burdens based on toxicokinetic models derived from studies of patients injected with radium.
Dosimetry	Calculation of absorbed dose based on organ and tissue burden.	Calculation of absorbed dose based on organ or tissue burden and cross irradiation terms from all other organs.
Risk Coefficients	Risk estimated using the geometric mean of the absolute and relative risk coefficients from the 1972 BEIR I report.	Risk estimated using the absolute risk coefficient from the 1980 BEIR III report.

b. Basis for the 1991 MCL for Gross Alpha Particle Activity. In 1991, EPA proposed to retain the 15 pCi/L MCL for gross alpha particle activity, but modify it by excluding radium-226, as well as uranium and radon. The exclusion of uranium and radon was based on the fact that the Agency anticipated setting separate NPDWRs for these contaminants with the finalization of the 1991 proposal. The proposed exclusion of Ra–226 was based on the 1991 risk estimate which suggested that its unit risk was small enough not to warrant regulation within gross alpha. The 1991 limit was intended to limit the lifetime cancer risk due to ingestion of naturally-occurring and man-made alpha particle emitters in drinking water to between 10^{-6} and 10^{-4}, the Agency's target risk range for carcinogens. Specifically, this limit was based on the following considerations:

Using RADRISK modeling, EPA estimated that continuous consumption of 15 pCi/L of most alpha particle emitters in drinking water at 2 L/day would pose a lifetime cancer risk between 10^{-6} and 10^{-4}.

EPA performed the risk assessment for the alpha emitters using RADRISK (EPA 1991, proposed rule). The model was used to estimate radiation dose to organs, the dose was used to calculate risk to organs, and the risks to organs were summed to estimate overall risk. EPA used RADRISK to calculate concentrations of alpha emitters corresponding to lifetime mortality and incidence risks of 10^{-4}, assuming ingestion of two liters of drinking water daily, and presented those values in appendix C of the 1991 proposed rule.

In determining the risks from ingestion of alpha emitters in drinking water, EPA was particularly interested in polonium-210 and isotopes of thorium and plutonium, because these radionuclides had been observed in water and may cause health effects at relatively low concentrations.

However, the BEIR IV report concluded that there was no direct measure of risk for most polonium isotopes based on the human data, and suggested several possible means of estimating risk. EPA, as discussed, relied on RADRISK in assessing polonium risk. The model estimated that continuous ingestion of two liters per day of drinking water containing 14 pCi/L would pose a lifetime fatal cancer risk of 1×10^{-4}.

EPA also consulted the BEIR IV report for available information on the adverse effects of thorium. Epidemiological studies of patients injected with Thorotrast, a contrast agent consisting of ThO_2 and used in medical radiology from the 1920s to 1955, showed clear increases in liver cancer, as well as possible increases in leukemia and other cancers. However, the BEIR IV report discussed the limitations of these data for assessing the risk due to other forms of thorium that might have different metabolic behaviors and effects. Using RADRISK, EPA estimated that, at a lifetime fatal cancer risk level of 1×10^{-4}, derived drinking water concentrations for thorium isotopes ranged from 50 to 125 pCi/L, and noted that thorium concentrations in drinking water were generally near one pCi/L (EPA, 1991f).

EPA relied on the BEIR IV report for information on the health effects of plutonium isotopes and other transuranic radionuclides that were widely distributed in the environment in very low concentrations due to atmospheric testing of nuclear weapons from 1945 to 1963. The BEIR IV report concluded that plutonium exposures caused clear increases in cancers of the bone, liver, and lungs in animals, but not in humans. At that time, the limited available epidemiological studies had not demonstrated a clear association between plutonium exposure and the development of cancer in human exposure cases. The report recommended that assessing the risks of plutonium exposure should be based on analogy with other radionuclides and high-LET radiation exposure risks. Using RADRISK, EPA estimated that, at a lifetime fatal cancer risk level of 1×10^{-4}, derived drinking water concentrations for plutonium isotopes ranged from about 7 to 68 pCi/L, and noted that plutonium concentrations in drinking water were generally less than 0.1 pCi/L (EPA, 1991f).

c. Basis for the 1991 MCL for Beta Particle and Photon Radioactivity. In 1991, EPA proposed to alter the 4 mrem/yr MCL for beta particle and photon radioactivity. The Agency modified the standard by basing the limit on the committed effective dose equivalent (EDE). (An effective dose equivalent approach adjusts the dose that an individual organ may receive based on its radiosensitivity. The less radiosensitive an organ is, the greater the allowable radiation dose.) The MCL was also modified to include naturally-occurring beta/photon emitters. The 1991 proposed standard was intended to limit the lifetime cancer risk due to ingestion of naturally-occurring and man-made beta particle and photon emitters in drinking water to between 10^{-6} and 10^{-4}, the Agency's target risk range for carcinogens.

Using RADRISK modeling, EPA estimated that continuous consumption of two liters per day of drinking water containing a concentration of beta particle or photon emitting radiation corresponding to 4 mrem EDE/yr would pose a lifetime cancer risk of about 10^{-4}.

Comparison of the 1976 Regulation and 1991 Proposed Regulation. In 1976, EPA based the MCL for beta particle and photon emitters on a target dose rate of 4 mrem/yr. The annual average activity concentration of

individual radionuclides and mixtures of radionuclides resulting in a 4 mrem/yr dose to the total body or any internal organ was then calculated. This ''critical organ dose'' radiation protection philosophy was based on the recommendations of ICRP Publication 2 (see EPA 2000a).

The Agency was aware that in 1976, when exposed to equal doses of radiation, different organs and tissues in the human will exhibit different cancer induction rates. Consequently, EPA knew that the lifetime cancer risks for individual radionuclides would vary widely (from near 10^{-7} to 5.6×10^{-5} because the same dose equivalent would be applied to different critical organs, resulting in different cancer risks. However, at that time, EPA did not have an accepted method for equalizing risks. In addition, since no dose could be greater than 4 mrem to every organ, the associated risk was the ceiling for the risk of beta/photon emitters in drinking water.

This was addressed in 1991 when EPA proposed to adopt the effective dose equivalent, or EDE, radiation protection philosophy recommended by ICRP (1977) (see EPA 1991, proposed rule). The effective dose equivalent normalizes radiation doses and effects on a whole body basis for regulation of occupational exposures. The EDE is computed as the sum of the weighted organ-specific dose equivalent values, using weighting factors specified by the ICRP (1977, 1979; see EPA 1991, proposed rule). By changing to a limit of 4 mrem EDE/yr, EPA was able to derive activity concentrations for individual beta/photon emitters that corresponded to a more uniform level of risk. Using 4 mrem EDE and the metabolically-based dose calculations, the derived concentrations for most beta particle and photon emitters increased in 1991 as compared to the values calculated in 1976 (shown in Table II–3). As a result of derived concentrations increasing in 1991, the corresponding risks increased as well. EPA estimated that, for most of these radionuclides, the corresponding lifetime fatal cancer risk would be 1×10^{-4}, about twice as high as the risk level estimated in 1976.

d. Basis for the 1991 Proposed MCL for Uranium. In 1991, EPA proposed an MCL of 20 µg/L for uranium based on kidney toxicity and a corresponding limit of 30 pCi/L based on cancer risk. The MCLG was proposed at zero because of the carcinogenicity of uranium, and the MCL was proposed at the most sensitive endpoint, kidney toxicity. The MCL was based on kidney effects seen in the 30 day study in rats (see EPA 1991, proposed rule).

Using RADRISK modeling, EPA estimated that uranium in water posed a cancer risk of 5.9×10^{-7} per picoCurie per liter, assuming continuous intake of water of two liters per day. Concentrations in water of 1.7 pCi/L, 17 pCi/L and 170 pCi/L corresponded to lifetime mortality risks of approximately 1×10^{-6}, 1×10^{-5} and 1×10^{-4}, respectively. A concentration of 30 pCi/L of uranium-238 was thought to be equivalent to about 20 micrograms/L, the level considered to be protective against kidney toxicity (the corresponding mortality was 5×10^{-5}.

In determining the MCL for uranium in 1991, EPA proposed to regulate uranium at a level that would be protective of both kidney toxicity, resulting from the element's chemical properties, and carcinogenic potential due to radioactivity. The carcinogenic effects of uranium were based on the effects of ionizing radiation generally, the similarity of uranium to isotopes of radium, and on the effects of high activity uranium.

C. Today's Methodology for Assessing Risks From Radionuclides in Drinking Water

1. Background

Since 1991, EPA has refined the way in which it estimates potential adverse health effects associated with ingestion of radionuclides in drinking water. The Agency's new approach uses state-of-the-art methods, models and data that are based on more recent scientific knowledge. Compared with the approaches used in 1976 and 1991, the revised methodology includes several substantial refinements. Specifically, the new risk-assessment methodology:

- Accounts for age- and gender-specific water-consumption rates and radionuclide intakes, and for physiological and anatomical changes with age in quantifying costs and benefits;
- Uses Blue Book (see EPA 2000a) for estimating radiogenic risk: ICRP dosimetry model, 1990 vital statistics instead of 1980;
- Uses the most recent age-dependent biokinetic and dosimetric models recommended by the ICRP; Federal Guidance Report-13 dynamic input-output metabolic model;
- Incorporates the latest information on radiogenic human health effects summarized by the National Academy of Sciences and other national and international radiation-protection advisory committees;
- Includes updated life tables based on data from the National Center for Health Statistics that are used to adjust radionuclide risk estimates for competing causes of death; and
- Uses an improved computer program to handle the complex calculations of radiation doses and risks.

Overall, EPA believes that these refinements significantly strengthen the scientific and technical bases for estimating risks, and consequently, for deriving MCLs for radionuclides. A brief overview of this new methodology is summarized later in this section. Interested individuals are referred to two EPA publications Estimating Radiogenic Cancer Risks (EPA, 1994) and Federal Guidance Report No. 13 (EPA, 1999) for detailed discussions on the revised risk assessment methodology for radionuclides. Electronic copies of both documents are available for downloading at EPA's web site (http://www.epa.gov/radiation/rpdpubs.htm).

Federal Guidance Report No. 13: (EPA, 1999) presents the current methods, models, and calculational framework EPA uses to estimate the lifetime excess risk of cancer induction following intake or external exposure to radionuclides in environmental media. The report presents compilations of risk coefficients that may be used to estimate excess cancer morbidity (cancer incidence) and mortality (fatal cancer) risks resulting from exposure to radionuclides through various pathways.

The risk coefficients for internal exposure represent the incremental probability of radiogenic cancer morbidity or mortality occurring per unit of radioactivity inhaled or ingested. For most radionuclides, Federal Guidance Report No. 13 presents risk coefficients for seven exposure pathways: inhalation, ingestion of food, ingestion of tap water, ingestion of milk, external exposure from submersion in air, external exposure from the ground surface, and external exposure from soil contaminated to an infinite depth. For some radionuclides, however, only external exposure pathways are considered; these include noble gases and the short-lived decay products of radionuclides addressed in the internal exposure scenarios.

a. Radium. EPA set the current MCL of 5 pCi/L for radium-226 and radium-228, combined, based on limiting the lifetime excess total cancer risk to between 5×10^{-5} and 2×10^{-4}. In 1991, EPA proposed separate, and revised, MCLs for radium-226 and radium-228 of 20 pCi/L for each. At that time, EPA believed that the revised MCLs corresponded to lifetime excess fatal cancer risks of 1×10^{-4} each, or 2×10^{-4} combined, assuming lifetime ingestion. The more sophisticated model used today calculates a risk for Ra-228 at 5 pCi/l to be 2×10^{-4}, and the risk for 5 pCi/l of Ra-226 to be about 7.3×10^{-5}. Retaining a combined MCL at 5 pCi/L would produce the following risks shown in Table II–2.

