

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 141 and 142**

[WH-FRL-6707-2]

RIN 2040-AB75

**National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing a drinking water regulation for arsenic, as required by the 1996 amendments to the Safe Drinking Water Act (SDWA). The proposed health-based, non-enforceable goal, or Maximum Contaminant Level Goal (MCLG), for arsenic is zero, and the proposed enforceable standard, or maximum contaminant level (MCL), for arsenic is 0.005 mg/L. EPA is also requesting comment on 0.003 mg/L, 0.010 mg/L and 0.020 mg/L for the MCL. EPA is listing technologies that will meet the MCL, including affordable compliance technologies for three categories of small systems serving less than 10,000 people. This proposal also includes monitoring, reporting, public notification, and consumer confidence report requirements and State primacy revisions for public drinking water programs affected by the arsenic regulation.

In addition, in this proposal the Agency is clarifying compliance for State-determined monitoring after exceedances for inorganic, volatile organic, and synthetic organic

contaminants. Finally, EPA is proposing that States will specify the time period and sampling frequency for new public water systems and systems using a new source of water to demonstrate compliance with the MCLs. The requirement for new systems and new source monitoring will be effective for inorganic, volatile organic, and synthetic organic contaminants.

**DATES:** EPA must receive public comments, in writing, on the proposed regulations by September 20, 2000. EPA will hold a public meeting on this proposed regulation this summer. EPA will publish a notice of the meeting, providing date and location, in the **Federal Register**, as well as post it on EPA's Office of Ground Water and Drinking Water web site at <http://www.epa.gov/safewater>.

**ADDRESSES:** You may send written comments to the W-99-16 Arsenic Comments Clerk, Water Docket (MC-4101); U.S. Environmental Protection Agency; 1200 Pennsylvania Ave., NW, Washington, DC 20460. Comments may be hand-delivered to the Water Docket, U.S. Environmental Protection Agency; 401 M Street, SW; EB-57; Washington, DC 20460; (202) 260-3027 between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday. Comments may be submitted electronically to [ow-docket@epamail.epa.gov](mailto:ow-docket@epamail.epa.gov). See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing and docket review. The proposed rule and supporting documents, including public comments, are available for review in the Water Docket at the above address.

**FOR FURTHER INFORMATION CONTACT:** Regulatory information: Irene Dooley,

(202) 260-9531, email: [dooley.irene@epa.gov](mailto:dooley.irene@epa.gov). Benefits: Dr. John B. Bennett, (202) 260-0446, email: [bennett.johnb@epa.gov](mailto:bennett.johnb@epa.gov) General information about the regulation: Safe Drinking Water Hotline, phone: (800) 426-4791, or (703) 285-1093, email: [hotline.sdwa@epa.gov](mailto:hotline.sdwa@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**Regulated Entities**

A public water system, as defined in 40 CFR 141.2, provides water to the public for human consumption through pipes or other constructed conveyances, if such system has "at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year." A public water system is either a community water system (CWS) or a non-community water system (NCWS). A community water system, as defined in § 141.2, is "a public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents." The definition in § 141.2 for a non-transient, non-community water system [NTNCWS] is "a public water system that is not a [CWS] and that regularly serves at least 25 of the same persons over 6 months per year." EPA has an inventory totaling over 54,000 community water systems and approximately 20,000 non-transient, non-community water systems nationwide. Entities potentially regulated by this action are community water systems and non-transient, non-community water systems. The following table provides examples of the regulated entities under this rule.

TABLE OF REGULATED ENTITIES

Category	Examples of potentially regulated entities
Industry .....	Privately owned/operated community water supply systems using ground water or mixed ground water and surface water.
State, Tribal, and Local Government .....	State, Tribal, or local government-owned/operated water supply systems using ground water or mixed ground water and surface water.
Federal Government .....	Federally owned/operated community water supply systems using ground water or mixed ground water and surface water.

The table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the

applicability criteria in §§ 141.11 and 141.62 of the rule. If you have any questions regarding the applicability of this action to a particular entity, consult Irene Dooley, the regulatory information person listed in the **FOR FURTHER INFORMATION CONTACT** section.

**Additional Information for Commenters**

Please submit an original and three copies of your comments and enclosures

(including references). To ensure that EPA can read, understand, and therefore properly respond to comments, the Agency would prefer that comments cite, where possible, the paragraph(s) or sections in the notice or supporting documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed. Electronic comments must be submitted as a WordPerfect 5.1, WP6.1

or WP8 file or as an ASCII file avoiding the use of special characters. Comments and data will also be accepted on disks in WP5.1, WP6.1 or WP8, or ASCII file format. Electronic comments on this Notice may be filed online at many Federal Depository Libraries. Commenters who want EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted.

#### Availability of Docket

The docket for this rulemaking has been established under number W-99-16, and includes supporting documentation as well as printed, paper versions of electronic comments. The docket is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays, at the Water Docket; EB 57; U.S. EPA; 401 M Street, SW; Washington, D.C. For access to docket materials, please call (202) 260-3027 to schedule an appointment.

#### Abbreviations Used in This Proposed Rule

>—greater than  
 ≥—greater than or equal to  
 <—less than  
 ≤—less than or equal to  
 §—Section  
 ACWA—Association of California Water Agencies  
 AA—activated alumina  
 As (III)—trivalent arsenic. Common inorganic form in water is arsenite  
 As (V)—pentavalent arsenic. Common inorganic form in water is arsenate  
 ATSDR—Agency for Toxic Substances and Disease Registry, U.S. Department of Health & Human Services  
 ASTM—American Society for Testing and Materials  
 ASV—anodic stripping voltammetry  
 AWQC—Ambient Water Quality Criterion  
 AWWA—American Water Works Association  
 BAT—best available technology  
 BFD—Blackfoot disease  
 BOD—biochemical oxygen demand  
 BOSC—Board of Scientific Counselors, ORD  
 CASRN—Chemical Abstracts Service registration number  
 CCA—chromated copper arsenate  
 CCR—consumer confidence report  
 CDC—Centers for Disease Control and Prevention  
 CFR—Code of Federal Regulations  
 CPI—Consumer Price Index  
 CSFII—Continuing Survey of Food Intakes by Individuals  
 CV—coefficient of variation=standard deviation divided by the mean × 100  
 CWS—community water system

CWSS—Community Water System Survey  
 DBPs—disinfection byproducts  
 DBPR—Disinfectants/Disinfection By-products Rule  
 DMA—Di-methyl arsenic acid, cacodylic acid, (CH<sub>3</sub>)<sub>2</sub>HAsO<sub>2</sub>  
 DSMA—Disodium methanearsonate  
 DWSRF—Drinking Water State Revolving Fund  
 DNA—Deoxyribonucleic acid  
 EB—East Tower Basement  
 EDL—Estimated Detection Limit  
 EDR—Electrodialysis Reversal  
 e.g.—such as  
 EJ—Environmental Justice  
 EO—Executive Order  
 EPA—U.S. Environmental Protection Agency  
 FDA—Food and Drug Administration  
 FR—Federal Register  
 FTE—full-time equivalents (employees)  
 GDP—Gross Domestic Product  
 GFAA—Graphite Furnace Atomic Absorption  
 GHAA—Gaseous Hydride Atomic Absorption  
 GI—gastrointestinal  
 gw—ground water  
 HRRCA—Health Risk Reduction and Cost Analysis  
 IARC—International Agency for Research on Cancer  
 ICP-MS—Inductively Coupled Plasma Mass Spectroscopy  
 i.e.—that is  
 ICP-AES—Inductively Coupled Plasma-Atomic Emission Spectroscopy  
 IESWTR—Interim Enhanced Surface Water Treatment Rule  
 IOCs—inorganic contaminants  
 IRFA—Initial Regulatory Flexibility Analysis  
 IRIS—Integrated Risk Information System  
 IX—Ion exchange  
 K—thousands  
 kg—kilogram, which is one thousand grams  
 L—Liter, also referred to as lower case "l" in older citations  
 LC<sub>50</sub>—The concentration of a chemical in air or water which is expected to cause death in 50% of test animals living in that air or water  
 LCP—laboratory certification program  
 LD<sub>50</sub>—The dose of a chemical taken by mouth or absorbed by the skin which is expected to cause death in 50% of the test animals so treated  
 LOAEL—Lowest-observed-adverse-effect level  
 LS—lime softening  
 LT2ESWTR—Long-Term 2 Enhanced Surface Water Treatment Rule  
 M—millions  
 m<sup>3</sup>—Cubic meters  
 MCL—maximum contaminant level  
 MCLG—maximum contaminant level goal

MDL—method detection limit  
 Metro—Metropolitan Water District of Southern California  
 mg—Milligrams—one thousandth of gram, 1 milligram = 1,000 micrograms  
 mg/kg—milligrams per kilogram  
 mg/m<sup>3</sup>—Milligrams per cubic meter  
 microgram (μg)—One-millionth of gram (3.5 × 10<sup>-8</sup> oz., 0.00000035 oz.)  
 μg/L—micrograms per liter  
 M/DBP—Microbial/Disinfection By-product  
 MMA—Mono-methyl arsenic, arsonic acid, CH<sub>3</sub>H<sub>2</sub>AsO<sub>3</sub>  
 MOS—margin of safety  
 MSMA—Monosodium methanearsonate  
 NAOS—National Arsenic Occurrence Survey  
 NAS—National Academy of Sciences  
 NAWQA—National Ambient Water Quality Assessment, USGS  
 NCI—National Cancer Institute  
 NCWS—non-community water system  
 NDWAC—National Drinking Water Advisory Council  
 NELAC—National Environmental Laboratory Accreditation Council  
 NIRS—National Inorganic and Radionuclide Survey  
 NIST—National Institute of Standards and Technology  
 NOAEL—No-observed-adverse-effect level  
 NODA—notice of data availability  
 NOEL—No-observed-effect level  
 NPDWR—National Primary Drinking Water Regulation, OGWDW  
 NRC—National Research Council, the operating arm of NAS  
 NTNCWS—non-transient non-community water system  
 NTTAA—National Technology Transfer and Advancement Act of 1995  
 NWIS—National Water Information System  
 O&M—operational and maintenance  
 OGWDW—Office of Ground Water and Drinking Water  
 PBMS—Performance-Based Measurement System  
 PE—performance evaluation, studies to certify laboratories for EPA drinking water testing  
 P.L.—Public Law  
 PNR—Public notification rule  
 POD—point of departure  
 POE—Point-of-entry treatment devices  
 POU—Point-of-use treatment devices  
 ppb—Parts per billion. Also, μg/L or micrograms per liter  
 ppm—Parts per million. Also, mg/L or milligrams per liter  
 PQL—Practical quantitation level  
 PRA—Paperwork Reduction Act  
 PT—performance testing  
 PWS—Public water systems  
 PWSS—Public Water Systems Supervision  
 RCRA—Resource Conservation and Recovery Act

REFs—relative exposure factors  
 RFA—Regulatory Flexibility Act  
 RfD—Reference dose  
 RIA—Regulatory Impact Analysis  
 RMCL—Recommended Maximum Contaminant Level  
 RO—reverse osmosis  
 RWS—Rural Water Survey  
 SAB—Science Advisory Board  
 SBA—Small Business Administration  
 SBREFA—Small Business Regulatory and Enforcement Flexibility Act, SBA  
 SDWA—Safe Drinking Water Act of 1974, as amended  
 SDWIS—Safe Drinking Water Information System  
 SER—Small Entity Representative for SBREFA  
 SISNOSE—Substantial impact on a significant number of small entities, SBREFA  
 SM—Standard Methods for the Examination of Water and Wastewater  
 SMRs—Standardized mortality ratios, comparing deaths in test areas to deaths in unexposed areas  
 SSCTs—Small System Compliance Technologies  
 STP—GFAA—Stabilized Temperature Platform Graphite Furnace Atomic Absorption  
 SW—Office of Solid Waste publication or test method  
 SW-846—Solid Waste publication #846, Test Methods for Solid and Hazardous Waste  
 TC—toxicity characteristic  
 TDS—total dissolved solids  
 TNC—transient, non-community  
 TOC—total organic carbon  
 µg—Microgram, 1000 micrograms = 1 milligram  
 UMRA—Unfunded Mandates Reform Act  
 U.S.—United States  
 USDA—U.S. Department of Agriculture  
 USGS—U.S. Geological Survey  
 USPHS—U.S. Public Health Service  
 VSL—Value of Statistical Life  
 WESTCAS—Western Coalition of Arid States  
 WHO—World Health Organization  
 WITAF—Water Industry Technical Action Fund  
 WS—water supply  
 WTP—Willingness to pay

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## I. Summary of Regulation

EPA is proposing an arsenic regulation for community water systems, which are systems that provide piped water to at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents. This proposal will require non-transient, non-community water systems (NTNCWS) to monitor for arsenic and report exceedances of the MCL. The proposed health-based, non-enforceable goal, or Maximum Contaminant Level Goal (MCLG), is zero, based on EPA's revised risk characterization.

EPA evaluated the analytical capability and laboratory capacity, likelihood of water systems choosing treatment technologies for several sizes of systems based on source water properties, and the national occurrence of arsenic in water supplies to determine the proposed Maximum Contaminant Level (MCL). Furthermore, the Agency analyzed the quantifiable and nonquantifiable costs and health risk reduction benefits likely to occur at the treatment levels considered, and the effects on sensitive subpopulations. Based on the determination that the

costs for the feasible MCL do not justify the benefits, EPA is proposing an MCL of 0.005 mg/L and requesting comment on 0.003 mg/L, 0.010 mg/L, and 0.020 mg/L. The treatment technologies for large systems are primarily coagulation/filtration and lime softening, while EPA expects that small systems (serving less than 10,000 people) will be able to use ion exchange, activated alumina, reverse osmosis, nanofiltration, and electro dialysis reversal. The effective date will be five years after the final rule comes out for community water systems serving 10,000 people or less, and three years after promulgation for all other community water systems. EPA is proposing that States applying to adopt the revised arsenic MCL may use their most recently approved monitoring and waiver plans or note in their primacy application any revisions to those plans.

The Agency is clarifying the procedure used for determining compliance after exceedances for inorganic, volatile organic, and synthetic organic contaminants in this proposal. Finally, EPA is proposing in this proposal that States will specify the time frame which new systems and systems using a new source of water have to demonstrate compliance with the MCL's including initial sampling frequencies and compliance periods for new systems and systems that use a new source of water for inorganic, volatile organic, and synthetic organic contaminants.

## II. Background

### A. What Is the Statutory Authority for the Arsenic Drinking Water Regulation?

Section 1401 of the Safe Drinking Water Act (SDWA) requires a "primary drinking water regulation" to specify a maximum contaminant level (MCL) if it is economically and technically feasible to measure the contaminant and include testing procedures to insure compliance with the MCL and proper operation and maintenance. In addition, section 1401(1)(D)(i) requires EPA to establish the minimum quality of untreated, or raw, water taken into a public water system. A national primary drinking water regulation (NPDWR) that establishes an MCL also lists the technologies that are feasible to meet the MCL, but systems are not required to use the listed technologies (section 1412(b)(3)(E)(i)). As a result of the 1996 amendments to SDWA, when issuing a NPDWR, EPA will also list affordable technologies for small systems serving 10,000 to 3301, 3300 to 501, and 500 to 25 that achieve compliance with the MCL or treatment technique. EPA can list modular (packaged) and point-of-

entry and point-of-use treatment units for the three small system sizes, as long as the units are maintained by the public water system or its contractors. Home units must contain mechanical warnings to notify customers of problems (section 1412(b)(4)(E)(ii)). In section 1412(b)(12)(A) of SDWA, as amended August 6, 1996, Congress directed EPA to propose a national primary drinking water regulation for arsenic by January 1, 2000 and issue the final regulation by January 1, 2001. At the same time, Congress directed EPA to develop a research plan by February 2, 1997 to reduce the uncertainty in assessing health risks from low levels of arsenic and conduct the research in consultation with the National Academy of Sciences, other Federal agencies, and interested public and private entities. The amendments allowed EPA to enter into cooperative agreements for research.

Section 1412(a)(3) requires EPA to propose a maximum contaminant level goal (MCLG) simultaneously with the national primary drinking water regulation. The MCLG is defined in section 1412(b)(4)(A) as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." Section 1412(b)(4)(B) specifies that each national primary drinking water regulation will specify a maximum contaminant level (MCL) as close to the MCLG as is feasible, with two exceptions added in the 1996 amendments. First, the Administrator may establish an MCL at a level other than the feasible level if the treatment to meet the feasible MCL would increase the risk from other contaminants or the technology would interfere with the treatment of other contaminants (section 1412(b)(5)). Second, if benefits at the feasible level would not justify the costs, EPA may propose and promulgate an MCL "that maximizes health risk reduction benefits at a cost that is justified by the benefits (section 1412(b)(6))."

When proposing an MCL, EPA must publish, and seek public comment on, the health risk reduction and cost analyses (HRRCA) of each alternative maximum contaminant level considered (section 1412(b)(3)(C)(i)). This includes the quantifiable and nonquantifiable benefits from reductions in health risk, including those from removing co-occurring contaminants (not counting benefits resulting from compliance with other proposed or final regulations), costs of compliance (not counting costs resulting from other regulations), any increased health risks (including those from co-occurring contaminants) that

may result from compliance, incremental costs and benefits of each alternative MCL considered, and the effects on sensitive subpopulations (e.g., infants, children, pregnant women, elderly, seriously ill, or other groups at greater risk). EPA must analyze the quality and extent of the information, the uncertainties in the analysis, and the degree and nature of the risk.

The 1996 amendments also require EPA to base its action on the best available, peer-reviewed science and supporting studies and to present health effects information to the public in an understandable fashion. To meet the latter obligation, EPA must specify, among other things, the methodology used to reconcile inconsistencies in the scientific data for the final regulation (section 1412(b)(3)(B)(v)).

Section 1451(a) allows EPA to delegate primary enforcement responsibility to federally recognized Indian Tribes, providing grant and contract assistance, using the procedures applied to States. Section 1413(a)(1) allows EPA to grant States primary enforcement responsibility for NPDWRs when EPA has determined that the State has adopted regulations that are no less stringent than EPA's. States must adopt comparable regulations within two years of EPA's promulgation of the final rule, unless a two-year extension is justified. State primacy also requires, among other things, adequate enforcement (including monitoring and inspections) and reporting. EPA must approve or deny State applications within 90 days of submission (section 1413(b)(2)). In some cases, a State submitting revisions to adopt a national primary drinking water regulation has enforcement authority for the new regulation while EPA action on the revision is pending (section 1413(c)).

#### B. What Is Arsenic?

Arsenic is an element that occurs naturally in rocks, soil, water, air, plants, and animals. Arsenic is a metalloid, which exhibits both metallic and nonmetallic chemical and physical properties. The primary valence states for arsenic are 0, -3, +3 and +5. Although arsenic is found in nature to a small extent in its elemental form (0 valence), it occurs most often as inorganic and organic compounds in either the As (III) (+3) or As (V) (+5) valence states. The trivalent forms of inorganic arsenic [As (III) (e.g., arsenite,  $\text{H}_3\text{AsO}_3$ )] and the pentavalent forms [As (V) (e.g., arsenate,  $\text{H}_2\text{AsO}_4^-$ ,  $\text{HAsO}_4^{2-}$ )] are inorganic species which tend to be more prevalent in water than the organic arsenic species (Irgolic, 1994;

Clifford and Zhang, 1994). The dominant inorganic species present in water is largely a function of the pH and the oxidizing/reducing conditions which affects the need for pretreatment and removal effects. Arsenates are more likely to occur in aerobic surface waters and arsenites are more likely to occur in anaerobic ground waters.

#### C. What Are the Sources of Arsenic Exposure?

##### 1. Natural Sources of Arsenic

There are numerous natural sources as well as human activities that may introduce arsenic into food and drinking water. The primary natural sources include geologic formations (e.g., rocks, soil, and sedimentary deposits), geothermal activity, and volcanic activity. Arsenic and its compounds comprise 1.5–2% of the earth's crust (Welch, personal communication). While concentrations of arsenic in the earth's crust vary, the average concentrations are generally reported to range from 1.5 to 5 mg/kg. Arsenic is a major constituent of many mineral species in igneous and sedimentary rocks. It is commonly present in the sulfide ores of metals including copper, lead, silver, and gold. There are over 100 arsenic-containing minerals, including arsenic pyrites (e.g.,  $\text{FeAsS}$ ), realgar ( $\text{AsS}$ ), lollingite ( $\text{FeAs}_2$ ,  $\text{Fe}_2\text{As}_3$ ,  $\text{Fe}_2\text{As}_5$ ), and orpiment ( $\text{As}_2\text{S}_3$ ). Geothermal water can be a source of inorganic arsenic in surface water and ground water. Welch *et al.* (1988) identified fourteen areas in the Western United States where dissolved arsenic concentrations ranged from 80 to 15,000  $\mu\text{g/L}$ . In addition, natural emissions of arsenic are associated with forest fires and grass fires. Volcanic activity appears to be the largest natural source of arsenic emissions to the atmosphere (ATSDR, 1998). Arsenic compounds, both inorganic and organic, are also found in food.

##### 2. Industrial Sources of Arsenic

Major present and past sources of arsenic include wood preservatives, agricultural uses, industrial uses, mining and smelting. The human impact on arsenic levels in water depends on the level of human activity, the distance from the pollution sources, and the dispersion and fate of the arsenic that is released. The production of chromated copper arsenate (CCA), an inorganic arsenic compound and wood preservative, accounts for approximately 90% of the arsenic used annually by industry in the United States (USGS, 1998; USGS, 1999). CCA is used to pressure treat lumber, which

is typically used for the construction of decks, fences, and other outdoor applications. In addition to wood preservatives, the other EPA-registered use of inorganic arsenic is for sealed ant bait. In the past, agricultural uses of arsenic included pesticides, herbicides, insecticides, defoliants, and soil sterilants. Inorganic arsenic pesticides are no longer used for agricultural purposes; the last agricultural application was voluntarily canceled in 1993 (58 FR 64579, US EPA, 1993b).

Organic forms of arsenic are constituents of some agricultural pesticides that are currently used in the U.S. Monosodium methanearsonate (MSMA) is the most widely applied organoarsenic pesticide, which is used to control broadleaf weeds and is applied to cotton (Jordan *et al.*, 1997). Small amounts of disodium methanearsonate (DSMA, or cacodylic acid) are also applied to cotton fields as herbicides. The Food and Drug Administration regulates other organic arsenicals (e.g., roxarsone and arsanilic acid) used as feed additives for poultry and swine for increased rate of weight gain, improved feed efficiencies, improved pigmentation, and disease treatment and prevention. These additives undergo little or no metabolism before excretion (NAS, 1977; Moody and Williams, 1964; Aschbacher and Feil, 1991).

Arsenic and arsenic compounds (arsenicals) are used for a variety of industrial purposes, including: electrophotography, catalysts, pyrotechnics, antifouling paints, pharmaceutical substances, dye and soaps, ceramics, alloys (automotive solder and radiators), battery plates, optoelectronic devices, semiconductors, and light emitting diodes in digital watches (Azcue and Nriagu, 1994). In addition, burning of fossil fuels, combustion of wastes, mining and smelting, pulp and paper production, glass manufacturing, and cement manufacturing can result in emissions of arsenic to the environment (US EPA, 1998). Arsenic has been identified as a contaminant of concern at 916 of the 1,467 National Priorities List (Superfund) hazardous waste sites (ATSDR, 1998).

##### 3. Dietary Sources

Because arsenic is naturally occurring, the entire population is exposed to low levels of arsenic through food, water, air, and contact with soil. The National Research Council report (NRC, 1999) described in sections III.C. and III.E.3. provides Food and Drug Administration (FDA) "market basket" data for total arsenic intake by age

group. NRC assumed that, for fish and seafood, inorganic arsenic is 10% of the total arsenic and that other food contains entirely inorganic arsenic. These assumptions are probably high and conservative for public health protection to avoid underestimating the contributions from food. Table 3–5 in the 1999 NRC report characterizes inorganic arsenic intake from food in the U.S. as being 1.3 µg/day for infants under one year old, 4.4 µg/day for 2-year olds, almost 10 µg/day for 25–30 year-old males, with a maximum of 12.5 µg/day for 60–65 year-old males (females had lower arsenic intake in every age group). MacIntosh et al. (1997) estimated that 785 adults had a mean inorganic arsenic consumption of 10.22 µg/day, with a standard deviation of 6.54 µg/day and a range of 0.36–123.84 µg/day based on semi-quantitative food surveys.

Likewise, the 2 L/day assumption of adult drinking water intake used to develop the MCLG does not represent intake by the average person; rather it represents intake of a person in the 90th percentile. (See Section X.B.1.a. for a description of water consumption for the general population.)

#### 4. Environmental Sources

Internal exposure after skin contact with water or soil containing arsenic or inhalation of arsenic from air is believed to be low. Studies of inorganic arsenic absorption from skin from cadavers estimated 0.8% uptake from soil and 1.9% uptake from water over a 24-hour period (Wester *et al.*, 1993). EPA's arsenic health assessment document for the Clean Air Act (US EPA, 1984) cited respiratory arsenic as being about 0.12 µg/day from a daily ventilation rate of 20 m<sup>3</sup> using a 1981 national average arsenic air concentration of 0.006 µg/m<sup>3</sup>. Assuming 30 percent absorption, the daily amount of arsenic from breathing would be 0.03 µg, so air is a minor source of arsenic (50 FR 46936 at 46960; US EPA, 1985b). At this time, EPA is basing health risks on estimates of arsenic exposure from food and water. The Centers for Disease Control and Prevention (CDC) is initiating a study of arsenic intake from bathing. EPA requests comment on whether available data on skin absorption and inhalation indicate that these are significant exposure routes that should be considered in the risk assessment.