TABLE II–2.—MORTALITY RISK OF RADIUMS FOR CONCENTRATION COMBINATIONS AT THE MCL

Radium-226		Radium-228		Ra-226 + Ra-228	
pCi/L	Risk	pCi/L	Risk	pCi/L	Risk at 5 pCi/L
0	0	5	2.0×10^{-4}	5	2.0×10^{-4}
1	1.5×10^{-5}	4	1.6×10^{-4}	5	1.8×10^{-4}
2	2.9×10^{-5}	3	1.2×10^{-4}	5	1.5×10^{-4}
3	4.4×10^{-5}	2	8.1×10^{-5}	5	1.3×10^{-4}
4	5.8×10^{-5}	1	4.1×10^{-5}	5	9.9×10^{-5}

TABLE II–2.—MORTALITY RISK OF RADIUMS FOR CONCENTRATION COMBINATIONS AT THE MCL—Continued

Radium-226		Radium-228		Ra-226 + Ra-228	
pCi/L	Risk	pCi/L	Risk	pCi/L	Risk at 5 pCi/L
5	7.3×10^{-5}	0	0	5	7.3×10^{-5}

b. Alpha Emitters. Both the current and 1991 proposed MCLs for alpha-emitting radionuclides permit up to 15 pCi/L of alpha particle radioactivity in drinking water from individual and multiple alpha emitters. EPA established the current gross alpha MCL of 15 pCi/L (including radium-226 and excluding radon and uranium) to account for the risk from radium-226 at 5 pCi/L (the radium regulatory limit) plus the risk from polonium-210, which the Agency believed was the next most radiotoxic element in the uranium decay chain. The current risk estimated (FGR–13) indicates that the unit risk for Ra-226 is large enough to warrant its inclusion in gross alpha, as thought in 1976.

In 1991, EPA thought that exposure to 10 pCi/L of polonium-210 posed a lifetime fatal cancer risk comparable to that from continuous lifetime ingestion of about 1 pCi/L of radium-226, that is, between 0.5 and 2×10^{-4}. In 1991, EPA based the revised, adjusted gross alpha MCL on revised dose and risk calculations which indicated that the 15 pCi/L limit posed a lifetime cancer risk for most alpha emitters that fell within EPA's acceptable risk range of between 10^{-6} and 10^{-4}.

The current estimate of risk from polonium-210 at 7.0 pCi/L is 1×10^{-4}. The risk for radium-226 at 6.8 p/L is also 1×10^{-4}. When the current rule was written, 10 pCi/L of polonium-210 was believed to be equivalent to 1 pCi/L of radium-226; however, the risks are now equivalent. Thus polonium is ten times the risk it was thought to be relative to radium-226. Retaining a 15 pCi/L standard including radium-226 ensures that the risk of 15 pCi/L will not increase by allowing greater polonium (up to 15 pCi/L) in addition to the radium-226 in the radium standard. As expected, a uniform picoCurie limit results in widely differing risks (EPA 2000a).

c. Beta/Photon Emitters. As discussed elsewhere in this document, EPA is able to calculate the risks from individual beta/photon emitters using the FGR–13 methodology. It is now possible to calculate a risk equivalent to the current picoCurie limit for each beta/photon emitter. Appropriate adjustments are then possible in keeping with the original risk maximum of 5.6×10^{-5}. The derived concentration values for the beta particle and photon emitters from 1976 rule and 1991 proposal in comparison to today's newest risk model using 5.6×10^{-5} mortality are found in Table II–3.

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Table II-3. Comparison of derived values of Beta and Photon Emitters from 1976 and 1991

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
H-3 (HTO)	20,000	3.57e-05	60,900	1.09e-04			
Be-7	6,000	1.60e-05	43,500	1.16e-04			
C-11	NC		99,200	1.75e-04			
N-13			152,000				
C-14	2,000	1.09e-04	3,200	1.75e-04			
C-15			6,690,000				
O-15			495,000				
F-18 *	2,000	8.32e-06	39,500	1.64e-04			
Na-22	400	1.36e-04	466	1.59e-04			
Na-24			3,350	1.60e-04	Not in 1976, but in HB69	60	2.87e-06
Si-31 *	3,000	5.96e-05	10,200	2.02e-04			
P-33			1,870				
P-32	30	9.53e-06	641	2.04e-04			
S-35 (Inorg)	500	8.39e-06	12,900	2.16e-04			
Cl-36	700	7.86e-05	1,850	2.08e-04			
Cl-38 *	1,000	8.41e-06	21,200	1.78e-04			
K-42 *	900	4.08e-05	3,900	1.77e-04			
Ca-45	10	8.96e-07	1,730	1.55e-04			
Ca-47	80	1.80e-05	846	1.90e-04			
Sc-46	1,000	1.95e-05	863	1.68e-04	Error in 1976 Calculation	100	1.95e-05
Sc-47	300	2.97e-05	2,440	2.42e-04			
Sc-48	80	1.71e-05	766	1.64e-04			
V-48	90	2.16e-05	644	1.55e-04			
Cr-51	6,000	3.26e-05	38,000	2.06e-04			

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Mn-52	90	1.77e-05	733	1.44e-04			
Mn-54	300	2.23e-05	2,010	1.50e-04			
Mn-56 *	300	9.64e-06	5,640	1.81e-04			
Fe-55	2,000	6.84e-05	9,250	3.17e-04			
Fe-59	200	5.14e-05	844	2.17e-04			
Co-57	1,000	3.21e-05	4,870	1.57e-04			
Co-58	9,000	8.80e-04	1,590	1.57e-04	MCL switched with Co-58m	300	2.96e-05
Co-58m	300	1.18e-06	64,900	2.56e-04	MCL switched with Co-58	9000	3.55e-05
Co-60	100	5.20e-05	218	1.13e-04			
Ni-59	300	2.52e-06	27,000	2.27e-04			
Ni-63	50	1.02e-06	9,910	2.02e-04			
Ni-65 *	300	6.52e-06	8,810	1.92e-04			
Cu-64 *	900	1.70e-05	11,900	2.25e-04			
Zn-65	300	1.23e-04	396	1.62e-04			
Zn-69 *	6,000	1.62e-05	63,100	1.71e-04			
Zn-69m *	200	1.09e-05	4,220	2.30e-04			
Ga-67	NC		7,020	2.10e-04			
Ga-72 *	100	1.62e-05	1,190	1.93e-04			
Ge-71	6,000	1.13e-05	436,000	8.19e-04			
As-73	1,000	4.52e-05	7,850	3.55e-04			
As-74	100	1.97e-05	1,410	2.77e-04			
As-76	60	1.67e-05	1,060	2.95e-04			
As-77	200	1.44e-05	4,330	3.11e-04			
Se-75	900	2.65e-04	574	1.69e-04			
Br-82	100	5.86e-06	3,150	1.85e-04			
Rb-82			436,000				

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Rb-86	600	2.06e-04	485	1.67e-04			
Rb-87	300	5.41e-05	501	9.04e-05			
Rb-88	NC		29,100	1.83e-04			
Rb-89	NC		52,700	1.81e-04			
Sr-82	NC		241	2.29e-04			
Sr-85	21,000	1.75e-03	2,830	2.36e-04	Wrong critical organ selected	900	7.49e-05
Sr-85m	900	5.66e-07	237,000	1.49e-04	Wrong critical organ selected	21000	1.32e-05
Sr-89	20	1.66e-06	599	2.38e-04			
Sr-90	8	2.03e-05	42	1.06e-04			
Sr-91 *	200	1.90e-05	2,160	2.05e-04			
Sr-92	200	1.31e-05	3,100	2.03e-04			
Y-90	60	3.06e-05	510	2.60e-04			
Y-91	90	4.07e-05	576	2.60e-04			
Y-91m *	9,000	1.07e-05	132,000	1.57e-04			
Y-92 *	200	1.48e-05	2,870	2.13e-04			
Y-93	90	1.85e-05	1,200	2.47e-04			
Zr-93	2,000	8.55e-05	5,090	2.17e-04			
Zr-95	200	2.68e-05	1,460	1.96e-04			
Zr-97 *	60	2.14e-05	650	2.32e-04			
Nb-93m	1,000	2.29e-05	10,500	2.40e-04			
Nb-94	NC		707	1.63e-04			
Nb-95	300	2.16e-05	2,150	1.55e-04			
Nb-95m	NC		2,390	2.48e-04			
Nb-97 *	3,000	2.04e-05	23,500	1.60e-04			
Nb-97m			1,370,000				
Mo-99	600	3.54e-05	1,830	1.08e-04			

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Tc-95	NC		69,700	1.22e-03			
Tc-95m	NC		3,120	1.75e-04			
Tc-96	300	3.17e-05	2,050	2.17e-04			
Tc-96m *	30,000	3.44e-05	176,000	2.02e-04			
Tc-97	6,000	4.82e-05	32,500	2.61e-04			
Tc-97m	1,000	6.94e-05	4,450	3.09e-04			
Tc-99	900	7.28e-05	3,790	3.07e-04			
Tc-99m	20,000	4.61e-05	89,600	2.07e-04			
Ru-97	1,000	1.86e-05	7,960	1.48e-04			
Ru-103	200	2.22e-05	1,810	2.01e-04			
Ru-105 *	NC		4,990	2.13e-04	Error in 1976, listed as Rh-105	300	1.28e-05
Rh-105m			5,551,000				
Ru-106	30	3.66e-05	203	2.48e-04			
Rh-103m *	30,000	1.03e-05	471,000	1.62e-04			
Rh-105 *	300	2.00e-05	3,720	2.48e-04	Error: should be listed as Ru-105		
Rh-106	NC		1,240,000	1.97e-04			
Pd-100	NC		1,300	1.53e-04			
Pd-101	NC		13,400	1.67e-04			
Pd-103	900	3.18e-05	6,940	2.45e-04			
Pd-107	NC		36,600	2.59e-04			
Pd-109	300	2.99e-05	2,120	2.12e-04			
Ag-105	300	1.63e-05	2,700	1.47e-04			
Ag-108			626,000				
Ag-108m	NC		723	1.94e-04			
Ag-109m			16,700,000				
Ag-110			1,840,000				

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Ag-110m	90	2.86e-05	512	1.63e-04			
Ag-111	100	2.34e-05	1,080	2.53e-04			
Cd-109	600	9.81e-05	227	3.71e-05			
Cd-115	90	2.21e-05	958	2.35e-04			
Cd-115m	90	4.46e-05	339	1.68e-04			
In-113m *	3,000	9.36e-06	52,400	1.63e-04			
In-114			976,000				
In-114m *	60	4.37e-05	323	2.35e-04			
In-115	300	4.46e-04	35	5.22e-05			
In-115m *	1,000	1.30e-05	16,400	2.14e-04			
Sn-113	300	3.72e-05	1,740	2.16e-04			
Sn-121	NC		6,060	2.58e-04			
Sn-121m	NC		2,260	1.53e-04			
Sn-125	60	3.41e-05	446	2.54e-04			
Sn-126	NC		293	2.19e-04			
Sb-122	90	2.72e-05	810	2.45e-04			
Sb-124	60	2.27e-05	563	2.13e-04			
Sb-125	300	4.12e-05	1,940	2.67e-04			
Sb-126	NC		544	1.77e-04			
Sb-126m	NC		58,500	1.61e-04			
Sb-127	NC		818	2.35e-04			
Sb-129	NC		3,090	1.99e-04			
Te-125m	600	6.15e-05	1,490	1.53e-04			
Te-127	900	2.62e-05	7,920	2.31e-04			
Te-127m	200	5.71e-05	663	1.89e-04			
Te-129	2,000	1.21e-05	27,200	1.65e-04			

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Te-129m	90	4.07e-05	524	2.37e-04			
Te-131m	NC		26,800	4.58e-03			
Te-131	200	7.87e-07	971	3.82e-06			
Te-132	90	3.30e-05	580	2.13e-04			
I-122			211,000				
I-123	NC		10,700	2.13e-04			
I-125			151	1.10e-04	Not in 1976 list,but in HB69		
I-126	3	7.50e-06	81	2.02e-04			
I-129	1	4.22e-06	21	8.87e-05			
I-130	NC		1,190	2.17e-04			
I-131	3	3.91e-06	108	1.41e-04			
I-132 *	90	2.17e-06	8,190	1.98e-04			
I-133 *	10	4.13e-06	549	2.27e-04			
I-134 *	100	7.16e-07	21,400	1.53e-04			
I-135 *	30	2.62e-06	2,340	2.04e-04			
Cs-131	20,000	1.29e-04	22,800	1.47e-04			
Cs-134	20,000	3.22e-02	81	1.22e-04	Wrong critical organ selected	80	1.29e-04
Cs-134m *	80	1.41e-07	101,000	1.78e-04	Wrong critical organ selected	20,000	3.52e-05
Cs-135	900	1.48e-04	794	1.31e-04			
Cs-136	800	2.42e-04	518	1.57e-04			
Cs-137	200	2.14e-04	119	1.27e-04			
Cs-138	NC		25,600	1.75e-04			
Ba-131	600	3.57e-05	2,950	1.76e-04			
Ba-133			1,520				
Ba-133m			2,620				
Ba-137m			2,150,000				