#### D. What is the Regulatory History for Arsenic?

Regulation of arsenic has been the subject of scientific debate that has lasted for decades despite research and scientific review. The controversy has

affected policy and regulatory decisions for arsenic in drinking water from low, environmental exposure.

#### 1. Earliest U.S. Arsenic Drinking Water Standards

In 1942 the U.S. Public Health Service first established an arsenic drinking water standard for interstate water carriers at 0.05 mg arsenic per liter (mg/L, or 50 µg/L), as measured with a colorimetric method. The report did not cite any reason for choosing that level, but it defined "safety of water supplies" as "the danger, if any, is so small that it cannot be discovered by available means of observation (US Public Health Service 1943)." In 1946, the Surgeon General of the U.S. Public Health Service noted that the American Water Works Association had accepted the 1942 drinking water standards, including the arsenic standard (U.S. Public Health Service 1946). In 1962 (U.S. Public Health Service 1962) the U.S. Public Health Service issued more stringent drinking water standards for arsenic of 0.01 mg/L (10 µg/L) for a water supply in 42 CFR 72.205(b)(1) and 0.05 mg/L in 42 CFR 72.205(b)(2) as grounds for rejection of a water supply, as measured by the current edition of Standard Methods for the Examination of Water and Wastewater per 42 CFR 72.207(a).

The Safe Drinking Water Act of 1974 amended the Public Health Service Act and specified that EPA set primary and secondary drinking water standards. On December 24, 1975 (40 FR 59566 at 59570; US EPA, 1975), EPA issued a National Interim Primary Drinking Water Regulation for arsenic in § 141.23(b) of 0.05 mg/L (50 µg/L), effective 18 months later (§ 141.6). Commenters recommended an MCL of 100 µg/L, saying there were no observed adverse health effects (40 FR 59566 at 59576; US EPA, 1975). EPA noted long-term chronic effects at 300–2,750 µg/L, but observed no illnesses in a California study at 120 µg/L. Drinking 2 liters of water a day containing arsenic at 50 µg/L would provide approximately 10% of total ingested arsenic from food and water, estimated to be 900 µg/day. The section on arsenic noted that arsenic has been believed to be a carcinogen "[s]ince the early nineteenth century \* \* \*; however evidence from animal experiments and human experience has accumulated to strongly suggest that arsenicals do not produce cancer. One exception is a report from Taiwan \* \* \*. The text goes on to note occupational skin and lung cancer from arsenic dust and skin cancer in England from drinking water with 12 mg/L. (US EPA, 1976 Appendix A).

#### 2. EPA's 1980 Guidelines

Scientific data at the time the 1980 Ambient Water Quality Guidelines were formulated did not support a safe or "threshold" concentration for carcinogens, so EPA's public health policy was

"that the recommended concentration for maximum protection of human health is zero. In addition, the Agency presented a range of concentrations corresponding to incremental cancer risks of 10<sup>-7</sup> to 10<sup>-5</sup> (one additional case of cancer in populations ranging from ten million to 100,000, respectively) \* \* \* [that did not necessarily represent] an Agency judgement on an 'acceptable' risk level (45 FR 79318 at 79323, US EPA, 1980)."

In the November 28, 1980 **Federal Register** document, using its then current risk assessment approach (assumed toxicity increased as a natural logarithm linear function across species), EPA set the Clean Water Act surface water quality criterion for arsenic at 2.2 nanograms (ng/L) (0.0022 µg/L) at an increased cancer risk of 10<sup>-6</sup>. The criterion was to prevent skin cancer in humans drinking contaminated water and eating aquatic organisms from those water bodies (45 FR 79318 at 79326). The 1980 **Federal Register** notice indicated that drinking water standards consider a range of factors, including health effects, technological and economic feasibility of removal, and monitoring capability. On the other hand the Clean Water Act criteria of section 304(a)(1) "have no regulatory significance under the SDWA." The Clean Water Act section 304(a)(1) criteria are more similar to the health-based goals of the recommended maximum contaminant levels (now referred to as MCLGs), than to MCLs; and differences in mandates "may result in differences between the two numbers." (45 FR 79318 at 79320; US EPA, 1980). In 1992, the Clean Water Act criterion was recalculated based on the updated cancer risk assessment in EPA's Integrated Risk Information System (IRIS) database, to a level of 0.018 µg/L for arsenic at a 10<sup>-6</sup> cancer risk (57 FR 60848; US EPA, 1992c).

#### 3. Research and Regulatory Work

The 1980 National Academy of Science (NAS) Volume III of "Drinking Water and Health" report encouraged EPA to research whether arsenic is essential for humans, as demonstrated in four studies of mammalian species. The 1983 NAS Volume V report projected that 0.05 mg/kg of total arsenic may be a desirable level for people, and 25 to 50 µg a day may be required (as cited in 50 FR 46936 at 46960; US EPA, 1985b).

In 1983, EPA requested comment on whether the arsenic MCL should consider carcinogenicity, other health effects, and nutritional requirements, and whether MCLs are necessary for separate valence states (e.g., arsenite vs. arsenate) (48 FR 45502 at 45512; US EPA, 1983). On November 13, 1985, EPA proposed (50 FR 46936; US EPA, 1985b) a recommended maximum contaminant level (RMCL), a non-enforceable health goal now known as an MCLG, of 50 µg/L based on the 1983 NAS conclusion that 50 µg/L balanced toxicity and possible essentiality and provided "a sufficient margin of safety" (50 FR 46936 at 46960). EPA also requested comment on alternate RMCLs of 100 µg/L based on noncarcinogenic effects (calculated from an animal study and an uncertainty factor of 1000) and 0 µg/L based on carcinogenicity (50 FR 46936 at 46961). EPA chose not to base the proposed RMCL on the animal study because each dose group had only four Rhesus monkeys. Also, at that time, studies had "not detected increased risks via drinking water in the USA" (50 FR 46936 at 46960). The 1985 proposed drinking water regulation preamble noted the 1980 excess cancer risk values derived from the ambient water quality criteria were based on skin cancer using the 1968 Tseng *et al.* study (50 FR 46936 at 46961).

The June 19, 1986 amendments to the Safe Drinking Water Act (SDWA; Public Law 99-339) converted the 1975 interim arsenic standard to a National Primary Drinking Water Regulation (section 1412(a)(1)), subject to revision by 1989 (section 1412(b)(1)). Review of the arsenic risk assessment issues caused the Agency to miss the 1989 deadline for proposing a revised NPDWR. As a result of a citizen suit to enforce the deadline, EPA entered into a consent decree providing deadlines for issuing the arsenic rule.

In 1988, EPA's Risk Assessment Forum issued the Special Report on Ingested Inorganic Arsenic: Skin Cancer; Nutritional Essentiality (EPA/625/3-87/013), in part, to evaluate the validity of applying skin cancer data from Taiwanese studies (published in 1968 and 1977) in dose-response assessments in the U.S. As described in the report, the maximum likelihood estimate of risk ranged from  $3 \times 10^{-5}$  to  $7 \times 10^{-5}$  for a 70-kilogram person consuming 2 liters of water per day contaminated with 1 µg of arsenic per liter. Calculated at the 50 µg/L standard, the U.S. lifetime risk of skin cancer ranged from  $1 \times 10^{-3}$  to  $3 \times 10^{-3}$ , which means one to three skin cancers would occur in a group of one thousand people drinking water containing arsenic at 50 µg/L. Existing

studies could not determine whether arsenic was an essential nutrient.

After reviewing the scientific evidence for carcinogenicity, EPA's Science Advisory Board (US EPA, 1989a and b) stated in its August 1989 and September 1989 reports that (1) the animal studies suggesting arsenic is an essential nutrient are not definitive; (2) the skin changes seen in hyperkeratosis may not always result in skin cancer; (3) the 1968 Taiwan data demonstrate that high doses of ingested arsenic can cause skin cancer; (4) the Taiwan study is inconclusive to determine cancer risk at levels ingested in the United States (U.S.); and (5) As (III) levels below 200–250 µg per day may be detoxified. SAB recommended that EPA set the MCL using a non-linear dose-response (at some low dose, arsenic would not be toxic). The SAB report recommended that EPA revise the risk assessment based on dose of arsenic to target tissues (the concentration of arsenic that damages tissues, rather than the concentration in water) and consider detoxification.

The SAB also reviewed EPA's April 12, 1991 Arsenic Research Recommendations (US EPA, 1991c). The final report provided SAB's recommendations (US EPA, 1992a) and "identified research needed to resolve major uncertainties about inorganic arsenic cancer risk" to evaluate if work could be done in three to five years. It noted that "important work can be done within the time available. Although the results from this work will not completely resolve any issue, \* \* \* the results will likely significantly improve the Agency's ability to evaluate the risk. \* \* \* through improved knowledge of arsenic metabolism and \* \* \* as a carcinogen." The report reflected uncertainty as to whether or not EPA could obtain enough data to regulate arsenic using a non-linear model, which needed more information on how arsenic induces cancer. The group noted that it would take longer than five years to develop an animal model to help understand the toxicity of arsenic. SAB recommended four short-term studies: (a) Investigation of chromosome damage, arsenic metabolites, and the times cells are most susceptible to arsenic, (b) study of human liver capacity to add methyl groups to arsenic, (c) identifying the species in urine in several populations to look for evidence of saturation of methylation enzymes, and (d) comparing methylated arsenic excreted in the U.S., Taiwan, Mexico, and Argentina to consider the effect of nutritional or genetic differences on methylation capacity. However, if time were not a factor, SAB

ranked developing an animal model of arsenic-induced cancer as the first priority.

In 1993 SAB reviewed EPA's draft "Drinking Water Criteria Document on Inorganic Arsenic (US EPA, 1993a)." In 1995, SAB reviewed the analytical methods, occurrence estimate, treatment technologies, and approach for assigning costs in the regulatory impact analysis (US EPA, 1995). Besides highlighting previous SAB reviews of 1989, 1992, and 1994 on health effects, the 1995 report recommended changes to the practical quantitation limit approach, use of occurrence data, review of technologies, and support for the decision tree, with some reservations.

EPA held internal workgroup meetings throughout 1994, addressing risk assessment, treatment, analytical methods, arsenic occurrence, exposure, costs, implementation issues, and regulatory options. EPA decided in early 1995 to defer the arsenic regulation in order to better characterize health effects and assess cost-effective removal technologies for small utilities.

The 1996 amendments to SDWA included a new statutory deadline for the arsenic regulations, as discussed in section II.A.

#### E. EPA's Arsenic Research Plan

EPA held a workshop in March 1994 entitled "Workshop on Developing an Epidemiology Research Strategy for Arsenic in Drinking Water." The cover letter to the final report (US EPA, 1997b), dated April 14, 1997, notes that EPA has been using the recommendations to direct its research directions. The report listed ten projects and seventeen conclusions on exposure, endpoints, study design and statistical power, population selection, feasibility of conducting a study in the U.S., international studies, importance of developing biomarkers to measure health effects of arsenic, and animal studies.

In 1995, the Water Industry Technical Action Fund (WITAF) (funded by the American Water Works Association, National Association of Water Companies, Association of Metropolitan Water Agencies, National Rural Water Association, and National Water Resources Association), the AWWA Research Foundation, and the Association of California Water Agencies (ACWA) sponsored an Expert Workshop on Arsenic Research Needs in Ellicott City, MD, May 31–June 2, 1995. The final report (AWWA *et al.*, 1995) identified research projects in mechanisms, epidemiology, toxicology, and treatment. It identified ten high

priority projects which would need over \$3 million to fund, eleven medium priority projects needing over \$6 million, and ten low priority projects costing over \$9 million, that totaled over \$19 million in research needs.

Congress recognized the importance of health effects research in regulating arsenic, as demonstrated by the 1996 statutory requirement to develop a research plan within 180 days "in support of drinking water rulemaking to reduce the uncertainty in assessing health risks associated with exposure to low levels of arsenic \* \* \* (section 1412(b)(12)(A)(ii)). In the research plan EPA recognized that "[t]he research needs are broader than those that EPA can address alone, and it is anticipated that other entities will be involved in conducting some of the needed research (US EPA, 1998a)." (See section III.E.1. on industry-funded research and the arsenic research plan (at [www.epa.gov/ORD/WebPubs/final/arsenic.pdf](http://www.epa.gov/ORD/WebPubs/final/arsenic.pdf)) for EPA-funded projects.) In December 1996, EPA submitted its draft research plan for peer review by its Board of Scientific Counselors' (BOSC) Ad Hoc Committee, and the committee met in January 1997. The February 1998 Arsenic Research Plan addressed the June 1997 comments from BOSC.