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Ba-139	NC		13,800	1.74e-04			
Ba-140	90	3.91e-05	582	2.53e-04			
La-140	60	1.89e-05	652	2.06e-04			
Ce-141	300	3.93e-05	1,890	2.48e-04			
Ce-143	100	2.02e-05	1,210	2.45e-04			
Ce-144	NC		261	2.60e-04	Not in 1976 list, but in HB69	30	3.22e-05
Pr-142 *	90	2.20e-05	1,040	2.54e-04			
Pr-143	100	2.23e-05	1,170	2.61e-04			
Pr-144	NC		47,000	1.67e-04			
Pr-144m			112,000				
Nd-147 *	NC		1,250	2.64e-04	Not in 1976 list	200	4.23e-05
Nd-149 *	900	1.51e-05	11,700	1.97e-04			
Pm-147	NC		5,240	2.71e-04	Not in 1976 list, but in HB69		
Pm-148	NC		605	2.95e-04			
Pm-148m	NC		575	1.34e-04			
Pm-149	100	1.88e-05	1,380	2.60e-04			
Sm-151	1,000	1.60e-05	14,100	2.26e-04			
Sm-153	200	2.74e-05	1,830	2.51e-04			
Eu-152 *	60	1.16e-05	841	1.62e-04	Reclassified as Eu-154m	200	1.84e-05
Eu-154	200	6.46e-05	573	1.85e-04	MCL switched with Eu-152	60	1.94e-05
Eu-155	600	3.27e-05	3,590	1.95e-04			
Eu-156	NC		600	2.17e-04			
Gd-153	600	2.62e-05	4,680	2.04e-04			
Gd-159 *	200	1.82e-05	2,760	2.50e-04			
Tb-158	NC		1,250	1.81e-04			
Tb-160	100	2.50e-05	815	2.03e-04			

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Dy-165 *	1,000	1.29e-05	15,100	1.95e-04			
Dy-166	100	3.14e-05	830	2.61e-04			
Ho-166	90	2.35e-05	981	2.56e-04			
Er-169	300	2.14e-05	3,640	2.60e-04			
Er-171 *	300	1.76e-05	3,800	2.23e-04			
Tm-170	100	2.53e-05	1,030	2.61e-04			
Tm-171	1,000	1.99e-05	12,700	2.52e-04			
Yb-169	NC		1,830	2.09e-04			
Yb-175	300	2.44e-05	3,110	2.53e-04			
Lu-177	300	2.99e-05	2,550	2.54e-04			
Hf-181	200	3.64e-05	1,170	2.13e-04			
Ta-182	100	2.29e-05	842	1.93e-04			
W-181	1,000	1.15e-05	19,000	2.18e-04			
W-185	300	2.50e-05	3,440	2.86e-04			
W-187 *	200	2.11e-05	2,660	2.80e-04			
Re-183	2,000		5,400		Unknown risk		
Re-186	300	4.69e-05	1,880	2.94e-04			
Re-187	9,000	4.83e-06	582,000	3.13e-04			
Re-188 *	200	2.56e-05	1,790	2.29e-04			
Os-185	200	1.15e-05	2,460	1.42e-04			
Os-191	600	6.19e-05	2,380	2.46e-04			
Os-191m *	9,000	1.57e-04	14,300	2.49e-04			
Os-193	200	3.00e-05	1,690	2.54e-04			
Ir-190	600	9.88e-05	1,010	1.66e-04			
Ir-192	100	2.12e-05	957	2.03e-04			
Ir-194 *	90	2.21e-05	1,040	2.56e-04			

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Pt-191	300	1.51e-05	3,810	1.92e-04			
Pt-193	3,000	1.79e-05	46,100	2.75e-04			
Pt-193m	3,000	2.58e-04	3,020	2.59e-04			
Pt-197	300	2.23e-05	3,400	2.53e-04			
Pt-197m *	3,000	3.63e-05	17,500	2.12e-04			
Au-196	600		3,660		Unknown risk		
Au-198	100	1.79e-05	1,310	2.35e-04			
Au-199	NC				Not in 1976 list, but in HB69	600	5.10e-05
Hg-197	NC		5,760	2.52e-04	Not in 1976 list, but in HB69	880	3.85e-05
Hg-197m	NC					600	5.51e-05
Hg-198							
Hg-203	NC		2,390	2.27e-03	Not in 1976 list, but in HB69	60	5.7e-04
Tl-200	NC				Not in 1976 list, but in HB69	1200	2.7e+00
Tl-201	NC				Not in 1976 list, but in HB69	880	1.11e-05
Tl-202	300	1.50e-05	3,840	1.92e-04			
Tl-204	300	5.43e-05	1,680	3.04e-04			
Tl-207			400,000				
Tl-208			283,000				
Tl-209			358,000				
Pb-203	1,000	3.04e-05	5,060	1.54e-04			
Pb-209	NC		25,300	1.88e-04			
Pb-210	NC		1	3.34e-05			
Pb-211	NC		12,800	2.03e-04			
Pb-212	NC		123	9.81e-05			
Pb-214	NC		11,800	1.52e-04			
Bi-206	100	2.29e-05	656	1.50e-04			

Nuclide (*half-life of 24 hours or less)	1976 limits based on critical organ at 4 mrem/yr	1976 Risks	1991 proposed limits at 4 ede mrem/yr	1991 risks	Comments (HB69 means National Bureauof Standards Handbook-69)	Corrected limits based on 4 mrem/yr critical organ dose limit	Risk at corrected limits
Bi-207	200	3.31e-05	1,010	1.67e-04			
Bi-212			5,200				
Bi-213	NC		15,000	2.79e-04			
Bi-214	NC		18,900	1.55e-04			
Fr-223	NC		3,410	8.51e-04			
Ra-225	NC		9	3.80e-05			
Ra-228			7.85				
Ac-227	NC		1	1.06e-05			
Ac-228	NC		3,270	1.92e-04			
Th-231	NC		4,070	2.55e-04			
Th-234	NC		401	2.62e-04			
Pa-233	300	4.73e-05	1,510	2.38e-04			
Pa-234	NC		2,560	1.94e-04			
Pa-234m			930,000				
U-237	NC		1,780	2.46e-04			
U-240	NC		1,540	3.09e-04			
Np-236			5,960				
Np-238	NC		1,390	2.14e-04			
Np-239	NC		1,680	2.45e-04			
Np-240	NC		23,100	1.83e-04			
Np-240m			174,000				
Pu-241	NC		63	4.66e-06			
Pu-243	NC		16,400	2.27e-04			
Am-242m	NC		1	3.53e-06			
Bk-249					Not in 1976 list, but in HB69	1800	6.67e-05

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d. Uranium. Since the 1991 proposal, a number of new studies have been published in peer-reviewed journals. A literature search was conducted and covered the time period between January 1991 to July, 1998. Databases searched were TOXLINE, MEDLINE, EMBASE, BIOSIS, TSCATS and Current Contents (see EPA 2000a). The results of the literature search were reviewed and articles were identified, retrieved and reviewed and analyzed. Subsequently, the Toxicological Profile for URANIUM (Update) was published extending the database to September 1999 (see EPA 2000a).

i. Health Effects in Animals. The potential toxic effects of uranium following oral exposures have been evaluated in recent animal studies (see EPA 2000a). In a 28-day range-finding study, male and female Sprague-Dawley rats (15/sex/group) were administered concentrations of 0, 0.96, 4.8, 24, 124, or 600 mg uranyl nitrate/L (UN/L) in drinking water for a period of 28 days. Results of the study showed no significant dose-related effects on body weight gain, food intake, fluid consumption, clinical signs, or hematological parameters of treated animals when compared with control animals. Histologic examinations indicated no statistically significant differences in the incidence of a particular lesion in animals in the 600 mg UN/L treatment group when compared with animals in the control group. However, a slight increase in the number of affected animals in the 600 mg UN/L group was observed, when compared with the control group.

As discussed in the Technical Support Document (EPA 2000a), the long-term effects of exposure to low-levels of uranium in drinking water has been demonstrated. Female rabbits and male albino rats were exposed to 0, 0.02, 0.2, and 1 mg/kg uranyl nitrate for 12 months or 0.05, 0.6, 6, and 60 mg/L uranyl nitrate for 11 months, respectively. Results of the study indicated a decrease in acid phosphatase activity in the spleens of rabbits in the 1 mg/kg group, but not in rats, when compared to controls. A statistically-significant ($p<0.05$) increase in serum alkaline phosphatase activity was observed by the eleventh month of exposure in rats in the 6 and 60 mg/L groups, when compared with controls. A statistically-significant decrease in the content of nucleic acids in the renal and hepatic tissues was observed in rats in the 60 mg/L group and in rabbits in the 1 mg/kg group, when compared with controls.

ii. Health Effects in Humans. Recent epidemiological studies have evaluated the effects observed in humans exposed to uranium in the drinking water (see EPA 2000a). These studies demonstrate the relationship between uranium levels in the drinking water and urine albumin, an indicator of renal dysfunction, was evaluated. Three sites were selected for the controls (site 1) and the exposed groups (sites 2 and 3), with mean uranium water levels of 0.71, 19.6 and 14.7 µg/L reported for sites 1, 2 and 3, respectively. An index of uranium exposure was estimated for each study participant by multiplying the uranium concentration in the water supply by the average number of cups consumed at each residence and the total number of years at that residence. Based on the results of a linear regression analysis, which included terms for age, diabetes, sex, smoking, and the use of water filters and softeners, a statistically-significant association was reported for cumulative exposure to uranium and urine albumin levels. However, the authors noted that for most of the study participants, the urine albumin levels were within the range of normal values.

A recent study of a village in Nova Scotia (see EPA 2000a) demonstrated the renal effects following chronic exposure to uranium in the drinking water. Two groups were evaluated, a low exposure group (uranium levels < 1/L) and a high exposure group (uranium levels > 1µg/L). Twenty-four hour and 8-hour urine samples were collected and evaluated for uranium, creatinine, glucose, protein, b_2-microglobulin (BMG), alkaline phosphatase (ALP), gamma glutamyl transferase (GGT), lactate dehydrogenase (LDH), and N-acetyl-b-D-glucosaminidase (NAG). Statistically significant positive correlations were reported with uranium intake for glucose (males, females and pooled data), ALP (pooled data) and BMG (pooled data). No other statistically significant differences were reported. Based on these results, the authors concluded that the proximal tubule was the site of uranium nephrotoxicity.

In June 1998, a workshop was held by the USEPA to discuss issues associated with assessing the risk associated with uranium exposure and updating the RfD and MCLG for uranium. The numerous technical issues associated with the development of a risk assessment for uranium in drinking water were discussed. Based on these discussions, it was apparent that there is a range of values for each factor used in the development of the RfD and MCL for uranium. However, based upon the input received at the workshop and the most current information, EPA believes that the LOAEL for renal effects in male rats of 0.06 mg U/kg/day reported could be used for the development of an RfD for uranium (see EPA 2000a). The relative source contribution (RSC) was revised to 80 percent (0.8). The total uncertainty factor was determined to be about 100 (about 3 for animal to human extrapolation, about 10 for intraspecies differences, about 1 for a less than lifetime study, and about 3 for the use of a LOAEL), with the body weight of 70 kilograms (kg) and daily water consumption of two liters used in the calculation. These assumptions are consistent with the data presented at the workshop and appear to be reasonable and justifiable. EPA believes these factors allow for the calculation of a safe level of uranium in drinking water (in terms of chemical toxicity).

The application of the total uncertainty factor of 100 to the LOAEL of 0.06 mg/kg/day results in an RfD of 0.6 ug uranium/kg/day. The RfD can be used to determine the MCL by multiplying the RfD by body weight (70 kg) and RSC (0.8) and dividing by water consumption (2 L), resulting in a value of 17 ug uranium/L, which can be rounded off to 20 /L.

2. Consideration of Sensitive Sub-populations: Children's Environmental Health

In compliance with Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), risks to children from radionuclides have been considered. There is evidence that children are more sensitive to radiation than adults, the risk per unit exposure in children being greater than in adults.