Major areas covered in the research plan included studies to:

- Improve our qualitative and quantitative assessment of the human toxicity of arsenic;
- Understand mechanisms of arsenic toxicity that may aid in extension of the observed human findings when extrapolation is required;
- Measure exposures of the US population to arsenic from various sources (particularly diet) to allow better definition of cumulative exposures to arsenic;
- Refine treatment technologies that may better remove arsenic from water supplies;
- Improve methods for analyzing and monitoring arsenic in drinking water.

EPA also set priorities in the plan and identified projects that met the short term and long term criteria:

#### Short Term Criteria

1. Will the research improve the scientific basis for risk assessments needed for proposing a revised arsenic MCL by January 1, 2000?
2. Will the research improve the scientific basis for risk management decisions needed for proposing a revised arsenic MCL by January 1, 2000?

#### Long Term Criteria

1. Will the research improve the scientific basis for risk assessment and

risk management decisions needed to review and develop future MCLs beyond the year 2000?

2. Is the research essential to improving our scientific understanding of the health risks of arsenic?

The research plan included the following priority topics for research under the five major areas of investigation supporting drinking water rulemaking:

#### Exposure Analysis

- Arsenic speciation and preservation: Improvements in analytical methods to support water treatment decisions.
- Measurement of background exposures to arsenic in U.S. population, particularly inorganic arsenic intake in the U.S. diet.
- Development and evaluation of biomarkers (e.g., species of arsenic in urine) of exposures.
- Development of standard reference material for arsenic in water, food, urine, tissues.

#### Cancer Effects

- Further study of internal cancers associated with arsenic exposures.
- Dose response data on hyperkeratosis as a likely precursor to skin cancer.
- Research on factors influencing human susceptibility including age, genetic characteristics and dietary patterns.
- Metabolic and pharmacokinetic studies that can identify dose dependent metabolism.
- Mechanistic studies for arsenic-induced genotoxicity and carcinogenicity.

#### Noncancer Effects

- Development of human dose-response data for hyperkeratosis, cardiovascular disease, neurotoxicity and developmental effects.
- Development of additional health effects and hazard identification data on other non-cancer endpoints such as diabetes and hematologic effects.

#### Risk Management Research

- Identification of limitations of treatment technologies and impacts on water quality.
- Development of treatment technologies for small water systems.
- Development of data on cost and performance capabilities of various treatment options.
- Consideration of residuals management issues, including disposal options and costs.

#### Risk Assessment/Characterization

- Development of risk characterizations to provide interim support to States and local communities.
- Development of predictive tools and statistical models for assessing bioavailability, interactions and dose-response as better mass balance data become available.
- Comprehensive assessment of exposure levels and incorporation of data into risk estimates for better characterization of actual risks associated with arsenic exposure.
- Comprehensive assessment of arsenic mode of action provide a greater understanding of biological mechanisms and factors that may impact the shape of a dose response curve.
- Comprehensive assessment of non-cancer risks and consideration of appropriate modeling tools for quantitative estimation of non-cancer risks.
- Comprehensive assessment of human dose-response data for hyperkeratosis, cardiovascular disease, neurotoxicity and developmental effects.

#### III. Toxic Forms and Health Effects of Arsenic

##### A. What Are the toxic Forms of Arsenic?

Arsenic exists in several forms which vary in toxicity and occurrence. Accordingly, for this proposed regulation, it is important to consider those forms that can exert toxic effects and to which people may be exposed. For example, the metallic form of arsenic (0 valence) is not absorbed from the stomach and intestines and does not exert adverse effects. On the other hand, a volatile compound such as arsine ( $AsH_3$ ) is toxic, but is not present in water or food. Moreover, the primary organic forms (arsenobetaine and arsenocholine) found in fish and shellfish seem to have little or no toxicity (Sabbioni *et al.*, 1991). Arsenobetaine quickly passes out of the body in urine without being metabolized to other compounds (Vahter, 1994). Arsenite (+3) and arsenate (+5) are the most prevalent toxic forms of inorganic arsenic that are found in drinking water. However, recovery of identified arsenic species in vegetables, grains and oils has been limited and difficult, so little is known about types of species in these foods (NRC, 1999).

In animals and humans, inorganic pentavalent arsenic is converted to trivalent arsenic that can be methylated (*i.e.*, chemically bonded to a methyl group, which is a carbon atom linked to

three hydrogen atoms) to mono-methyl arsenic (MMA) and di-methyl arsenic acid (DMA), which are organic arsenicals. The primary route of excretion for arsenic metabolites is in the urine. Studies indicate that the organic arsenicals MMA and DMA were hundreds of times less likely to produce genetic changes in animal cells than inorganic arsenicals. Moreover, many studies reported organic arsenicals to be less reactive in tissues, to kill less cells, and to be more easily excreted in urine (NRC, 1999).

#### B. What Are the Effects of Acute Toxicity?

Inorganic arsenic can exert toxic effects after acute (short-term) or chronic (long-term) exposure. From human acute poisoning incidents, the LD<sub>50</sub> of arsenic has been estimated to range from 1 to 4 mg/kg (Vallee *et al.*, 1960, Winship, 1984). This dose would correspond to a lethal dose range of 70 to 280 mg for 50% of adults weighing 70 kg. At nonlethal, but high acute doses, inorganic arsenic can cause gastroenterological effects, shock, neuritis (continuous pain) and vascular effects in humans (Buchanan, 1962). Such incidents usually occur after accidental exposures. However, sometimes high dose acute exposures may be self-administered. For example, inorganic arsenic is a component of some herbal medicines and adverse effects have been reported after use. In one report of 74 cases (Tay and Seah, 1975), the primary signs were skin lesions (92%), neurological (*i.e.*, nerve) involvement (51%), and gastroenterological, hematological (*i.e.*, blood) and renal (*i.e.*, kidney) effects (19 to 23%). Although acute or short-term exposures to high doses of inorganic arsenic can cause adverse effects, such exposures do not occur from public water supplies in the U.S. at the current MCL of 50 µg/L. EPA's proposed drinking water regulation addresses the long-term, chronic effects of exposure to low concentrations of inorganic arsenic in drinking water.

#### C. What Cancers Are Associated With Arsenic?

Inorganic arsenic is a multi-site human carcinogen by the drinking water route. Asian, Mexican and South American populations with exposures to arsenic in drinking water generally at or above several hundred micrograms per liter are reported to have increased risks of skin, bladder, and lung cancer. The current evidence also suggests that the risks of liver and kidney cancer may also be increased following exposures to inorganic forms of arsenic. The weight

of evidence for ingested arsenic as a causal factor of carcinogenicity is much greater now than a decade ago, and the types of cancer occurring as a result of ingesting inorganic arsenic have even greater health implications for U.S. and other populations than the occurrence of skin cancer alone. (Until the late 1980s skin cancer had been the cancer classically associated with arsenic in drinking water.) Epidemiologic studies (*e.g.*, of people) provide direct data on arsenic risks from drinking water at exposure levels much closer to those of regulatory concern than environmental risk assessments based on animal toxicity studies.

#### 1. Skin Cancer

Early reports linking inorganic arsenic contamination of drinking water to skin cancer came from Argentina (Neubauer, 1947, reviewing studies published as early as 1925) and Poland (Geyer, 1898, as reported in Tseng *et al.*, 1968). However, the first studies that observed dose-dependent effects of arsenic associated with skin cancer came from Taiwan (Tseng *et al.*, 1968; Tseng, 1977). These studies focused EPA's attention on the health effects of ingested arsenic. Physicians physically examined over 40,000 residents from 37 villages and 7500 residents exposed to 0.017 mg/L arsenic (reference group). The study population was divided into three groups based on exposure to inorganic arsenic (0 to 0.29, 0.30 to 0.59 and ≥0.60 mg of inorganic As/Liter) measured at the village level. A dose- and age-related increase of arsenic-induced skin cancer among the villagers was noted. No skin cancers were observed in the low arsenic reference areas. The 1999 NRC report noted that the "primary limitation of this study \* \* \* was the lack of detail" reported, such as grouping individuals into "broad exposure groups" (rather than grouping into 37 village exposures). This limits the usefulness of these studies. However, these Tseng reports and other corroborating studies such as those by Albores *et al.* (1979) and Cebrian *et al.* (1983) on drinking water exposure and exposures to inorganic arsenic in medicines (Cuzick *et al.*, 1982) and in pesticides (Roth, 1956) led the EPA, using skin cancer as the endpoint, to classify inorganic arsenic as a human carcinogen (Group A) by the oral route (US EPA, 1984).

#### 2. Internal Cancers

Exposure to inorganic arsenic in drinking water has also been associated with the development of internal cancers. "No human studies of sufficient statistical power or scope

have examined whether consumption of arsenic in drinking water at the current MCL results in an increased incidence of cancer or noncancer effects (NRC, 1999, pg. 7)."

Chen *et al.* (1985) used standardized mortality ratios (SMRs) to evaluate the association between ingested arsenic and cancer risk in Taiwan. (SMRs, ratios of observed to expected deaths from specific causes, are standardized to adjust for differences in the age distributions of the exposed and reference populations.) The authors found statistically significant increased risks of mortality for bladder, kidney, lung, liver and colon cancers. A subsequent mortality study in the same area of Taiwan found significant dose-response relationships for deaths from bladder, kidney, skin, and lung cancers in both sexes and from liver and prostate cancer for males. They also found increases in peripheral and cardiovascular diseases but not in cerebrovascular accidents (Wu *et al.*, 1989). There are several corroborating reports of the increased risk of cancers of internal organs from ingested arsenic including two from two South American countries. In Argentina, significantly increased risks of death from bladder, lung and kidney cancer were reported (Hopenhayn-Rich *et al.*, 1996; 1998). In a population of approximately 400,000 in northern Chile, Smith *et al.* (1998) found significantly increased risks of bladder and lung cancer mortality.

There have only been a few studies of inorganic arsenic exposure via drinking water in the U.S., and most have not considered cancer as an endpoint. People have written EPA asking that the new MCL be set considering that these U.S. studies have not seen increases in cancers at the low levels of arsenic exposure in U.S. drinking water. Optimally, low-exposure arsenic studies involve long-term residency (20–40 years with known drinking water arsenic exposure), access to health records, populations large enough to detect statistically significant increases in cancers and other health endpoints, and limited use of multiple sources of water (bottled, filtered, beverages, food prepared outside the home).

Recently, Lewis *et al.* (1999) conducted a mortality study of a population in Utah whose drinking water contained relatively low concentrations of arsenic (averaged 18–191 µg/L). They reported no significant increase in bladder or lung mortality. They did report a statistically significant dose-response for an increased risk of prostate cancer mortality. Smoking is an established risk factor for bladder and lung cancer, and inorganic arsenic

behaves as a comutagen even though it is not mutagenic alone (NRC, 1999, pg. 200). It is possible that inorganic arsenic potentiates other risk factors for these cancers. This potential role is consistent with the NRC, 1999 view that arsenic's mode of action may be to interfere with cell "housekeeping" functions that normally repair genetic damage and ensure that damaged cells die (programmed cell death) rather than reproduce (see section III.D.2. below).

#### D. What Non-Cancer Effects Are Associated With Arsenic?

A large number of adverse noncarcinogenic effects have been reported in humans after exposure to drinking water highly contaminated with inorganic arsenic. The earliest and most prominent changes are in the skin, *e.g.*, hyperpigmentation and keratoses (calus-like growths). Other effects that have been reported include alterations in gastrointestinal, cardiovascular, hematological (*e.g.*, anemia), pulmonary, neurological, immunological and reproductive/developmental function (ATSDR, 1998).

The most common symptoms of inorganic arsenic exposure appear on the skin and occur after 5–15 years of exposure equivalent to 700 µg/day for a 70 kg adult, or within 6 months to 3 years at exposures equivalent to 2,800 µg/day for a 70 kg adult (pg. 131 NRC, 1999). They include alterations in pigmentation and the development of keratoses which are localized primarily on the palms of the hands, the soles of the feet and the torso. The presence of hyperpigmentation and keratoses on parts of the body not exposed to the sun is characteristic of arsenic exposure (Yeh, 1973, Tseng, 1977). The same alterations have been reported in patients treated with Fowler's solution (1% potassium arsenite; Cuzick *et al.*, 1982), used for asthma, psoriasis, rheumatic fever, leukemia, fever, pain, and as a tonic (WHO 1981 and NRC 1999).

Chronic exposure to inorganic arsenic is often associated with alterations in gastroenterological (GI) function. For example, noncirrhotic hypertension is a relatively specific, but not commonly found manifestation in inorganic arsenic-exposed individuals and may not become a clinical observation until the patient demonstrates GI bleeding (Morris *et al.*, 1974; Nevens *et al.*, 1990). Physical examination may reveal spleen and liver enlargement, and histopathological examination of tissue specimens may demonstrate periportal fibrosis (Morris *et al.*, 1974; Nevens *et al.*, 1990; Guha Mazumder *et al.*, 1997). There have been a few reports of

cirrhosis after inorganic arsenic exposure, but the authors of these studies did not determine the subjects' alcohol consumption (NRC 1999).