Risk coefficients used by the Agency for radiation risk assessment explicitly account for these factors. The age-specific, organ-specific risk per unit dose coefficients used in the lifetime risk model apply the appropriate age-specific sensitivities throughout the model. The model also includes age-specific changes in organ mass and metabolism. The risk estimate at any age is the best estimate for that age. In developing the lifetime risks, the model uses the life table for a stationary population. Use of the life table allows the model to account for competing causes of death and age-specific survival. 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. Since the intake by children is usually less than the intake by adults, it tends to partially mitigate the greater risk in children compared to adults when evaluating lifetime risk.

D. References

EPA, 1999. Cancer Risk Coefficients for Environmental Exposure to Radionuclides, Federal Guidance Report No. 13. US Environmental Protection Agency, Washington, DC, 1999. Uranium Issues Workshop—Sponsored by United States Environmental Protection Agency, Washington, DC ; June 23–24, 1998.

USEPA. ''Technical Support Document for the Radionuclides Notice of Data Availability.'' Draft. March, 2000. (EPA 2000a)

Appendix III—Analytical Methods

Table III–1 briefly summarizes the regulatory events associated with:

- The testing procedures for regulated radionuclides approved in 1976;
- Major analytical additions or changes proposed or discussed in the 1991 radionuclides rule;
- Testing procedures and protocols approved in the March 5, 1997—radionuclides methods rule (62 FR 10168, cited in 40 CFR 141.25); and
- Items discussed in today's NODA.

TABLE III–1.—BRIEF SUMMARY OF THE REGULATORY EVENTS ASSOCIATED WITH RADIOCHEMICAL METHODS

1976 National primary drinking water regulations	July 18, 1991—Radionuclides proposed rule	March 5, 1997-Radionuclide methods final rule	Today's notice of data availability
The 1976 NPDWR approved: * Radiochemical methods to analyze for gross alpha-particle activity, radium-226, total radium, gross beta-particle activity, strontium-89 and -90, cesium-134 and uranium * Defined the detection limit (DL) as the required measure of sensitivity and listed the required DL for each regulated radionuclide	The July 18, 1991—radionuclides rule proposed: * Fifty-six additional methods for compliance monitoring of radionuclides * Guidance for the sample handling, preservation and holding times that were cited in the 1990 U.S.EPA "Manual for the Certification of Laboratories Analyzing Drinking Water" * The use of practical quantitation limits (PQLs) and acceptance limits as the measures of sensitivity for radiochemical analysis	The March 5, 1997 final rule for radionuclide methods: * Approved 66 additional radionuclide techniques for gross alpha-particle activity, radium-226, radium-228, uranium, cesium-134, iodine-131, and strontium-90 Responded to comments regarding the analytical methods (excluding radon) received from the July 18, 1991 proposed radionuclides rule	Updates the public on changes that have occurred regarding radiochemical methods of analysis since the 1991 proposed rule. The updates discussed in today's NODA include: * A brief discussion of the analytical methods updates which were promulgated by the Agency on July 18, 1997 final rule. * Guidance for the sample handling, preservation and holding times listed in the 1997 U.S.EPA "Manual for the Certification of Laboratories Analyzing Drinking Water." * Recommendations for the analysis of short-lived, alpha-emitting radioisotopes (i.e., radium-224). * Revised cost estimates for radiochemical analysis. * The Agency's intent to continue to use the detection limits defined in the 1976 rule as the required measures of sensitivity. * Response to some of the comments on the 1991 proposed radionuclides. * The externalization of the Performance Evaluation Program. The Agency's plans to implement a Performance Based Measurement System.

A. The Updated 1997 Laboratory Certification Manual

A revised version of the certification manual was published in 1997 (EPA 815–B–97–001, EPA 1997b). Table III–2 lists the guidance for sample handling, preservation, holding times, and instrumentation which appeared in this manual. Table III–2 also includes additional recommendations for radiochemical instrumentation (footnoted by the number 6), which the Agency is requesting comment on.

TABLE III–2.—SAMPLE HANDLING, PRESERVATION, HOLDING TIMES AND INSTRUMENTATION

Parameter	Preservative [1]	Container [2]	Maximum holding time [3]	Instrumentation [4]
Gross Alpha	Concentrated HCl or HNO_3 to pH <2[5]	P or G	6 months	A, B or G
Gross Beta	Concentrated HCl or HNO_3 to pH <2[5]	P or G	6 months	A or G
Radium-226	Concentrated HCl or HNO_3 to pH <2	P or G	6 months	A, B, C[6], D or G
Radium-228	Concentrated HCl or HNO_3 to pH <2	P or G	6 months	A, B[6], C[6] or G
Uranium natural	Concentrated HCl or HNO_3 to pH <2	P or G	6 months	A[6], F, G[6], or O
Cesium-134	Concentrated HCl to pH <2	P or G	6 months	A, C or G
Strontium-89 and -90	Concentrated HCl or HNO_3 to pH <2	P or G	6 months	A or G
Radioactive Iodine-131	None	P or G	8 days	A, C or G
Tritium	None	G	6 months	E
Gamma/Photon Emitters	Concentrated HCl or HNO_3 to pH <2	P or G	6 months	C

[1] It is recommended that the preservative be added to the sample at the time of collection. It is recommended that samples be filtered if suspended or settleable solids are present at any level observable to the eye prior to adding preservative. This should be done at the time of collection. If the sample has to be shipped to a laboratory or storage area, however, acidification of the sample (in its original container) may be delayed for a period not to exceed 5 days. A minimum of 16 hours must elapse between acidification and start of analysis.

[2] P = Plastic, hard or soft; G = Glass, hard or soft.

[3] Holding time is defined as the period from time of sampling to time of analysis. In all cases, samples should be analyzed as soon after collection as possible. If a composite sample is prepared, a holding time cannot exceed 12 months.

[4] A = Low background proportional system; B = Alpha and beta scintillation system; C = Gamma spectrometer [Ge(Hp) or Ge (Li)]; D = Scintillation cell system; E = Liquid scintillation system; F = Fluorometer; G = Low background alpha and beta counting system other than gas-flow proportional; O = Other approved methods (e.g., laser phosphorimetry and alpha spectrometry for uranium).

[5] If HCl is used to acidify samples which are to be analyzed for gross alpha or gross beta activities, the acid salts must be converted to nitrate salts before transfer of the samples to planchets.

[6] Additional instrumentation that was not listed in the USEPA 1997 "Manual for the Certification of Laboratories Analyzing Drinking Water."

B. Recommendations for Determining the Presence of Radium-224

To determine the presence of the short-lived radium-224 isotope (half life ~3.66 days), the Agency recommends using one of the following several options.

1. Radium-224 by Gamma Spectrometry and Alpha Spectrometry

(a) Gamma Spectrometry. Radium-224 can be specifically determined by gamma spectrometry using a suitably prepared sample. In this method a precipitate in which the radium isotopes are concentrated is gamma counted. The primary advantage of this technique is specificity for radium gamma rays, radium-224 included. Other advantages of this method include:

• a simple sample preparation were radium isotopes are concentrated from samples 1 liter or larger;
• specificity for the radium-224 isotope based on a unique gamma energy;
• optimal accuracy and precision if the sample is counted within 72 hours of collection (40 hours is recommended);
• and is cost competitive with the gross methods because a single count rather that three counts (see the gross alpha methods discussion) is necessary to measure the radium-224 in a routine sample.

A gamma spectrometry method by Standard Methods is currently pending but for now the reader is referred to the method used by Parsa. (Parsa, 1998).

(b) Alpha Spectrometry. The alpha spectrometry method measures alphas emitted by radium-224 and its alpha emitting daughters. The alpha spectrometry method, used for the USGS occurrence survey (see appendix I and EPA 2000a), was a slight modification of an existing method (see EPA 2000a). Using an appropriate tracer (e.g. Ba-133), barium and radium isotopes are separated from other radionuclides and interferences using cation ion exchange chromatography. A prepared sample, counted for approximately 100 minutes using alpha spectrometry, can be used to measure the radium-224 in the sample and is capable of good accuracy and precision. Other alpha spectrometry techniques, similar to the modified method used for the USGS occurrence survey, should be sufficient for the detection of radium-224. It is cost competitive with the gross methods (discussed next) because a single count rather than three (for gross methods) is sufficient to for measurement of radium-224.

2. Gross Radium Alpha (Co-precipitation) Within 72 Hours

The presence of radium-224 can be determined indirectly using the radium-224 half-life decay and the gross radium alpha technique. Gross radium co-precipitation methods, like EPA 903.0, concentrate radium isotopes by co-precipitation, separating radium and radium-like isotopes from potential interferences. Relative to evaporative methods, the co-precipitation technique can be used for larger (> 1 L) sample sizes with a resulting increase in the method sensitivity. Initial analysis within 72 hours after sample collection (40 hours recommended for optimal data quality) using the co-precipitation methods yield results, reflecting both alpha-emitting radium isotopes (radium-224 and radium-226). For these to produce unambiguous results, radium-224 must be the dominant isotope present, i. e. the ratio of radium-224 to radium-226 must be three or greater. If this is the prevailing composition, the estimated contribution of radium-224 to the overall value can be ascertained by recounting the sample at 4 or 8 days intervals and calculating the change in the measured activity. The noted change will show a decrease with a 4 day half-life indicative of Ra-224. Formulas are available to calculate the initial radium-224 concentration present in the sample when collected. The advantages of this technique include:
• enhanced sensitivity (≥1 L samples);
• it does not require additional analyst training;
• it is specific for radium isotopes; and
• the resulting precipitate can be measured by a number of techniques, including proportional counting, alpha scintillation counting, or gamma counting.

3. Evaporative Gross Alpha-Particle Analysis Within 72 Hours

The radium-224 isotope, when in equilibrium with its decay progeny, emits four alpha particles. Three of these alpha particles equilibrate almost immediately (within 5 minutes) after sample preparation and add to or amplify the sample count rate. This count rate amplification can be exploited for the measurement of radium-224 in a sample at low concentration (<15 pCi/L). The presence of the radium-224 radioisotope in drinking water may be ascertained by performing an initial evaporative gross alpha-particle analysis within 72 hours (40 hours recommended) after sample collection. In the absence of any other alpha-emitting nuclide (e.g., uranium or radium-226) and if the gross alpha-particle value is above the MCL, the sample may be re-counted at 4- and 8-day intervals to determine if the observed decrease in activity follows the 3.66 day half-life of radium-224. A decrease in the gross alpha value with a 4-day decay rate indicates the likely presence of radium-224. Formulas are available to calculate the concentration of radium-224 in the initial sample. The advantages of this option include:
• the method is similar to the general method for evaporative gross alpha;
• it requires no special training of the analyst; and
• it can be a definitive test if other alpha-emitting nuclides are known to be absent.

The Agency recognizes that analysis within the 72-hour time frame creates difficulties in shipping and handling and may increase the price of the analysis.

C. Revised Cost Estimates for Radiochemical Analysis

The cost estimates for radiochemical analysis from the 1991 proposed rule and the revised cost estimates are shown in Table III–3.

TABLE III–3.—THE 1991 AND 1999 ESTIMATED COSTS OF ANALYSES FOR RADIONUCLIDES

Radionuclides	Approximate cost $ (1991)[1]	Approximate cost $ (1999)[2]
Gross Alpha and beta	35	45
Gross alpha—coprecip.	35	45
Radium-226	85	90
Radium-228	100	110
Uranium (total)	45	48 (LP)
Uranium (isotopic)	125	128 (AS)
Radioactive Cesium (-134)	100	125
Radioactive Strontium	105	144
Total Strontium (-89 and -90)	.....	153
Radioactive Iodine -131	100	131
Tritium	50	60
Gamma/Photon Emitters	110	142

Source:
[1] 56 FR 33050; July 18, 1991.
[2] USEPA, 2000a.
Abbreviations: LP = laser phosphorimetry; AS = alpha spectrometry.
Note: Estimated costs are on a per-sample basis; analysis of multiple samples may have a lower cost.

D. The Detection Limits as the Required Measures of Sensitivity

Table III–4 cites the detection limits or the required sensitivity for the specific radioanalyses that were listed in the 1976 rule and are also cited in 40 CFR 141.25.

TABLE III–4.—REQUIRED REGULATORY DETECTION LIMITS FOR THE VARIOUS RADIOCHEMICAL CONTAMINANTS (40 CFR 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 NIPDWR 1976 table IV–2A and 2B

E. References

Parsa, B., 1998. Contribution of Short-lived Radionuclides to Alpha-Particle Radioactivity in Drinking Water and Their Impact on the Safe Drinking Water Act Regulations, Radioactivity and Radiochemistry, Vol. 9, No. 4, pp. 41–50, 1998. USEPA, 1991. National Primary Drinking Water Regulations; Radionuclides; Proposed Rule. **Federal Register**. Vol. 56, No. 138, p. 33050. July 18, 1991.