Development of peripheral vascular disease (hardening of the arteries to the arms and legs, that can cause pain, numbness, tingling, infection, gangrene, and clots) after inorganic arsenic exposure has also been reported. In Taiwan, blackfoot disease (BFD, a severe peripheral vascular insufficiency which may result in gangrene of the feet and other extremities) has been the most severe manifestation of this effect. Tseng (1977) reported over 1,000 cases of BFD in the arsenic study areas of Taiwan. Less severe cases of peripheral vascular disease have been described in Chile (Zaldivar *et al.*, 1974) and Mexico (Cebrian, 1987). In a Utah study, increased SMRs for hypertensive heart disease were noted in both males and females after exposure to inorganic arsenic-contaminated drinking water (Lewis *et al.*, 1999). These reports link exposure to inorganic arsenic effects on the cardiovascular system.

Studies in Taiwan (Lai *et al.*, 1994) and Bangladesh (Rahman *et al.*, 1998) found an increased risk of diabetes among people consuming arsenic-contaminated water. Two Swedish studies found an increased risk of mortality from diabetes among those occupationally exposed to arsenic (Rahman and Axelson, 1995; Rahman *et al.*, 1998).

Although peripheral neuropathy (numbness, muscle weakness, tremors, ATSDR 1998) may be present after exposure to short-term, high doses of inorganic arsenic (Buchanan, 1962; Tay and Seah, 1975), there are no studies that definitely document this effect after exposure to levels of less than levels (<50 µg/L) of inorganic arsenic in drinking water. Hindmarsh *et al.* (1977) and Southwick *et al.* (1983) have reported limited evidence of peripheral neuropathy in Canada and the U.S., respectively, but it was not reported in studies from Taiwan, Argentina or Chile (Hotta, 1989, as cited by NRC 1999).

There have been a few, scattered reports in the literature that inorganic arsenic can affect reproduction and development in humans (Borzysonyi *et al.*, 1992; Desi *et al.*, 1992; Tabacova *et al.*, 1994). After reviewing the available literature on arsenic and reproductive effects, the National Research Council panel (NRC 1999) wrote that "nothing conclusive can be stated from these studies."

Based on the studies mentioned in this section, it is evident that inorganic arsenic contamination of drinking water can cause dermal and internal cancers,

affect the GI system, alter cardiovascular function, and increase risk of diabetes, based on studies of people exposed to drinking water well above the current arsenic MCL. EPA's MCL is chosen to be protective of the general population within an acceptable risk range, not at levels at which adverse health effects are routinely seen (see section III.F.7. on risk considerations).

#### E. What Are the Recent Developments in Health Effects Research?

##### 1. Funding of Health Effects Research

As mentioned earlier in section II.A., Congress recognized that we needed more research to determine the health effects at low levels of arsenic (below the observed health effects and below 50 µg/L). On December 6, 1996, EPA issued a **Federal Register** notice (61 FR 64739; US EPA, 1996e) asking for public comment on four arsenic health research topics to fund research projects with \$2 million from EPA appropriations and \$1 million in funds raised by water industry groups (US EPA, 1996d). In addition, the Office of Research and Development's (ORD's) Board of Scientific Counselors (BOSC) peer reviewed the draft research topics and the arsenic research plan. In the fall of 1997, EPA and the industry partners funded their respective choices for arsenic research, after having the applications peer reviewed. EPA issued three grants for the following research: Dose Response of Skin Keratoses and Hyper-Pigmentation, Arsenic Glutathione Interactions and Skin Cancer, and Cellular Redox Status. The water industry groups awarded two contracts, studying Contribution of Arsenic From Dietary Sources and Tumor Studies in Mice.

##### 2. Expert Panel on Arsenic Carcinogenicity

As part of the Integrated Risk Information System (IRIS) update effort, EPA sponsored an "Expert Panel on Arsenic Carcinogenicity: Review and Workshop" in May 1997 (US EPA, 1997d). The panel evaluated existing data to comment on arsenic's carcinogenic mode of action and the effect on dose-response extrapolations. The panel noted that arsenic compounds have not formed DNA adducts (*i.e.*, bound to DNA) nor caused point mutations. Trivalent inorganic forms inhibit enzymes, but arsenite and arsenate do not affect DNA replication. The panel discussed several modes of action, concluding that arsenic indirectly affects DNA, inducing chromosomal changes. The panel thought that arsenic-induced

chromosomal abnormalities could possibly come from errors in DNA repair and replication that affect gene expression; that arsenic may increase DNA hypermethylation and oxidative stress; that arsenic may affect cell proliferation (cell death appears to be nonlinear); and that arsenic may act as a co-carcinogen. Arsenite causes cell transformation but not mutation of cells in culture. It also induces gene amplification (multiple copies of DNA sequences) in a way which suggests interference with DNA repair or cell control instead of direct DNA damage. The panel noted that all identified modes of action support a nonlinear dose-response curve, that few data supports any one mode as most important, and that more than one mode of action may be operating. At low doses the slope of the dose response would decrease, and at very low doses "might effectively be linear but with a very shallow slope, probably indistinguishable from a threshold."

In terms of implications for the risk assessment, the panel noted that risk per unit dose estimates from human studies can be biased either way. For the Taiwanese study, the " \* \* \* biases associated with the use of average doses and with the attribution of all increased risk to arsenic would both lead to an overestimation of risk (US EPA, 1997d, page 31)." While health effects are most likely observed in people getting high doses, the effects are assigned to the average dose of the exposure group. Thus, risk per unit dose estimated from the average doses would lead to an overestimation of risk (US EPA, 1997d, page 31).

### 3. NAS Review of EPA's Risk Assessment

In 1997, at EPA's request, the National Academy of Sciences' (NAS) Subcommittee on Arsenic of the Committee on Toxicology of the National Research Council (NRC) met. Their charge was to review EPA's assessments of arsenic. The NAS/NRC Subcommittee finished their work in March 1999 (The report can be viewed from the National Academy Press website: [www.nap.edu/books/0309063337/html/index.html](http://www.nap.edu/books/0309063337/html/index.html)). The detailed discussion of their work is in section III.F. In general, the NRC report confirms and extends concerns about human carcinogenicity of drinking water containing arsenic and offers perspective on dose-response issues and needed research. For the decisions in this regulation, the EPA has relied upon the NRC report as presenting the best available, peer reviewed science as of its completion and has augmented it with

more recently published, peer reviewed information. Further work on the risk assessment will also be done before the final rule is issued to analyze the risks of internal cancers. The NRC provided risk numbers for bladder cancer using the Agency's approach. The NRC report noted that "some studies have shown that excess lung cancer deaths attributed to arsenic are 2-5 fold greater than the excess bladder cancer deaths. \* \* \* (NRC, 1999, pg. 8)." The NRC recommended that EPA analyze risks of internal cancers both separately and combined. Peer-reviewed quantitative analysis of lung tumor risk is expected to be available for consideration in the final rulemaking. Meanwhile, this proposal, in a "what if" analysis (discussed in section X.B), estimates the potential monetary benefits that would result if the lung cancer and bladder cancer risks were the same, which would be the case if the excess lung cancer deaths actually were 2- to 5-fold greater than the excess bladder cancer deaths.

### 4. May 1999 Utah Mortality Study

EPA scientists conducted an epidemiological study of 4,058 Mormons exposed to arsenic in drinking water in seven communities in Millard County, Utah (Lewis *et al.*, 1999). The 151 samples from their public and private drinking water sources had arsenic concentrations ranging from 4 to 620 µg/L with seven mean (arithmetic average) community exposure concentrations of 18 to 191 µg/L and all seven community exposure medians (mid-point of arsenic values) <200 µg/L. Observed causes of death in the study group (numbering 2,203) were compared to those expected from the same causes based upon death rates for the general white male and female population of Utah. Several factors suggest that the study population may not be representative of the rest of the United States. The Mormon church, the predominant religion in Utah, prohibits smoking and consumption of alcohol and caffeine. Utah had the lowest statewide smoking rates in the U.S. from 1984 to 1996, ranging from 13 to 17%. Mormon men had about half the cancers related to smoking (mouth, larynx, lung, esophagus, and bladder cancers) as the U.S. male population from 1971 to 1985 (Lyon *et al.*, 1994). The Utah study population was relatively small (~4,000 persons) and primarily English, Scottish, and Scandinavian in ethnic background.

While the study population males had a significantly higher risk of prostate cancer mortality, females had no significant excess risk of cancer

mortality at any site. Millard County subjects had higher mortality from kidney cancer, but this was not statistically significant. Both males and females in the study group had less risk of bladder, digestive system and lung cancer mortality than the general Utah population. The Mormon females had lower death rates from breast and female genital cancers than the State rate. These decreased death rates were not statistically significant.

Although deaths due to hypertensive heart disease were roughly twice as high as expected in both sexes, increases in death did not relate to increases in dose, calculated as the years of exposure times the median arsenic concentration. The Utah data indicate that heart disease should be considered in the evaluation of potential benefits of U.S. regulation. Vascular effects have also been reported as an effect of arsenic exposure in studies in the U.S. (Engel *et al.* 1994), Taiwan (Wu *et al.*, 1989) and Chile (Borgono *et al.*, 1977). The overall evidence indicating an association of various vascular diseases with arsenic exposure supports consideration of this endpoint in evaluation of potential noncancer health benefits of arsenic exposure reduction.

### 5. 1999 Review of Health Effects

Tsai *et al.* (1999) estimated standardized mortality ratios (SMR's) for 23 cancer and non-cancer causes of death in women and 27 causes of death in men in an area of Taiwan with elevated arsenic exposures (Tsai, *et al.*, 1999). The SMRs in this study are an expression of the ratio between deaths that were observed in an area with elevated arsenic levels and those that were expected to occur, compared to both the mortality of populations in nearby areas without elevated arsenic levels and to the national population. Drinking water (250-1,140 µg/L) and soil (5.3-11.2 mg/kg) in the Tsai (1999) population study had high arsenic content. There are, of course, possible differences between the population and health care in Taiwan and the United States; and arsenic levels in the U.S. are not generally as high as they were in the study area of Taiwan. However, the study gives an indication of the types of health effects that may be associated with arsenic exposure via drinking water. The study reports a high mortality rate (SMR > 3) for both sexes from bladder, kidney, skin, lung, and nasal cavity cancers and for vascular disease. Females also had high mortalities for laryngeal cancer.

The SMRs calculated by Tsai (1999) used the single cause of death noted on the death certificates. Many chronic

diseases, including some cancers, are not generally fatal. Consequently, the impact indicated by the SMR in this study may underestimate the total impact of these diseases. The causes of death reported in this study are consistent with what is known about the adverse effects of arsenic. Tsai *et al.* (1999) identified "bronchitis, liver cirrhosis, nephropathy, intestinal cancer, rectal cancer, laryngeal cancer, and cerebrovascular disease" as possibly "related to chronic arsenic exposure via drinking water," which had not been reported before. In addition, people in the study area were observed to have nasal cavity and larynx cancers not caused by occupational exposure to inhaled arsenic.

#### 6. Study of Bladder and Kidney Cancer in Finland

Kurtio *et al.* (1999) conducted a case-cohort design study of 61 bladder and 49 kidney cancer cases and 275 controls to evaluate the risk of these diseases with respect to arsenic drinking water concentrations. In this study the median exposure was 0.1 µg/L, the maximum reported was 64 µg/L, and 1% of the exposure was greater than 10 µg/L. The authors reported that very low concentrations of arsenic in drinking water were significantly associated with being a case of bladder cancer when exposure occurred 2–9 years prior to diagnosis. Arsenic exposure occurring greater than 10 years prior to diagnosis was not associated with bladder cancer risk. Arsenic was not associated with kidney cancer risk even after consideration of a latency period.

#### F. What Did the National Academy of Sciences/National Research Council Report?

##### 1. The National Research Council and Its Charge

Due to controversy surrounding the risk assessment of inorganic arsenic, EPA asked the National Research Council (NRC) to do the following: (1) Review EPA's characterization of potential human health risks from ingestion of inorganic arsenic in drinking water; (2) review the available data on the carcinogenic and noncarcinogenic effects of inorganic arsenic; (3) review the data on the metabolism, kinetics and mechanism(s)/mode(s) of action of inorganic arsenic; and (4) identify research needs to fill data gaps. To accomplish this task, NRC convened a panel of scientific experts with backgrounds in chemistry, toxicology, genetics, epidemiology, nutrition, medicine, statistics and risk assessment. In addition to the general

expertise of the panel members, many had conducted research on inorganic arsenic. NRC identified the thirteen scientists with "diverse perspectives and technical expertise" that peer reviewed the draft report. The report noted that "EPA did not request, nor did the subcommittee endeavor to provide, a formal risk assessment for arsenic in drinking water (NRC, 1999)."

##### 2. Exposure

Arsenic is naturally occurring and ubiquitously distributed in the earth's surface. Because of this, the general population is exposed to low levels of arsenic through the food supply. The NRC report provides FDA market basket data for inorganic arsenic intake by age group which, along with similar data for water intake, will permit communication of total exposure estimates of the general population by age group. The assumption is made in the FDA data that, for fish and seafood, inorganic arsenic is 10% of total arsenic. This 10% assumption is acknowledged to be conservative and has been adopted for public health protection so as not to underestimate the contribution from fish and seafood. Likewise, the 2 L/day assumption of adult drinking water intake does not represent intake by the average person; rather it represents intake of a person in the 90th percentile.

##### 3. Essentiality

The NRC report examined the question of essentiality of arsenic in the human diet. It found no information on essentiality in humans and only data in experimental animals suggesting growth promotion (arsenicals are fed to livestock for this reason). Inorganic arsenic has not been found to be essential for human well-being or involved in any required biochemical pathway. Given this and the fact that arsenic occurs naturally in food, consideration of essentiality is not necessary for public health decisions about water.

##### 4. Metabolism and Disposition

Data from humans show that inorganic arsenic is readily absorbed and transported through the body. It has a half-life in the body of approximately four days and is primarily excreted in the urine. If a human is exposed to the inorganic arsenate form (+5 valence), the arsenite will be reduced to arsenite (+3). Some of the arsenite will be sequentially methylated to form monomethylarsonic acid (MMA) and dimethylarsinic acid (DMA). This methylation process decreases acute toxicity and facilitates excretion from the body. Individuals and populations

vary in their metabolism of arsenic. Such variations may be due to genetic differences, species and dose of inorganic arsenic ingested, nutrition, disease and possibly other factors. Whether these methylated products (MMA and DMA) play a role in the development of cancer and noncancer endpoints is unknown at the present time (NRC, 1999). The NRC report recommended that experiments be conducted on the factors affecting interspecies differences in inorganic arsenic toxicity including use of human tissue when available.

##### 5. Human Health Effects and Variations in Sensitivity

The NRC panel concluded that there is sufficient evidence that chronic ingestion of inorganic arsenic causes bladder, lung and skin cancers and adverse noncancer effects on the cardiovascular systems, mainly from studies exposed to "several hundred micrograms per liter. Few data address the degree of cancer risk at lower concentrations of ingested arsenic (NRC, 1999, pg. 130)." The Utah study (Lewis *et al.*, 1999), published after the NRC report, indicates that cardiovascular effects can occur at lower exposures than those seen in the studies available for the NRC report. At the present time, the NRC report indicates that there is insufficient evidence to judge whether inorganic arsenic can affect reproduction or development in humans. However, inorganic arsenic can pass through the placenta (Concha *et al.*, 1998), and developmental toxicity needs investigation. In animal studies, intraperitoneal (injection into the abdominal cavity) administration of inorganic arsenic can cause malformations, and oral dosing has been reported to alter fetal growth and viability. The NRC report recommended additional studies to characterize the dose-response curve for inorganic arsenic-induced cancer and noncancer health endpoints. They also stated that the reported beneficial effects of inorganic arsenic in animals should be carefully monitored. In addition, the potential effects of inorganic arsenic on human reproduction should be investigated.

There are many factors (genetics, diet, metabolism, health and sex) that may affect a human's response to inorganic arsenic exposure. For example, reduction in methylation of inorganic arsenic methylation can cause humans to retain more arsenic in their tissues. The retention of a greater arsenic load could place a person at a greater risk. The NRC report (1999) recommended that various factors that have the ability

to alter a human's response to inorganic arsenic exposure be carefully examined. Specifically, these studies should focus on the extent of human variability with respect to metabolism, tissue deposition and excretion under different environmental conditions.

Humans are variable in their metabolic processing of inorganic arsenic, and internal dose will vary from person to person because of this as well as because of diet, nutritional status, lifestyle, and health status. Human variability also exists in response characteristics (susceptibility). The full quantitative extent of this variability is not known. For instance, men are more susceptible than women to bladder cancer throughout the world even though bladder cancer rates vary from region to region. We do not know whether arsenic may have a greater effect at different ages (e.g., infants v.s. adults).

#### 6. Modes of Action

Knowledge of a "mode of action" means that data are available to describe the key events at the cellular and/or subcellular level that lead to the development of the cancer or noncancer endpoint. A number of potential modes of carcinogenic action have been proposed for arsenic, with varying degrees of supporting data. The key events in the cancer process caused by arsenic exposure are not known. Nevertheless, the data are sufficient to support the conclusion of the NRC report and the EPA 1997 expert panel workshop report that: "Arsenic exposure induces chromosomal abnormalities without direct reaction with DNA (US EPA, 1997d)."

There is strong evidence against a mode of action for inorganic arsenic involving direct reaction with DNA. One of the hallmarks of direct DNA reactivity is multi-species carcinogenic activity. For arsenic, long-term bioassays for carcinogenic activity in rats, mice, dogs, and monkeys have been uniformly negative (Furst, 1983). The kinds of genetic alterations seen in both *in vivo* and *in vitro* studies of arsenic effects are at the level of loss and rearrangement of chromosomes; these are results of errors of "cellular housekeeping" either in DNA repair or in chromosome replication. The NRC and EPA expert panel (US EPA, 1997d) reports examined several lines of evidence for various modes of action that might be operative. These included changes in DNA methylation patterns that could change gene expression and repair, oxidative stress, potentiation of effects of mutations caused by other agents, cell proliferative effects, and

interference with normal DNA repair processes. Further examination in both of these reports of dose-response shapes associated with these effects led to the conclusion that they involve processes that have either thresholds of dose at which there would be no response or sublinearity of the dose response relationship (response decreasing disproportionately as dose decreases).

The NRC report concluded: "For arsenic carcinogenicity, the mode of action has not been established, but the several modes of action that are considered plausible (namely, indirect mechanisms of mutagenicity) would lead to a sublinear dose-response curve at some point below the point at which a significant increase in tumors is observed. \* \* \* However, because a specific mode (or modes) of action has not yet been identified, it is prudent not to rule out the possibility of a linear response."

The NRC report noted that in certain *in vitro* studies of human and animal cells, genotoxic effects have been shown to occur at submicromolar concentrations of arsenite that are similar to concentrations found in urine of humans ingesting water at the current MCL. This emphasizes the potentially low margin of exposure (health effects observed at concentrations eight times above the MCL) for arsenic in water at the current MCL.

For noncancer effects, inhibition of cellular respiration in mitochondria by arsenic may be the focal point of its toxicity. In addition, inorganic arsenic causes oxidative stress that could play a role in the development of adverse health effects. The NRC report (1999) recommended that biomarkers of inorganic arsenic exposure and cancer appearance be thoroughly studied. Such data might better characterize the dose-response effects of inorganic arsenic at lower exposure levels. For noncancer effects, a greater understanding of arsenic's effects on cellular respiration and subsequent effects of methylation and oxidative stress are needed (NRC, 1999).

NRC recommended several mode of action studies, using biomarkers, to help predict the shape of the dose-response curve for cancer and non-cancer endpoints. NRC concluded that " \* \* \* Additional epidemiological evaluations are needed to characterize the dose-response relationship for arsenic-associated cancer and non-cancer endpoints, especially at low doses."

#### 7. Risk Considerations

The NRC study used the results of epidemiological, (i.e., human) studies;

research on the mode of action, and information about factors affecting sensitivity to arsenic to project to risks to the U.S. population. The numerical estimation of risk in the NRC report has several features to consider. The range of drinking water levels associated with health endpoints in the available studies is generally hundreds of ppb which is, however, within a factor of 10 of the existing standard of 50 ppb. Because of uncertainty about the shape of the dose-response relationship below this range of observed responses, the NRC report used the approach of the 1996 EPA proposed carcinogen risk assessment guidelines (US EPA, 1996b). For the male bladder cancer deaths which were emphasized in the report, NRC used a lower limit on the dose associated with a 1% (1 in 100) cancer response, and the  $LED_{01}$  is estimated to be ~400 ppb. This is a point of departure for extrapolating to exposure levels outside the range of observed data based on inference. Consistent with the proposed revisions to the Guidelines for Cancer Risk Assessment, the report shows both a linear extrapolation and a margin of exposure extrapolation (difference between the point of departure and selected exposure). Because current data on potential modes of action are supportive of sub-linear extrapolations, the linear approach could overestimate risk at low doses. However, EPA believes that within the several-fold range (10x) just below the point of departure, this should make little difference. EPA's scientists note that it makes an increasing difference as dose decreases, and the difference results in an overestimate of risk at lower exposures. With a straight-line extrapolation from the point of departure, the report estimated risk to be  $1.0$  to  $1.5 \times 10^{-3}$  at the current MCL of 50 ppb and the margin of exposure to be less than 8.

As described further in section X.A., EPA used parts of NRC's risk analysis and applied U.S. water consumption, weights, and estimate of population exposed to arsenic to model the U.S. population risk. In selecting the proposed MCL, EPA considered the uncertainties of the quantitative dose-response assessment for inorganic arsenic's health effects, particularly the possible nonlinearity of the dose-response and multiple cancer risks. Given the current outstanding questions about human risk at low levels of exposure, decisions about safe levels are public health policy judgments.

#### 8. Risk Characterization

In 1983 the National Academy of Sciences (NAS, 1983) defined risk

assessment as containing four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Risk characterization is the process of estimating the health effects based on evaluating the available research, extrapolating to estimate health effects at exposure levels, and characterizing uncertainties. In risk management, regulatory agencies such as EPA evaluate alternatives and select the regulatory action. Risk management considers "political, social, economic, and engineering information" using value judgments to consider "the acceptability of risk and the reasonableness of the costs of control (NAS, 1983)."

Unlike most chemicals, there is a large data base on the effects of arsenic on humans. Inorganic arsenic is a human poison, and oral or inhalation exposure to the chemical can induce many adverse health conditions in humans. Specifically oral exposure to inorganic arsenic in drinking water has been reported to cause many different human illnesses, including cancer and noncancer effects, as described in Section III. The NRC panel (1999) reviewed the inorganic arsenic health effects data base. The panel members concluded that the studies from Taiwan provided the current best available data for the risk assessment of inorganic arsenic-induced cancer. (There are corroborating studies from Argentina and Chile.) They obtained more detailed Taiwanese internal cancer data and modeled the data using the multistage Weibull model and a Poisson regression model. Three Poisson data analyses showed a 1% response level of male bladder cancer at approximately 400  $\mu\text{g}$  of inorganic arsenic/L. The 1% level was used as a Point of Departure (POD) for extrapolating to exposure levels outside the range of observed data.

For an agent that is either acting by reacting directly with DNA or whose mode of action has not been sufficiently characterized, EPA's public health policy is to assume that dose and response will be proportionate as dose decreases (linearity of the extrapolated dose-response curve). This is a science policy approach to provide a public health conservative assessment of risk. The dose-response relationship is extrapolated by taking a straight line from the POD rather than by attempting to extend the model used for the observed range. This approach was adopted by the NRC report which additionally noted that using this approach for arsenic data provides results with alternative models that are consistent at doses below the observed

range whereas extending the alternative models below the observed range gives inconsistent results. Drawing a straight line from the POD to zero gives a risk of 1 to 1.5 per 1,000 at the current MCL of 50  $\mu\text{g}/\text{L}$ . Since some studies show that lung cancer deaths may be 2- to 5-fold higher than bladder cancer deaths, the combined cancer risk could be even greater. The NRC panel also noted that the MCL of 50  $\mu\text{g}/\text{L}$  is less than 10-fold lower than the 1% response level for male bladder cancer. Based on its review, the consensus opinion of the NRC panel was that the current MCL of 50  $\mu\text{g}/\text{L}$  does not meet the EPA's goal of public-health protection. Their report recommended that EPA lower the MCL as soon as possible.

#### IV. Setting the MCLG

##### A. How Did EPA Approach It?

For the decisions in this regulation, the EPA has relied upon the NRC report as presenting the best available, peer reviewed science as of its completion and has augmented it with more recently published, peer reviewed information. EPA used the 1999 NRC report and other published scientific papers to characterize the potential health hazards of ingested inorganic arsenic. As NRC (1999) noted, DMA may enhance the carcinogenicity of other chemicals, but more data are needed. Based on current knowledge, the organic forms of arsenic in fish and shellfish do not appear to present a significant risk to humans. The overall weight of evidence indicates that the inorganic arsenate and arsenite forms found in drinking water are responsible for the adverse health effects of ingested arsenic. EPA focused its risk assessment on the carcinogenic effects of inorganic arsenic (the forms found in drinking water sources).

A factor that could modify the degree of individual response to inorganic arsenic is its metabolism. There is ample evidence (NRC, 1999) that the quantitative patterns of inorganic arsenic methylation vary considerably and that the extent of this variation is unknown. It is certainly possible that the metabolic patterns of people affect their response to inorganic arsenic.