USEPA, 1997a. National Primary Drinking Water Regulations; Analytical Methods for Radionuclides; Final Rule and Proposed Rule. Vol. 62, No. 43, p. 10168. March 5, 1997.

USEPA, 1997b. ''Manual for the Certification of Laboratories Analyzing Drinking Water.'' EPA 815–B–97–001. 1997.

USEPA, 2000a. ''Technical Support Document for the Radionuclides Notice of Data Availability.'' 2000.

Appendix IV—Treatment Technologies and Costs

A. Introduction

This section describes updates to EPA's previous evaluations of the feasibility and costs of treatment technologies for the removal of radionuclides from drinking water. Prior to this update, the latest evaluation was the 1992 ''Technologies and Costs document'' for radionuclides in drinking water (EPA 1992). The updates to the 1992 radionuclides Technologies and Costs document comprise an updated Technologies and Costs Document (EPA 1999a) and a radium compliance cost study (EPA 1998a), which are described later in this section. This section also describes other relevant documents, including the1998 **Federal Register** notice of the ''Small Systems Compliance Technology List'' (SSCTLs) for the currently regulated radionuclides (63 FR 42032) and its supporting guidance document (EPA 1998b). Both of the documents supporting the SSCTs can be obtained on-line at ''http://www.epa.gov/OGWDW/standard/tretech.html''.

The SSCTLs for the meeting the MCLs for combined radium-226 and radium-228, gross alpha emitters, and combined beta and photon emitters are included in ''Announcement of Small System Compliance Technology Lists for Existing National Primary Drinking Water Regulations and Findings Concerning Variance Technologies,'' published in the **Federal Register** on August 6, 1998 (63 FR 42032). The supporting guidance document cited previously includes information regarding small systems treatment and waste disposal concerns relevant to radionuclide contaminants and was made publicly available on September 15, 1998. Further evaluations of small systems treatment technology applicability and affordability have been done since the SSCTLs for radionuclides were published, including an analysis of SSCTs for uranium (EPA 1999b). These evaluations are summarized later in this section.

B. Treatment Technologies Update

1. Updates on Performance of Technologies for Removal of Regulated Radionuclides and Uranium

One of the purposes of the update to the radionuclides Technologies and Costs (T&C) document (EPA 1999a) was to update the treatment technology performance sections of the 1992 radionuclides T&C document. The peer-reviewed literature revealed no new significant sources of information regarding performance for the previously described technologies, nor did it reveal literature regarding any new treatment technologies for radionuclides in drinking water. Both the 1992 and 1999 radionuclides T&C documents include performance evaluations of the BATs proposed in 1991 for the regulated radionuclides and uranium (56 FR 33050, Jul. 18, 1991) and additional technologies that were reviewed as potential BATs for the 1991 proposed rule, but that were not proposed as BAT for various reasons.

Although the 1999 T&C document concludes that the peer-reviewed literature describes no new technologies since the 1992 T&C document was completed, there have been some developments that are significant. In particular, both package plant [1] technologies, including those equipped with remote control/communication capabilities, and point-of-entry (POE)/point-of-use (POU) versions [2] of existing technologies have become more widely applicable for use for compliance. This is true both because of improvements in these technologies themselves (NRC 1997) and since the 1996 SDWA explicitly allows package plants and POE/POU devices to be used as compliance technologies for small systems (section 1412.b.4.E). Package plant technologies and POE/U technologies are discussed in more detail in the Technical Support Document (EPA 2000a).

2. Treatment Technologies Evaluated as Compliance Technologies for Radionuclides

The following technologies are reviewed in the 1999 radionuclides T&C document: (1) for radium, the 1991 proposed Best Available Technologies (BATs), which are lime softening, ion exchange, and reverse osmosis; and two other applicable technologies with significant radium removal data, electrodialysis reversal and greensand filtration; (2) for uranium, the 1991 proposed BATs, which are coagulation/filtration, ion exchange, lime softening, and reverse osmosis; and two other applicable technologies, electrodialysis reversal and activated alumina; (3) for gross alpha particle activity, the 1991 proposed BAT, which is reverse osmosis; and one other applicable technology, ion exchange; and (4) for beta particle activity and photon radioactivity, the 1991 proposed BATs, which are ion exchange and reverse osmosis. No other technology studies pertinent to total beta and photon activity were found, but this is largely due to the fact that treatment applicability depends on what specific beta and photon emitters are present and so should be evaluated on a case-by-case basis. This consideration also applies to gross alpha activity. It is likely that reverse osmosis, being applicable to a broad range of inorganic contaminants, including radionuclide contaminants, is the best alternative for situations where multiple radionuclides occur.

3. Data on Additional Treatment Technologies

The 1999 radionuclides T&C document does not identify any new treatment technologies for radionuclides, but does provide information on two additional variants of coagulation/filtration for uranium removal: direct filtration and in-line filtration.

4. Small Systems Compliance Technology List and Guidance Manual for the Regulated Radionuclides and Uranium

The 1996 SDWA identifies three categories of small drinking water systems, those serving populations between 25 and 500, 501 and 3,300, and 3,301 and 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

[1] Package plants are skid mounted factory assembled centralized treatment units that arrive on site ''virtually ready to use''. Package plants offer several advantages. First, since they combine elements of the treatment process into a compact assembly (such as chemical feeders, mixers, flocculators, basins, and filters), they tend to require lesser construction and engineering costs. Another advantage is that many package plant technologies are becoming more automated and thus can be less demanding of operators than their fully engineered counter-parts (EPA 1998b).

[2] 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 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 (EPA 1998b).

treatment technique. Two classes of small systems technologies are identified for future National Primary Drinking Water Regulations (NPDWRs): compliance technologies and variance 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 (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.

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)).

In the case of the currently regulated radionuclides, *i.e.,* combined radium-226 and -228, gross alpha activity, and total beta and photon activity, 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).

Small systems compliance technologies for the currently regulated radionuclides, combined radium-226 and -228, gross alpha emitters, and total beta and photon activity, were listed and described in the **Federal Register** on August 6, 1998 (EPA 1998a) and in an accompanying guidance manual (EPA 1998b). Small systems compliance technologies for uranium were also evaluated (EPA 1999a). Small systems compliance technologies (SSCTs) 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. The SSCT list for uranium is 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.

Tables IV–1 and IV–2 summarize the small systems compliance technologies listed in the 1998 SSCTL for combined radium-226, and -228, gross alpha emitters, total beta and photon activity. Table IV–1 is shown as it will be updated when uranium is regulated. Table IV–1 describes limitations for each of the listed technologies and Table IV–2 lists SSCTs for each contaminant.

TABLE IV–1.—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) IE	([b])	Basic	All ground waters
3. Reverse Osmosis (RO)	([c])	Advanced	Surface waters usually require pre-filtration.
4. POU 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.

Limitations Footnotes to Table IV–2: 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 IV–2 lists the Small Systems Compliance Technologies for the currently regulated radionuclides. Technology numbers refer to the technologies listed in Table IV–1.

TABLE IV–2.—COMPLIANCE TECHNOLOGIES BY SYSTEM SIZE CATEGORY FOR RADIONUCLIDE NPDWRS (AFFORDABILITY NOT CONSIDERED, EXCEPT FOR URANIUM, DUE TO STATUTORY LIMITATIONS)

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
Total beta particle activity and photon activity, average annual concentration	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

Note: [1] Numbers correspond to those assigned to technologies found in the table ''List of Small Systems Compliance Technologies for the Currently Regulated Radionuclides.''

C. Waste Treatment, Handling and Disposal Guidance

In the proposed radionuclides rule of July 1991, EPA referenced a 1990 EPA draft report entitled ''Suggested Guidelines for Disposal of Drinking Water Treatment Wastes Containing Naturally-Occurring Radionuclides'' (EPA 1990). That 1990 report offered guidance to system managers, engineers, and State agencies responsible for the safe handling and disposal of treatment wastes that, in many cases, were not specifically addressed by any statute. That guidance report was later updated in 1994 (EPA 1994).

The guidance provided information on the following: (1) Background on water treatment processes and characteristics of wastes generated; (2) rationale for radiation protection, including citation of programs and regulations affecting other sources of such waste; (3) guidelines for several methods of disposal of solid and liquid type wastes containing the subject radionuclides; and, (4) the specification of practical guidance to protect workers and others who may handle or be exposed to water-treatment wastes containing radiation above background levels.

The Technical Support Document (EPA 2000a) discusses disposal methods and issues, including comments received in reference to the 1990 ''Suggested Guidelines for Disposal of Drinking Water Treatment Wastes Containing Naturally-Occurring Radionuclides,'' and the 1994 update to this report.

D. Unit Treatment Cost Updates

Treatment costs for coagulation/filtration (including direct filtration and in-line filtration), lime softening, ion exchange, reverse osmosis, electrodialysis reversal, greensand filtration, point-of-use (POU) reverse osmosis, POU ion exchange, and point-of-entry cation exchange were updated in the appendix to the 1999 radionuclides T&C document. This update includes land-cost considerations and waste-disposal cost estimates. Cost estimates were made using standard EPA treatment technology costing models. Outputs were updated to current dollars using standard engineering costing indices, e.g., the Bureau of Labor's Chemical and Allied Products Index. Costs for individual technologies were analyzed in terms of water usage, removal efficiency, interest rate, and other variables.

In addition to cost model updates, EPA has performed a study of the actual costs of treatment and other compliance measures for the radium standard (EPA 1998c), which provided a ''snapshot'' of the costs incurred by water systems in complying with the existing combined radium-226 and radium-228 MCL. Studies of this nature allow EPA to compare modeled costs used in regulatory impact assessments with real-world data for the purposes of model validation and cost estimate amendments. They also allow EPA to check assumptions about the prevalence of use of particular water-treatment technologies.

The study comprises data compiled from contacts with water-treatment personnel, State representatives, and EPA Regional representatives within EPA Regions 5 (IL, IN, MI, MN, OH, and WI) and 8 (CO, MT, ND, SD, UT, and WY). Specifically, data were obtained regarding water systems in California, Florida, Idaho, Illinois, Indiana, Ohio, Wisconsin, and Wyoming. State Agencies and EPA Regional offices identified 136 systems as having water sources with combined radium-226 and radium-228 above the MCL of 5 pCi/L. Of these, 55 of the systems were contacted, of which 29 were either treating for radium or were in the process of selecting a treatment method. The remaining systems were either further behind in treatment selection plans or pursuing other compliance measures. All of the systems that were currently treating for radium were in compliance with the MCL. Twenty-six of these systems responded with cost data, of which 17 were small systems (design flow < 1 mgd). Thirty-five percent of the small systems reported were using reverse osmosis which, at an average total treatment cost of $3.02 per thousand gallons, was the most expensive treatment technology identified. Other treatment options used were lime softening and ion exchange. These had average total treatment costs of $2.36 and $0.73 per thousand gallons, respectively. Unit costs are discussed in more detail in the Technical Support Document (EPA 2000a).

EPA requests comments on its analysis of treatment technologies, costs, and treatment residuals disposal.

E. References

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

USEPA. Office of Drinking Water. Suggested Guidelines for Disposal of Drinking Water Treatment Wastes Containing Naturally-Occurring Radionuclides (July 1990 draft).

USEPA. National Primary Drinking Water Regulations; Radionuclides; Proposed Rule. Federal Register. Vol. 56, No. 138, p. 33050. July 18, 1991.

USEPA. Technologies and Costs for the Removal of Radionuclides from Potable Water Supplies. Prepared by Malcolm Pirnie, Inc. July 1992.

USEPA. Office of Ground Water and Drinking Water. Suggested Guidelines for Disposal of Drinking Water Treatment Wastes Containing Radioactivity (June 1994 draft).

USEPA. Announcement of Small Systems Compliance Technology Lists for Existing National Primary Drinking Water Regulations and Findings Concerning Variance Technologies. Federal Register. Vol. 63, No. 151, p. 42032. August 6, 1998. (EPA 1998a).

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

USEPA. ''Actual Cost for Compliance with the Safe Drinking Water Act Standard for Radium-226 and Radium-228.'' Final Report. Prepared by International Consultants, Inc. July 1998. (EPA 1998c).

USEPA Technologies and Costs for the Removal of Radionuclides from Potable Water Supplies. Draft. Prepared by International Consultants, Inc. April, 1999. (EPA 1999a).

USEPA. ''Small System Compliance Technology List for the Radionuclides Rule.'' Prepared by International Consultants, Inc. Draft. April 1999. (EPA 1999b).

USEPA. ''Technical Support Document for the Radionuclides Notice of Data Availability.'' Draft. March, 2000. (EPA 2000a)

Appendix V—Economics and Impacts Analysis

A. Overview of the Economic Analysis

1. Background

Analysis of the costs, benefits, and other impacts of regulations is required under the Safe Drinking Water Act Amendments of 1996, Executive Order 12866 (Regulatory Planning and Review), and EPA's internal guidance for regulatory development. These

requirements are new relative to the 1991 proposal for revisions to the existing National Primary Drinking Water Regulations (NPDWRs) for radionuclides.

The actions that are anticipated to have regulatory impacts are evaluated in this section. These actions are: (1) the correction the monitoring deficiency for combined radium-226 and radium-228; and (2) the establishment of a uranium NPDWR with an MCL of 20 µg/L; or (3) the establishment of a uranium NPDWR with an MCL of 40 µg/L; or (4) the establishment of a uranium NPDWR with an MCL of 80 µg/L. See ''Combined Ra-226 and Ra-228'' in the today's NODA (section III, part F) for a discussion of the monitoring corrections that will be finalized for the combined radium-226 and radium-228 (''combined radium'') NPDWR. See ''Uranium'' in the NODA (section III, part H) for a discussion of the options being considered for finalization for the uranium NPDWR.

2. Economic Analysis of the Regulatory Actions Being Considered for Radionuclides in Drinking Water

The economic analysis summarized here supports the finalization of the 1991 Radionuclides proposal. The more detailed economic analysis (the Health Risk Reduction and Cost Analysis, EPA 2000b) may be obtained from the Water Docket, as described in the Introduction to today's NODA (see **ADDRESSES**). It provides central-tendency estimates of national costs and benefits and presents information on the data sources and analytic approaches used, including a qualitative discussion of the analytical limitations and uncertainties involved. Further uncertainty analyses will be performed to support the analyses summarized here and will be reported in the preamble to the final rule. It should be noted that these additional uncertainty analyses are not expected to alter regulatory decisions.

The basic steps in a comprehensive economic analysis include: (1) Estimating baseline conditions in the absence of revisions to the regulations; (2) predicting actions that water systems will use to meet each regulatory option (the ''decision tree''); (3) estimating national costs resulting from compliance actions; (4) estimating national benefits resulting from compliance; and (5) assessing distributional impacts and equity concerns. In today's NODA, we present preliminary estimates of national costs and benefits for the options evaluated, focusing on monitoring and compliance costs and reductions in cancer risks. Other national costs and benefits (e.g., state administrative costs and risk reductions from incidental treatment of co-occurring contaminants) and potential distributional impacts are described qualitatively (see EPA 2000a and EPA 2000b).

The first step in the economic analysis, defining the analytical baseline, requires that water systems be apportioned into several groups based on their predicted levels of radionuclides and the current monitoring scheme. In the case of the radionuclides NPDWRs, this provides unusual challenges. This is partly due to the fact that several community water systems are not complying with the existing regulations, which is reflected in the occurrence database used for this work (the National Inorganics and Radionuclides Survey, ''NIRS'; see EPA 1991, proposed rule and EPA 2000a). Also, as discussed in the Introduction to today's NODA, there are weaknesses in the current monitoring requirements that has lead to a situation in which some water systems having combined radium levels greater than the MCL of 5 pCi/L will not have knowledge of this fact (and hence are not presently in violation of the combined radium NPDWR). Both of these influences, the existing unresolved radionuclides NPDWR violations and the monitoring deficiencies, must be accounted for in the analytical baseline.

The regulatory baseline and other analytical baselines are benchmarks to measure regulatory impacts against. Generating a national-level contaminant occurrence profile is an important part of this benchmarking process. The database used as the basis for this model, NIRS, is described in appendix I of today's NODA (Occurrence). The analysis of regulatory impacts uses this system-size stratified baseline occurrence model [1] to estimate the percentages of water systems with contaminant levels within specified values (e.g., 30 to 50% above the MCL). This information is then combined with other models to estimate the compliance costs and benefits associated with each option. Examples of models relevant to national costs estimation include ''model systems [2],'' compliance cost equations [3], and the compliance action prediction model or ''decision trees [4].'' Examples of models relevant to risk reduction and benefits estimation include the risk models described in appendix II and the risk reduction valuation models described in the Technical Support Document (EPA 2000a).

The analytical baseline for combined radium reflects full compliance with the existing regulations as written, which have been fully enforceable since the 1986 reauthorization of the SDWA. This approach assumes that, in the absence of any changes to the radionuclides NPDWRs, EPA and the States will eventually ensure that all systems fully comply with the existing regulations. This approach allows us to separate out the predicted number of systems with combined radium levels in excess of the MCL that have knowledge of the violation (''systems in violation'') from the predicted number of systems that have levels in excess of the MCL, but that would not have knowledge of this under the current monitoring requirements. Since uranium is not currently regulated, no such corrections are necessary. It was also determined that treatment installed to remove the other radionuclides should not significantly impact the uranium analytical baseline.[5]

B. Approach for Assessing Occurrence, Risks and Costs for Community Water Systems

1. Assessing Occurrence

To develop estimates of the baseline radionuclides occurrence profile for community water systems, we began by extrapolating from data obtained through EPA's National Inorganics and Radionuclides Survey (NIRS). This survey measured radionuclide concentrations at 990 community ground water systems between 1984 and 1986. For detailed information on the design of NIRS, see Longtin 1988. For detailed information on how NIRS was used in this work, see the background documents (EPA 2000a and 2000b).

We made adjustments to the NIRS data to address certain limitations, including (1) the small size of the sample of systems serving populations greater than 3,300 persons; (2) the decay of radium-224 prior to analysis of the NIRS water samples; (3) the need to convert mass measurements of uranium to activity levels; and, (4) the lack of information on surface water systems. The analyses and discussions that follow concentrate on CWSs serving retail populations of less than one million persons. Discussions of preliminary and future economic impacts analyses of Non-Transient Non-Community Water Systems (NTSC systems) and the largest CWSs follow later in this section. The two occurrence approaches we examined are described next. For a discussion of the relative strengths and weaknesses of the two approaches to estimating occurrence, see the Technical Support Document (EPA 2000a).

[1] The NIRS database is stratified into four categories: systems serving between 25–500 persons, 501—3,300 persons, 3,301–10,000 persons, and 10,001–1,000,000 persons. Because of the small sample size used to describe the larger systems, our model uses only three categories: we combine the two categories for systems serving greater than 3,301 persons into a single category.

[2] Model systems describe the universe of drinking water systems by breaking it down into discrete ''system size categories'' by population served. There are nine size categories: 25–100 persons served; 101–500; 501–1,000; 1,001–3,300; 3,301–10,000; 10,001–50,000; 50,001–100,000; 100,000–1,000,000; > 1,000,000. Within each size category, the systems are described by a single set of ''typical characteristics'' by source water type (ground versus surface water) and ownership type (public versus private ownership). These characteristics include the average and design flows and the distribution of numbers of entry points per system.

[3] Unit compliance costs models include water treatment cost models (e.g., W/W Cost and the WATER model) and models for other compliance options, like alternate water well sources and purchasing water. For a discussion of the standard EPA water treatment cost models, see EPA 1999d.

[4] Decision trees are models of the relative probabilities that water systems will choose particular compliance actions when in violation. The probabilities are estimated based on considerations of source water type, system size, water quality, required removal efficiency, unit costs, treatment issues (e.g., co-treatment and pre-/post-treatment requirements), and residuals disposal costs and issues.

[5] While the treatments installed to eliminate gross alpha and combined radium may also reduce uranium levels, we do not quantify these impacts in this analysis. We make no adjustment for three reasons. First, the NIRS data suggest that systems with elevated levels of gross alpha or combined radium rarely report uranium concentrations above levels of concern. Second, some types of treatment used to remove gross alpha or radium are less effective in removing uranium. Lastly, radium and uranium occur at higher levels under very different aquifer conditions: radium tends to occur at high levels in water with low dissolved oxygen and high total dissolved solids, while uranium occurs at higher levels in oxygen-rich waters with low total dissolved solids (see the Technical Support Document, EPA2000a).

2. ''Direct Proportions Approach'' to Estimating Occurrence

Because of uncertainties related to extrapolating from the NIRS database to national-level estimates, we applied two approaches for estimating the national-level central-tendency occurrence estimate. First, we assumed that national occurrence is directly proportional to the occurrence levels measured in NIRS. For example, if the radionuclide concentration in one percent of the samples from NIRS representing a particular water system size category are greater than the MCL, we assumed that one percent of all systems in that size class would be out of compliance at the national level (It is worth noting that using NIRS to extrapolate to the State or regional level is not valid, since NIRS was designed to be representative at the national-level, but not at these other levels). In cases where this approach predicts ''zero probability'' of non-compliance for a system size category (i.e., no samples in NIRS were above the MCL being considered), this approach is flawed, since the expectation is that this finding actually reflects a small probability, not ''zero probability.'' In other words, in situations where ''zero impact'' is predicted, it is much more likely that a very small number of water systems will be impacted compared to true ''zero impact.'' For this reason, we also used a mathematical model to simulate the occurrence distribution, in which these ''zero probabilities'' are replaced by estimated small probabilities.

3. ''Lognormal Model Approach'' to Estimating Occurrence

The second approach recognizes that ''true'' radionuclides occurrence will most likely be spread over a range wider than that observed in the survey. This approach assumes that ''probability plots'' of the NIRS data are lognormally distributed. A probability plot compares the radionuclide concentration for the various samples to the probability of a given sample having that level or less, where this probability is estimated from the actual occurrence data from NIRS. An assumption of lognormality means that a probability plot for the logarithms of the radionuclide levels would be expected to be linear (fall on a straight line).

Inspection of the NIRS data suggests that it is distributed in a roughly lognormal pattern, with most systems reporting concentration levels well below the MCLs of concern. Several other studies also suggest that the distribution of radionuclide occurrence in drinking water systems is likely to follow a lognormal distribution [6], so this assumption should be robust in most cases. If the NIRS data were perfectly lognormally distributed, both approaches would lead to similar estimates of occurrence. This is usually the case. However, it should be noted that there instances of significant deviations between the two approaches. For example, the direct proportions approach predicts that 0.4 % of the systems serving more than 500 persons will be impacted (61 systems) by an MCL of 20 pCi pCi/L for uranium, whereas the lognormal model approach predicts that 1.8% of systems will be impacted (255 systems), amounting to a difference in prediction of almost 200 impacted water systems in this size category. There are several possible explanations for this deviation, but the important point is that the use of both approaches allows the data gap to be recognized and fully considered.

A statistical software package (''Stata'') was used to estimate a lognormal distribution that best fits the data for systems in each size class. We then used the fitted log means and log standard deviations of the resulting distributions to estimate the number of systems out of compliance with each regulatory option using standard statistical equations. More detail regarding the occurrence models and the estimation of the numbers of impacted systems can be found elsewhere (EPA 2000a and 2000b).

4. Assessing Risk

After determining the number of systems out of compliance with each regulatory option under consideration, we assessed the risk reductions that would result from these systems taking actions to come into compliance. The approach for the risk analysis begins with the development of intrinsic ''risk factors'' for each group of radionuclides. These risk factors are composites that involve multiplying EPA's best estimates of unit mortality and morbidity cancer risk coefficients (risk per pCi) for each group of radionuclides by standard assumptions regarding drinking water ingestion to determine the risk factors associated with drinking water exposure (risk per pCi/L). We then applied the individual risk factors [7] to the estimates of the reduction in exposure associated with each regulatory change under consideration, taking into account the population exposed. The calculation of risk factors from risk coefficients and a discussion of exposure assumptions are detailed elsewhere (EPA 2000a). The risk factors (per pCi/L in drinking water) used in the risk reduction analyses are summarized in Table V–1.