There are studies underway in humans and experimental animals under the EPA research plan and other sponsorships. Over the next several years these will provide better understanding of the mode(s) of carcinogenic action of arsenic, metabolic processes that are important to its toxicity, human variability in metabolic processes, and the specific contributions of various food and other

sources to arsenic exposure in the U.S. These are important issues in projecting risk from the observed data range in the epidemiologic studies to lower environmental exposures experienced from U.S. drinking water.

Until further research is completed, questions will remain regarding the dose-response relationship at low environmental levels. The several Taiwan studies have strengths in their long-term observation of exposed persons and coverage of very large populations (>40,000 persons). Additionally, the collection of pathology data was unusually thorough. Moreover, the populations were quite homogeneous in terms of lifestyle. Limitations in exposure information exist that are not unusual in such studies. In ecological epidemiology studies of this kind, the exposure of individuals is difficult to measure because their exposure from water and food is not known. This results in uncertainties in defining a dose-response relationship. The studies in Chile and Argentina are more limited in extent, (e.g., years of coverage, number of persons, or number of arsenic exposure categories analyzed), but provide important findings which corroborate one another and those of the Taiwan studies.

These epidemiological studies provide the basis for assessing potential risk from lower concentrations of inorganic arsenic in drinking water, without having to adjust for cross-species toxicity interpretation. Ordinarily, the characteristics of human carcinogens can be explored and experimentally defined in test animals. Dose-response can be measured, and animal studies may identify internal transport, metabolism, elimination, and subcellular events that explain the carcinogenic process. Arsenic presents unique problems for quantitative risk assessment because there is no test animal species in which to study its carcinogenicity. While such studies have been undertaken, it appears that test animals, unlike humans, do not respond to inorganic arsenic exposure by developing cancer. Their metabolism of inorganic arsenic is also quantitatively different than humans. Inorganic arsenic does not react directly with DNA. If it did, it would be expected to cause similar effects across species and to cause response in a proportionate relationship to dose. Moreover, its metabolism, internal disposition, and excretion are different and vary across animal and plant species and humans—in test studies and in nature.

Until more is known, EPA will take a traditional, public health conservative approach to considering the potential risks of drinking water containing inorganic arsenic. EPA recognizes that the traditional approach may overestimate risk, as explained in the next section.

#### B. What Is the MCLG?

EPA concludes that exposure to inorganic arsenic induces cancer in humans. It also is associated with adverse noncancer effects such as hypertension (NRC, 1999). The NRC report stated that "Data on the modes of action for carcinogenicity can help to predict the shape of cancer dose-response curves below the level of direct observation of tumors. \* \* \* For arsenic carcinogenicity \* \* \* modes of action that are considered most plausible (namely, indirect mechanisms of mutagenicity) lead to a sublinear dose-response at some point below the level at which a significant increase in tumors is observed. However, because a specific mode (or modes) of action has not been identified at this time, it is prudent not to rule out the possibility of a linear response (NRC 1999, pgs. 213–214)." The expert panel report (US EPA, 1997d, pg. 31) stated: "\* \* \* for each of the modes of action regarded as plausible, the dose-response would either show a threshold or would be nonlinear. \* \* \* [H]owever, "the dose response for arsenic at low doses would likely be truly nonlinear—*i.e.*, with a decreasing slope as the dose decreased. However, at very low doses such a curve might effectively be linear but with a very shallow slope, probably indistinguishable from a threshold." In the absence of a known mode of action(s), EPA has no basis for determining the shape of a sublinear dose-response curve for inorganic arsenic. As a result, consistent with EPA public health policy, EPA will continue to use a linear dose-response curve for inorganic arsenic effects. Using a linear type of a dose-response curve, EPA is proposing an MCLG of zero. The Agency welcomes comments on setting a nonzero MCLG and submission of data supporting a nonzero MCLG.

#### C. How Will a Health Advisory Protect Potentially Sensitive Subpopulations?

The NRC report was inconclusive about the health risks to pregnant woman, developing fetus, infants, lactating women, and children. When the Agency completes this rulemaking, it intends to issue a health advisory on arsenic in drinking water, in order to decrease risk to sensitive subpopulations prior to the

implementation of the new MCL. The effective date of a revised MCL will be three to five years after the final rule is issued (2004–2006).

A health advisory is a non-regulatory document that supports water providers in their independent decisions on actions to take regarding water contaminants and their communication with the general public. In the health advisory on arsenic the Agency intends to address a precautionary step to protect infants. This step would be to avoid using water containing high levels of arsenic to make up infant formula. The reason for this precaution is that epidemiologic studies indicate that arsenic in drinking water (Lewis *et al.*, 1999) affects the cardiovascular system. While there are no studies of effects of arsenic on human infants, both the cardiovascular system and brain (and its vascular system) continue to develop after birth (Thompson, P.M *et al.* 2000); thus, the effects discussed in this notice on the cardiovascular system raise a concern about potential effects of arsenic on infant development. In large part, causes of cerebrovascular incidents (stroke) in children are not understood except for certain, known associations with organic diseases and genetic diseases. Congenital and acquired heart disease are the most common cause of stroke in children. The current toxicity data on arsenic do not contradict this precautionary view.

#### D. How Will the Clean Water Act Criterion Be Affected by This Regulation?

EPA is also working to harmonize the human health arsenic criteria for the Clean Water Act (CWA) and the SDWA. The major reason for the present difference (discussed in section II.D.) between the MCL and the Ambient Water Quality Criterion (AWQC) was the result of using separate bases for determining the two standards. The AWQC for arsenic was derived from the risk assessment for arsenic-induced skin cancer, while the current SDWA MCL, adopted in 1975 as a National Interim Primary Drinking Water Regulation, evolved from the U.S. Public Health Service standard dating back to the 1940s. The Agency will use the conclusions of the NRC (1999) report to form the human health basis for both the AWQC and the MCL. However, the CWA and SDWA statutes require that the Agency consider different factors during the derivation of a standard. For example, SDWA requires that the Agency consider: (1) Cost/benefit analyses, including sizes of the public water systems, (2) the level of arsenic that can be analyzed by laboratories on

a routine basis, [*i.e.*, the practical quantitation limit (PQL)] and (3) treatment techniques for removing the chemical from the water. On the other hand, the CWA requires the EPA to consider water and fish consumption (including amount of fish eaten, percent lipid in the fish and the bioaccumulation factor for the chemical in the fish), but not cost/benefits, analytical or treatment techniques. Accordingly, developing an AWQC under the CWA may produce a standard that differs from the MCL derived under the SDWA even though both standards are based on the same health endpoint. The Agency will begin work on a new AWQC for arsenic after promulgating the MCL for arsenic.

#### V. EPA's Estimates of Arsenic Occurrence

One of the key components in the development of the proposed arsenic rule is the analysis of arsenic occurrence in public water supplies, both community water systems (CWS) and non-transient, non-community, water systems (NTNCWS). EPA's national occurrence assessment of arsenic provides a basis for estimating:

- (1) The number of systems expected to exceed various arsenic levels;
  - (2) the number of people exposed to the different levels of arsenic; and
  - (3) the variability in arsenic levels in water systems among the wells and/or entry points to the distribution system.
- EPA uses the estimate of the total number of systems and populations affected in the United States in its cost-benefit analysis. EPA is seeking comment on its analysis of arsenic occurrence in the U.S., as well as requesting additional data.

#### A. What Data Did EPA Evaluate?

For previous occurrence analyses EPA used four older national arsenic databases: (1) The National Inorganic and Radionuclide Survey (NIRS), conducted from 1984 to 1986, for ground water CWSs; (2) a 1976–1977 National Organic Monitoring Survey (NOMS); (3) a 1978–1980 Rural Water Survey (RWS); and (4) the 1978 Community Water System Survey (CWSS) for surface water CWSs. However, these older databases have several limitations. First, the surveys of surface water systems will not reflect changes in raw water sources which occurred in the last twenty years. Second, filtration treatment added to comply with the Surface Water Treatment Rule (110 54 FR 27486, June 29, 1989) would tend to decrease arsenic exposure, through incidental arsenic removal. Finally, most of the

data were censored (reported as less than the analytical test method detection level or reporting limit, *e.g.*, “not detected” or “<5 µg/L”). NIRS, CWSS, and RWS, respectively, had 93%, 97%, and 90% censored data. This limits the estimation of low level occurrence of arsenic and makes it statistically difficult to extrapolate occurrence with the limited amount of non-censored data. The EPA Science Advisory Board recommended that EPA abandon the older data when sufficient new data become available because of

the high percentage of censored data in the older surveys and the difficulty of using highly censored data sets to estimate occurrence (US EPA, 1995). Therefore, with improved analytical techniques for detecting arsenic at lower levels, as low as 0.5 µg/L, and the lower reporting limits in the new data received by EPA, the Agency focused the data evaluation on post-1980 data sources for estimating national occurrence.

Since 1992, EPA OGWDW has received arsenic databases from other EPA offices, States, public water

utilities, and associations. EPA combined the compliance monitoring data obtained from States into the “25 States” database. The Agency evaluated the databases listed in Table V-1. (Note that EPA’s database, the Safe Drinking Water Information System (SDWIS), only records violations of the current arsenic MCL, so it is censored at 50 µg/L.) A more detailed description of the databases and evaluations are presented in the EPA document titled “Arsenic Occurrence in Public Drinking Water Supplies,” (US EPA, 2000b).

TABLE V-1.—SUMMARY OF ARSENIC DATA SOURCES

Data source	Reporting level (µg/L)	Number of CWSs	Source water	Water type
25 States <sup>1</sup> .....	<1 to 10 .....	>19,000 .....	Surface, Ground .....	finished.
Metro <sup>2</sup> .....	1 .....	140 .....	Surface, Ground .....	raw & finished.
NAOS <sup>3</sup> .....	0.5 .....	<517 .....	Surface, Ground .....	raw & predicted finished.
USGS <sup>4</sup> .....	1 .....	not available (20,000 sites).	Ground .....	raw.
ACWA <sup>5</sup> .....	0.1 to 1 .....	180 (1,500 sam- ples).	Surface, Ground .....	finished.
WESTCAS <sup>6</sup> .....	not available .....	not available .....	Ground .....	finished.

<sup>1</sup> Arsenic compliance monitoring data from community water systems (CWSs) from Alabama, Alaska, Arizona, Arkansas, California, Illinois, Indiana, Kentucky, Kansas, Maine, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Texas, and Utah.

<sup>2</sup> Metropolitan Water District of Southern California (MWDSC, or Metro) 1992–1993 national survey of 140 CWSs serving more than 10,000 people.

<sup>3</sup> 1996 National Arsenic Occurrence Survey (NAOS) funded by the Water Industry Technical Action Fund (WITAF), which includes the following organizations: American Water Works Association, National Association of Water Companies, Association of Metropolitan Water Agencies, National Rural Water Association, and National Water Resources Association.

<sup>4</sup> U.S. Geological Survey (USGS) ambient (raw water) ground water from approximately 20,000 wells throughout the U.S. used for various purposes, including public supply, research, agriculture, industry and domestic supply.

<sup>5</sup> 1993 survey from 180 water agencies, utilities, and cities in southern California, conducted by the Association of California Water Agencies (ACWA).

<sup>6</sup> 1997 Western Coalition of Arid States (WESTCAS) Research Committee Arsenic Occurrence Study which aggregated arsenic data (*e.g.*, median arsenic value for county, city, or provider) from Arizona, New Mexico, and Nevada.

*B. What Databases Did EPA Use?*

EPA evaluated the databases for representativeness, accuracy and coverage of community water systems in the U.S. EPA determined that the compliance monitoring data from the 25 States (“25-States database”) would establish the most accurate and scientifically defensible national occurrence and exposure distributions of arsenic in public ground water and surface water supplies. Figure V.1 shows the coverage of these States in the U.S. The 25-States database provides more finished water arsenic data, from over 19,000 ground and surface water CWSs, than the other national databases. EPA is interested in finished water data, rather than raw water data, because it indicates the current arsenic levels in water systems after treatment and reflects their customers’ level of exposure to arsenic. The 25-States database provides system and individual arsenic data for a significant number of CWSs in each State. The arsenic data can be linked directly to

specific water systems by their identification code to obtain additional information in SDWIS, such as population served, system type (*e.g.*, CWS, NTNCWS), source type (*e.g.*, ground water, surface water, purchased water, ground water under the influence), and location. For this reason, EPA chose to use the compliance monitoring data from the States of California, Nevada, New Mexico, and Arizona, rather than the data about these States from ACWA and WESTCAS.

Most of the 25-States data had reporting limits of less than 2 µg/L. In addition, the database includes multiple samples from the water systems over time and from multiple sources within the systems. The multiple samples provide for a more accurate estimate of the arsenic levels in the systems, than a survey with one sample per system. The arsenic compliance monitoring data provides point-of-entry or well data within systems from eight States, which is used for intrasystem variability

analysis (discussed in Section V.G). Intrasystem variability analysis provides an understanding of the variation of arsenic levels within a system, from well to well or entry point to entry point.