The unit [8] risk factors applied in this analysis refer to the aggregated small changes in the probability of incurring cancer over a large population. These unit probabilities can be interpreted in two ways: as the unit lifetime excess probability of cancer induction averaged over age and gender for all individuals in a population or as the risk for a statistically ''averaged individual.'' It should be noted that no one individual is truly average, since the averaging also occurs over gender. Given a model of radionuclide occurrence, the population risks of excess cancer incidence can be estimated before and after a given regulatory option for the individuals comprising the population, with the difference being equal to the reduced risk. These reductions in individual cancer incidence probabilities may then be summed over the population to indicate the central-tendency number of ''statistical cancer cases avoided'' annually. However, it should be kept in mind that for many reasons, including the large variance associated with such risk factors, it is impossible to ''check this prediction'' in any meaningful way. In interpreting reduced risks for given options, it is arguably best to think of them in terms of reduced average ''individual excess risk,'' rather than ''cases avoided,'' for the reasons just described. For example, it is much easier to understand the idea that an individual's average lifetime risk of developing cancer due to exposure to radionuclides in drinking water has been reduced from three in ten thousand to one in ten thousand for a number of water systems under a given option then to understand that an average of 0.5 cancer cases are avoided annually at the national level for that option. The use of ''individual excess risk'' avoids much the confusion about ''statistical cases,'' which are conceptually difficult to understand.

TABLE V–1.—AVERAGE INDIVIDUAL RISK FACTORS, AVERAGE WATER CONSUMPTION (1.1 L/PERSON/DAY) (PER PCI/L)

Regulatory option	Morbidity		Mortality	
	Lifetime ingestion	Annual ingestion	Lifetime ingestion	Annual ingestion
Gross Alpha: changes in monitoring requirements (weighted average of Ra-224 and Ra–226)	5.24E–06	7.48E–08	3.26E–06	4.65E–08
Gross Alpha: changes in MCL (Ra–224 only)	4.77E–06	6.81E–08	2.90E–06	4.15E–08

[6] See the Technical Support Document (EPA 2000a) and the HRRCA (EPA 2000b).

[7] This analysis focuses on changes in cancer risks from tap water ingestion. Individuals may be exposed to radionuclides in drinking water through other pathways (e.g., inhalation while showering), and uranium may have toxic effects on the kidneys; however, we expect that any changes in these types of risks will be, while not insignificant, much smaller than the changes in cancer risks from ingestion, and hence discuss them only qualitatively in this analysis.

[8] ''Unit risk factors and ''unit risks'' refer to the risk per pCi/L in drinking water. They are not estimates of cancer incidence per se, but rather are indicators of the ''potency'' of a radionuclide. To get estimates of the risks of cancer incidence for an exposed population, the unit risk factors must be used in conjunction with a radionuclide drinking water occurrence model. These population risks refer to the estimated numbers of excess statistical cases of cancer that a population will face under a given set of exposure assumptions.

TABLE V–1.—AVERAGE INDIVIDUAL RISK FACTORS, AVERAGE WATER CONSUMPTION (1.1 L/PERSON/DAY) (PER PCI/L)—Continued

Regulatory option	Morbidity		Mortality	
	Lifetime ingestion	Annual ingestion	Lifetime ingestion	Annual ingestion
Combined Radium: changes in monitoring requirements (weighted average of Ra–226 and Ra–228)	2.30E–05	3.28E–07	1.63E–05	2.32E–07
Combined Radium: changes in MCL (Ra–228 only)	2.98E–05	4.26E–07	2.12E–05	3.03E–07
Uranium: establish MCL (simple average of U–234, U–235, and U–238)	1.95E–06	2.79E–08	1.26E–06	1.81E–08

5. Estimating Monetized Benefits

In this section, we summarize the information used in estimating monetized benefits. A description of the methodology used for these estimates is found in the Technical Support Document (EPA 2000a), which provides background information on: (1) The economic concepts that provide the foundation for benefits valuation; (2) the methods that are typically used by economists to value risk reductions, such as wage-risk, cost of illness, and contingent valuation studies; (3) the approach for valuing the reductions in fatal cancer risks and nonfatal cancer risks; (4) the use of these techniques to estimate the value of the risk reductions attributable to the regulatory options for radionuclides in drinking water; and (5) the limitations and uncertainties involved in the estimation. For more detail on the methodology employed, see the Health Risk Reduction and Cost Analysis (HRRCA, EPA 2000b).

This benefits analysis is based on two basic types of valuation: fatal cancer risk reductions and non-fatal cancer risk reductions. Fatal cancer risk reductions are valued in terms of the ''value of a statistical life'' (VSL), which does not refer to the value of an identifiable individual, but rather refers to the value of small reductions in mortality risks over a large population. For example, let us assume that a regulatory option results in a risk reduction of ''one statistical fatal cancer case.'' This refers to the summation of small risk reductions over a large number of persons such that the summation equals ''one case'' (say, one hundred thousand persons each face a risk reduction of 1/100,000). Using our methodology, the resulting benefits would be equal to ''one statistical life.'' Continuing the example, if each person were willing to pay $20 for such a risk reduction (1/100,000), the resulting VSL would be $2 million ($20 times 100,000 persons). However, since there is no direct information on what persons are willing to pay for the risks we are interested in, we must use indirect methods for estimating the VSL. The currently accepted methodology involves transferring the VSL from studies of the wage increases that persons ''demand'' in exchange for accepting jobs with slightly higher chances of accidental fatality (''wage-risk studies''). There are a number of assumptions involved in making this transfer, which are discussed in more detail in the background documentation (EPA 2000a and 2000b).

Valuing nonfatal cancer risk reductions is often done with ''cost of illness studies,'' which examine the actual direct (*e.g.,* medical expenses) and indirect (*e.g.,* lost work or leisure time) costs incurred by affected individuals. Unfortunately, this valuation does not measure the ''willingness to pay'' to avoid nonfatal cancers, but rather assumes that benefits are equal to the avoided costs. The studies used and assumptions involved are discussed elsewhere (EPA 2000a and 2000b).

Because of the uncertainties involved in valuations, we used an estimate of the range of values of reductions in fatal and non-fatal risks attributable to the radionuclides regulations using the following estimates (1998 dollars):

Fatal Risk Reduction Valuations (''Value of a Statistical Life'', VSL):

Best Estimate: Value of fatal risk reductions = Statistical lives saved * $5.9 million per statistical life.

Low End Estimate: Value of fatal risk reductions = Statistical lives saved * $1.5 million per statistical life.

High End Estimate: Value of fatal risk reductions = Statistical lives saved * $11.5 million per statistical life.

Non-Fatal Risk Reduction Valuations

Best Estimate: Value of nonfatal risk reductions (medical costs only) = Statistical cases averted * $0.10 million.

Low End Estimate: Value of nonfatal risk reductions (medical costs only) = Statistical cases averted * $0.09 million.

High End Estimate: Value of nonfatal risk reductions (medical costs only) = Statistical cases averted * $0.11 million.

6. Estimating the Costs of Compliance

The last component of the analysis involves estimating the costs of compliance for each regulatory option. The options under consideration will increase the costs of monitoring for all regulated systems, as well as require a small fraction of the systems to take action to reduce the contaminant levels in their finished water to achieve compliance. Examples of compliance actions include installing treatment, purchasing water from another system, changing the water source used (*e.g.,* installing a new well), blending the contaminated water with other source water that is below the MCL, and, in cases where the contaminated well is not essential to meet capacity, stopping production from the contaminated well. The cost analysis models both new capital costs and, and when appropriate, incremental operations and maintenance costs for this variety of compliance options. The inputs used in the cost analysis and a comparison of the modeled costs for treatment, alternate source, purchased water to case studies can be found in the Technical Support Document (EPA 2000a) and elsewhere (EPA 1998a).

C. Summary of Annual Costs and Benefits

1. Estimates of Costs and Benefits for Community Water Systems

The following results reflect the regulatory options that are currently being considered. Results for the other options that were analyzed (correction of monitoring deficiencies for gross alpha and changes to MCLs for gross alpha and Ra-228), but that EPA does not plan to adopt, are located in the Technical Support Document (EPA 2000a). In addition to EPA's preferred options, we have included all results in the Technical Support Document to allow interested stakeholders to comment on these other options, if desired.

Table V–2 shows the summarized results for EPA's analysis of risk reductions, benefits valuations, and costs of compliance (see EPA 2000b for a break-down of the summary by water 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 each of the regulatory options assessed. The ranges shown reflect the two occurrence model methodologies previously described, the ''direct proportions'' and ''lognormal model'' approaches. The ranges in occurrence predictions necessarily result in ranges of estimates for risk reductions, benefits valuations, and compliance costs. There are two ranges shown for values of cancer cases avoided, the ''best-estimate range,'' based on the best-estimate of risk reduction valuations, and the ''low/high-estimate range,'' which reflects the use of the two occurrence models and the uncertainty in the risk reduction valuations (''low-end'' versus ''high-end'' estimates). These ranges do not reflect uncertainty in other model inputs, like risk factors in the case of risk reduction estimates and treatment unit costs in the case of compliance costs. Quantitative uncertainty analyses for risk reductions, benefits, and compliance costs will be conducted and reported in the preamble to the final rule. EPA expects that these uncertainty analyses will not impact final decisions.

Eliminating the combined radium-226/-228 monitoring deficiency [9] is predicted to lead to 210 to 250 systems out of compliance with an MCL of 5 μg/L, affecting 33,000 to 460,000

[9] The monitoring deficiency will be corrected by requiring the separate analysis of Ra-228 for systems with gross alpha levels below 5 pCi/L.

persons. Implementing an MCL of 20 μg/L for uranium is predicted to impact 830 to 970 systems, affecting 470,000 to 2,100,000 persons. An MCL for uranium of 40 μg/L is predicted to impact 300 to 430 systems, affecting 47,000 to 850,000 persons; 80 μg/L is predicted to impact 40 to 170 systems, affecting 7,000 to 170,000 persons. These estimates for uranium are based on the assumption that the activity-to-mass ratio in drinking water is 1:1. EPA's current best-estimate for the average activity-to-mass ratio for the various uranium isotopes in drinking water is 0.9. EPA will update this assumption for the uranium options in the Regulatory Impact Assessment supporting the rule finalization. However, the impact is expected to be small. For example, using the lognormal occurrence distribution model for the 40 μg/L option, an assumption of an activity-to-mass ratio of 0.9 results in an estimated number of impacted systems of 370, a decrease of only 12–13%.

The estimated risk reduction range for the option addressing the combined radium monitoring deficiency is 0.3 to 0.5 cancer cases avoided annually, with an associated annual monetized benefits range of one to two million dollars. The risk reductions estimated for the uranium options range from 0.2 to 2 cases avoided annually for an MCL of 20 mg/L, 0.04 to 1.5 cases avoided annually for an MCL of 40 μg/L, and 0.01 to 1 case avoided annually for an MCL of 80 μg/L. The associated annual monetized benefits for the uranium options range from 0.6 to 8 million dollars (20 mg/L), 0.1 to 6 million dollars (40 μg/L), and less than 0.1 to 4 million dollars (80 μg/L).

Annual compliance costs range from 20 to 30 million dollars for the option addressing the combined radium monitoring deficiencies. Annual compliance costs for the uranium options range from 30 to 140 million dollars for an MCL of 20 mg/L, 6 to 60 million dollars for an MCL of 40 μg/L, and 5 to 30 million dollars for an MCL of 80 μg/L.

As demonstrated by this analysis the estimated range of central-tendency annual compliance costs exceed the ranges of central-tendency annual monetized benefits for all options. This is not surprising given that most of the systems impacted are small water systems, which tend to have much higher per customer compliance costs relative to large systems, while the per customer risk reduction is independent of water system size. Except in cases where risk reductions are quite large, it is predictable that estimated annual costs will outweigh estimated annual benefits for small water systems (given the current methodologies for estimating benefits). However, it should be pointed out that all of the regulatory options being considered have associated lifetime morbidity risks near or in excess of one in ten thousand, which is the upper bound on the preferred risk range according to EPA's policies on regulating drinking water contaminants. In the case of uranium, it is also important to recognize that there may be considerable non-quantified (not monetizable) benefits associated with reductions in kidney toxicity risks. If such benefits were quantified, it is likely that the net benefits would be more favorable for all uranium options.

Some commenters may argue that costs and benefits considerations should lead to the conclusion that the finalization of the correction of the combined radium monitoring deficiencies and/or the establishment of a NPDWR for uranium are not warranted. However, this conclusion would lead to a situation where customers of many ground water systems face lifetime morbidity risks greatly in excess of the acceptable risk upper limit of one in ten thousand. According to EPA's policies, the proper use of this flexibility should lead to regulatory decisions that have associated risks that are within or acceptably close to EPA's longstanding goals of limiting excess lifetime morbidity risks to the range of one in a million to one in ten thousand, except under unusual circumstances. EPA solicits comment on this interpretation of costs and benefits for the finalization of the 1991 radionuclides proposal.

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Table V-2

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 Excess Cancer Morbidity Risk at MCL[2,3,4]	Ranges of Total Cancer Cases Avoided Annually (fatal cases)	Best-Estimate Values of Avoided Cases, in millions of $ / year) (low-end/high-end[4,5] estimate)	Ranges of 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	270 - 320 systems (380 - 460 K persons)	1×10^{-4}	0.3 - 0.5 (0.2 - 0.4)	1 - 2 (0.3 - 4)	20 - 30
Systems predicted to be out of compliance with proposed options for uranium MCL:					
Uranium at 20 pCi/L (20 Ug/L)	830 - 970 systems (470 - 2,100 K persons)	5×10^{-5}	0.2 - 2 (0.1 - 1.5)	0.6 - 8 (0.2 - 16)	30 - 140
Uranium at 40 pCi/L (40 Ug/L)	300 - 430 systems (47 - 850 K persons)	1×10^{-4}	0.04 - 1.5 (0.02 - 1)	0.1 - 6 (< 0.1 - 12)	6 - 60
Uranium at 80 pCi/L (80 Ug/L)	40 - 170 systems (7 - 170 K persons)	2×10^{-4}	0.01 - 1 (< 0.01 - 0.7)	< 0.1 - 4 (< 0.1 - 8)	5 - 30

Notes:

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. 1×10^{-4} 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 Ra-226 and Ra-228 (2.3×10^{-5} per pCi/L). The "best-estimate"for a particular situation would depend on the actual levels of Ra-226 and Ra-228 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 7.1×10^{-11} per pCi), the assumptions about isotopic prevalence are not important. Here, we assumed that the simple average applied (3.83×10^{-6} per pCi/L).

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

5.. Ranges in parentheses reflect low and high estimates of values of cases avoided. The low-end estimate is based on the cases avoided estimate from the "direct proportions" occurrence model and the low-end risk reduction valuations estimates. The high-end estimate is based on the "lognormal model" for occurrence and the high-end risk reduction valuations estimates. All estimates (best, low, and high) include valuations for both fatal and non-fatal risk reductions.

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2. Uncertainties in the Estimates of Benefits and Costs

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 later in this section.

a. Uncertainties in Risk Reduction 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 risk.[10] Ranges that reflect uncertainty and variability in the risk coefficients will be used in a Monte Carlo analysis of risk reductions and benefits, the results of which will be reported in the preamble to the final rule.

In addition, as previously described in appendix I, ''Occurrence,'' the available occurrence data do not provide information on the contribution of individual radionuclides or isotopes to the total concentrations of gross alpha or uranium. Therefore, there is uncertainty involved in the assumptions about which radionuclides comprise the reported gross alpha or uranium activity. These and other uncertainties related to occurrence information (e.g., uncertainty in extending the NIRS database results to the national level) will also be incorporated in a Monte Carlo analysis of benefits to estimate the range of uncertainty surrounding the central-tendency estimates. Other inputs that will be used in the Monte Carlo analysis of 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.'' This uncertainty analysis is not expected to alter the regulatory options discussed in today's NODA.

b. Effects of the Inclusion of a Latency Period and Other Factors on the Estimate of Benefits. The expected analytical impacts of the inclusion of other factors, *e.g.,* a cancer-latency period, cancer premiums, and non-quantifiable benefits have been discussed in the recent radon proposed NPDWR (64 FR 59295). The relevant points are summarized briefly here and in more detail in the Technical Support Document for the Radionuclides NODA (USEPA 2000a).

There are several potentially important sources of uncertainty related to the valuations of risk reductions for the regulatory options examined. Since the mortality valuations dominate the estimated benefits, factors that affect the VSL are most important. Factors that may affect the VSL include discounting due to cancer latency periods,[11] cancer-related premiums that may raise the value of statistical life, and other currently non-quantifiable benefits. Cancer latency-related discounting would be expected to decrease the present VSL, while cancer premiums would tend to increase the present VSL. It is not clear whether an inclusion of all of these factors would be expected to result in a lower or higher present VSL. However, EPA is currently working with the Science Advisory Board (SAB) to determine how to best include these factors, whether the inclusion is quantitative or qualitative.

c. 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 (EPA 1998a and c, EPA 2000a). Preliminary data (202 compliance actions from 14 States) on nitrate violations suggest that only around a quarter (25%) of those systems talking 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. The prevalence of the use of these non-treatment options is a cross-cutting issue for future Regulatory Impact Assessments and probably will not be resolved before the radionuclides NPDWR is finalized. EPA is following up with this study and will report the results at a later date.

While these ''other than treatment'' options may cost as much as or more than treatment in some cases, they are expected to be less expensive on average, which largely explains their prevalence as compliance options. For example, EPA has recently estimated the costs associated with developing municipal wells to range from $0.08/kgal to $0.46/kgal, depending on system size, geologic setting, and other site specific parameters (EPA 1999b), with an average of $0.23/kgal for systems serving between 501 and 1,000 persons and $0.17/kgal for systems serving between 10,001 and 50,000 persons.[12] These costs include testing and drilling, steel casings with cement lining, pumps, including electrical connections and controls, and a pump shelter. For smaller, non-municipal PWS systems, we estimate that wells could cost from 10 to 80 percent of the costs presented for municipal systems. As shown in the Technical Support Document (EPA 2000a), these production costs are much lower than those for typical treatment, especially for small systems. When feasible, selection of such options may reduce compliance costs significantly. The Technical Support Document includes data on other non-treatment options like purchasing water and blending.

Preliminary uncertainty analyses suggest that variability in the unit compliance costs and decision tree assumptions dominate the over-all cost variability. To evaluate the potential variability in the compliance cost estimates, a Monte Carlo analysis will support the Regulatory Impact Assessment for the final rule. Inputs that influence cost variability include:

- Numbers of total systems in the various system size categories.
- Distributions of entry points per system in the various system size categories.
- Distributions of populations served by size category.
- Flow sizes as a function of population served.
- Daily household water consumption.
- Proportions of systems and sources exceeding regulatory limits.
- Unit costs (capital and O&M) of treatment technologies and annual costs of alternate source and regionalization.
- Proportions of non-compliant systems choosing between treatment, alternate source, and regionalization.

Since per system costs are much higher for very large systems, the assumptions used in the larger water system size categories can be expected to dominate the variability in national costs. Each of these inputs will be modeled using probability distributions that

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

[11] A latency period refers to the average amount of time that passes between the beginning of exposure to a carcinogen or multiple carcinogens and the on-set of fatal cancer. There is considerable uncertainty in estimating a ''typical latency period'' for the options studies here for many reasons, including the large ranges in estimated latency periods for given cancer types and the large uncertainty involved in predicting which type or types of cancer will result from exposure to a given radionuclide in drinking water. It is also uncertain what discounting rate would be appropriate in this situation. Some may argue that discounting is entirely inappropriate (a rate of zero) and others may argue that typical financial discount rates are appropriate (3 to 7%).

[12] This estimate is based on total capital costs ranging from approximately $135,000 to $550,000 per MGD of flow. The estimate assumes typical relationships between design and average daily flows and a capital discount rate of 3 or 7%.

reflect the state of the available data. In some cases, input variability will be estimated from SDWIS, the CWSS, or other sources (e.g., distributions of populations served, daily household water consumption, unit costs) . In other cases, input variability will have to be based on best professional judgement. Again, this uncertainty study is expected to provide useful information, but is not expected to result in changes to the regulatory decisions described in today's NODA.

D. Estimates of Costs and Benefits for Non-Transient Non-Community Water Systems

The available data are not sufficient to allow EPA to predict a central-tendency impact of the regulatory options on non-transient non-community water systems (NTSC systems). Instead, EPA conducted a ''what-if'' analysis of potential costs and benefits based on reasonable assumptions of the percentage of NTSC systems impacted by the various options (EPA 2000b). A ''what-if'' analysis allows us to pose hypothetical occurrence scenarios and to estimate costs and benefits for these scenarios. If the scenarios are chosen properly, they should bound the reasonable set of potential costs and benefits for NTSC systems. However, the estimates should not be interpreted as representing ''best estimates,'' which would be based on an occurrence survey of radionuclides occurring at NTSC systems. The Technical Support Document (EPA 2000a) provides details on the inputs and assumptions used for estimating regulatory impacts for NTSC systems. The resulting estimates of the percentage of systems out of compliance are provided in Table V–3.

TABLE V–3.—ASSUMPTIONS FOR HYPOTHETICAL ''WHAT-IF'' ANALYSIS FOR NON-TRANSIENT NON-COMMUNITY WATER SYSTEMS (APPROXIMATELY 19,300 SYSTEMS NATIONWIDE)

Regulatory option	Percent of national systems in states with elevated levels (1) (percent)	Upper bound: 10% of col. (1) (percent)	Lower bound: 1% of col. (1) (percent)
Gross Alpha at 15 pCi/L	60	6	1
Combined Radium at 5 pCi/L	79	8	1
Uranium at 20 pCi/L:			
Ground water	54	5	1
Surface water	29	3	0

We calculated risk reductions associated with each set of assumptions using the same analytic approach as outlined for the community water systems. However, we use lower water intake assumptions because the population affected generally is not at the location served full-time or year-round. The risk factors were estimated using the same risk coefficients as a starting point (risk per pCi), but use different water consumption assumptions to calculate lifetime excess risk factors (risk per pCi/L). A cost model is used to predict the annual compliance costs for these systems based on their size classes (EPA 2000); in general, non-transient non-community systems tend to use ground water and serve small populations.

The results of the analysis are summarized in Table V–4. If EPA requires non-transient non-community systems to comply with the gross alpha standard of 15 pCi/L, under the assumptions used in the analysis the number of systems out of compliance could range from 110 to 1,100 systems. The associated annual costs range from $1 million to $4 million and the statistical cancer cases (fatal and nonfatal) avoided annually range from 0.01 cases to 0.1 cases. For combined radium, the resulting number of impacted systems ranges from 150 to 1,500 systems with annual costs ranging from $1 million to $6 million and an associated number of annual statistical cancer cases avoided ranging from 0.02 cases to 0.2 cases. For a uranium MCL of 20 μg/L, the results suggest a range of impacted ground water systems from 100 up to 1,000 systems with annual costs ranging from $1 million to $4 million and an associated number of annual statistical cancer cases avoided ranging from less than 0.01 cases up to 0.04 cases. The resulting number of surface water systems impacted by a uranium MCL of 20 μg/L ranges from less than 10 to less than 20 systems. The associated national annual costs for surface water systems is less than $0.1 million up to 0.1 million with annual risk reductions of less than 0.01 statistical cancer cases.

TABLE V–4.—HYPOTHETICAL ''WHAT-IF'' RESULTS FOR NON-TRANSIENT NON-COMMUNITY WATER SYSTEMS

Regulatory option	Lower Bound Estimate			Upper Bound Estimate		
	Number of systems out of compliance	Annual costs (million dollars)	Statistical cancer cases avoided (cases)	Number of systems out of compliance	Annual costs (million dollars)	Statistical cancer cases avoided
Gross Alpha at 15 pCi/L	110	1	0.01	1,100	4	0.1
Combined Radium at 5 pCi/L	150	1	0.02	1,500	6	0.2
Uranium at 20 pCi/L:						
Ground water	100	1	<0.01	1,000	4	0.04
Surface water	< 10	0.03	<0.01	< 20	0.1	<0.01

Note: These results are based on hypothetical assumptions regarding the percent of systems likely to be out of compliance with each regulatory option as discussed in the preceding text. These are not estimates of actual compliance costs or risk reductions, and are provided for illustrative purposes only.

E. Impacts for Systems Serving Greater Than One Million Persons

Based on an Internet search of the available water quality information for water systems serving greater than one million persons (very large systems), there is no direct evidence that closing the monitoring deficiencies for radium will impact these systems. However, the internet search was not conclusive in ruling out the possibility that one or more systems serving greater than one million persons would be impacted by these options. For this reason, EPA has followed up with the few systems in question to determine the likelihood of impact. The follow-up confirmed that there were no impacts expected for these systems. Uranium occurrence data for these systems was collected to the extent feasible and there is no evidence of an impact at 20 or 40 μg/L.

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