EPA also received arsenic data from Florida, Idaho, Iowa, Louisiana, Pennsylvania, and South Dakota; however EPA did not include these States in the database. These States either provided data that (1) could not be linked to CWSs; (2) did not indicate if the results were censored or non-censored; (3) were all zero, without providing the analytical/reporting limit; or (4) rounded results to the nearest ten µg/L.

EPA used the USGS and NAOS databases and their occurrence estimates for comparison purposes. In addition, EPA used the NAOS approach to partitioning of the U.S. for its analysis.

We combined State data sets with different data naming conventions, and the database development and data

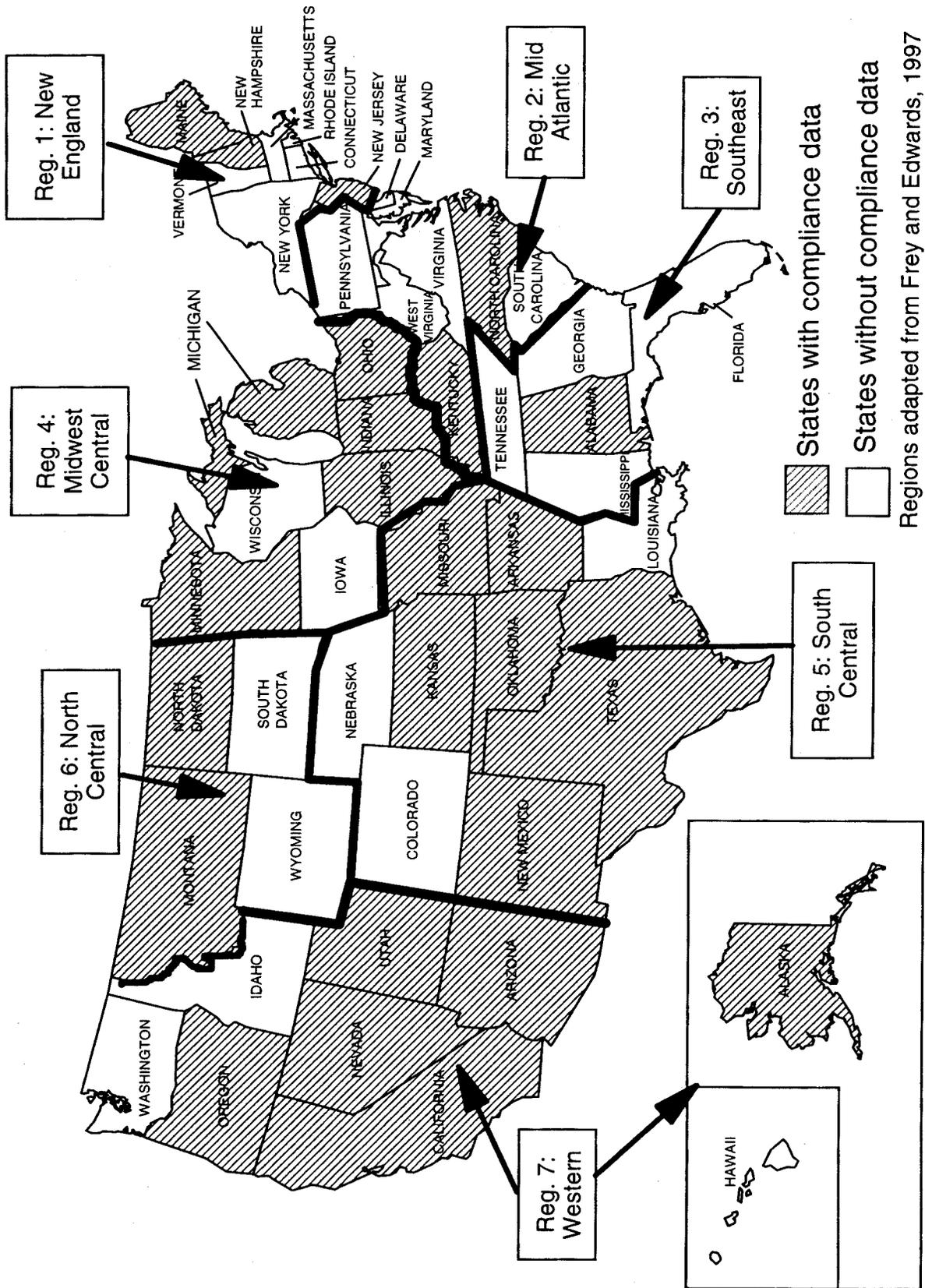
conditioning process is described in Appendix D-3 of the occurrence support document (US EPA, 2000b). Appendix D-1 identifies who provided the data and data provided for each State in the 25-State database. Appendix D-2 lists the data names we used to develop the national database. We assumed that the data represented

compliance sampling, and some States have reportedly provided source water data and compliance data. If you are aware of errors in our data set, please let us know. Also, additional data would reduce the uncertainty of our national occurrence estimate. We encourage commenters to submit arsenic compliance monitoring data sets either

from States not already in our data set, more recent data that were not included in the described data sets, or a more official version of compliance data. We will use this information to obtain a more representative national occurrence estimate for the final rule.

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Figure V-1. States with Arsenic Compliance Data in the 7 Regions



### C. How Did EPA Estimate National Occurrence of Arsenic in Drinking Water?

EPA derived the national estimates of arsenic occurrence in three steps: (1) Estimate system means; (2) estimate State distribution of system means; and (3) estimate national distributions of system means.

As discussed in section V.B, EPA determined that the 25-States database would be used for estimating national occurrence. EPA calculated a system average for each water system in its database. When the database provided 5 or more detected (greater than the reporting limit) arsenic samples in a system, we used the method of "regression on order statistics" (Helsel and Cohn, 1988) to extrapolate values for the non-detected observations, then calculated the arithmetic mean. When there were 1 to 4 detected values, we substituted half the reporting limit for each non-detected value (less than the reporting limit) and calculated an arithmetic average. When there were no detected values (all samples had non-detected values), we set the arsenic system average as a non-detect at the mode (most frequently occurring) of the reporting limits. As a result, each system has a calculated system mean, either a non-detected or detected value.

In order to estimate the distribution of systems means in a State, EPA aggregated the system means into a single distribution and derived separate estimates of percentage of systems with average arsenic values greater than 2, 3, 5, 10, 15, 20, 25, 30, 40, and 50 µg/L (referred to as exceedance estimates). We developed separate estimates for ground water and surface water systems. Within each State, EPA fit a lognormal distribution to the population of estimated system means, and used the fitted distribution to estimate exceedance probabilities. However, when fitting the lognormal distribution, EPA excluded system means which were estimated to be less than their reporting limit, since these require more extrapolation below the reporting limit and were judged to be less reliable. EPA also did not make exceedance estimates below the most frequently occurring reporting limit or censoring point in each of the States.

To estimate the national distribution of system means, EPA grouped the

States into the seven regions developed in the NAOS (Frey and Edwards, 1997). Frey and Edwards derived a natural occurrence factor by weighting detection, number of data points, and higher arsenic values from data in the USGS WATSTORE water quality database and the Metro survey. Then they grouped States into seven regions based on the calculated natural occurrence factors. Figure V.1 is a map of the U.S. with the NAOS regions. With this regional grouping of States, EPA developed separate regional estimates for surface water and ground water systems. In a separate analysis, EPA found the national result from using the NAOS regions to be similar to grouping States into different regions, based on a preliminary examination of generally related exceedance probabilities.

EPA derived each regional estimate by using exceedance estimates from the States with compliance monitoring data in the region, weighted by the number of community water systems in those specific States. For example, we used the exceedance estimates from Montana and North Dakota, weighted by the number of community water systems in those States, to derive the North Central region estimate. Within each region, we estimated the percentages of systems with average arsenic values greater than 2, 3, 5, 10, 15, 20, 25, 30, 40, and 50 µg/L. We then weighted the regional exceedance estimates, by the total number of community water systems in each region (including the number of community water systems in the States without compliance monitoring data) to obtain national estimates of percentages of systems with average arsenic values greater than 2, 3, 5, 10, 15, 20, 25, 30, 40, and 50 µg/L.

EPA believes that separate estimates are not justified for different system sizes. A graphical analysis ("box and whisker" plots) of the occurrence distributions suggests that in some regions, systems in different size categories do have different mean concentrations. However the differences in means are much smaller than the variability of the observed concentrations. Moreover, the differences do not vary with system size in a consistent way. For example, for ground water systems, arsenic concentrations in the New England Region (NAOS Region 1) decrease as

system size increases, while in the Mid-Atlantic and South Central regions (NAOS Regions 2 and 5), arsenic concentrations increase as system size increases. In the four remaining regions, no systematic patterns are evident. For these reasons, and because additional stratification decreases the precision of the estimates, EPA has not developed separate estimates for different system sizes.

The method of substitution that EPA used for non-detected concentrations (described above) is different from the method that water systems use for determining compliance with the MCL: We substituted positive values for non-detects, while for purposes of compliance, non-detected concentrations are treated as zero. Therefore, our estimates of occurrence will be higher on average than those found by water systems monitoring for compliance with the MCL. As a result we might overestimate both the costs and benefits of the proposed MCL. However we believe that our estimate of occurrence is justified, for two reasons. First, it is more accurate (less biased). Second, as the detection limits of analytical methods continue to improve (*i.e.*, lower than 1 µg/L), the difference between the two substitution methods will be small and will occur in the range below the MCL.

### D. What Are the National Occurrence Estimates of Arsenic in Drinking Water for Community Water Systems?

Arsenic is found in both ground water and surface water sources. Figure V.1 presents the regions of the United States referred to in this discussion. Table V-2 data indicate that higher levels of arsenic tend to be found in ground water sources (*e.g.*, aquifers) than in surface water sources (*e.g.*, lakes, rivers). The 25-States finished water data also indicate that the North Central, Midwest Central, and New England regions of the United States tend to have low to moderate (2–10 µg/L) ground water arsenic levels, while the Western region tends to have higher levels of ground water arsenic (>10 µg/L) than the other regions. Systems in the other regions of the U.S. may have high levels of arsenic (hot spots), while many systems and portions of the States in the listed regions may not have any detected arsenic in their drinking water.

TABLE V-2.—REGIONAL EXCEEDANCE PROBABILITY DISTRIBUTION ESTIMATES

Region	Percent of systems exceeding arsenic concentrations (µg/L) of:									
	2	3	5	10	15	20	25	30	40	50
<b>Ground Water Systems</b>										
New England .....	29	21	21	7	4	3	2	2	1	0.7
Mid Atlantic .....	.....	.....	*0.3	*1	0.3	0.1	0.06	0.03	0.009	0.003
South East .....	2	1	0.5	0.2	0.1	0.07	0.05	0.04	0.02	.01
Midwest .....	28	21	14	6	4	2	2	1	.8	0.5
South Central .....	27	19	10	4	2	1	0.8	0.5	0.3	0.2
North Central .....	29	21	13	6	4	2	2	1	0.9	0.6
West .....	42	31	25	12	7	5	4	3	2	1
<b>Surface Water Systems</b>										
New England .....	11	*8	*9	1.0	0.6	0.4	0.3	0.3	0.2	0.1
Mid Atlantic .....	.....	.....	*0.1	*0.1	0.01	0.001	0	0	0	0
South East .....	0.8	0.2	0.03	0.001	0	0	0	0	0	0
Midwest .....	4	3	1	0.4	0.2	0.1	0.1	0.07	0.05	0.03
South Central .....	9	4	1	0.3	0.1	0.08	0.05	0.03	0.02	0.01
North Central .....	20	10	4	0.8	0.2	0.1	0.05	0.02	0.008	0.003
West .....	19	13	7	3	2	1	0.8	0.6	0.4	0.3

\*Estimates at these regions and levels are inconsistent, in that the estimated % exceedances at lower values are smaller than the estimates at higher values. This inconsistency occurs because fewer States were used to estimate % exceedances at lower levels. EPA did not attempt to resolve the inconsistency, but combined the regional distribution into a national distribution which is consistent.

The estimates of the number of CWSs expected to exceed different arsenic levels is based on the distribution of average arsenic concentrations in water systems. Using the data from the 25-States database, EPA estimates that 5.4% of ground water CWSs and 0.7% of surface CWSs have average arsenic levels above 10 µg/L. Similarly, 12.1% and 2.9% of ground water CWSs and

surface water CWSs, respectively, have average arsenic levels above 5 µg/L. Tables V-3 and V-4 provide estimates by system size category. The percentage of systems that have average arsenic levels within a specific range does not vary across the system size categories. For example, 2.3% of ground water systems in each of the five system size categories have average arsenic levels in

the range of >10 µg/L to 15 µg/L. Therefore, the arsenic exceedance estimates have the same distribution in any system size. These estimates of percent (or probability) of systems that have average arsenic levels within a specific range are multiplied by the number of systems in each size category to derive the number of systems in Table V-3 and V-4.

TABLE V-3.—STATISTICAL ESTIMATES OF NUMBER OF GROUND WATER CWSS WITH AVERAGE ARSENIC CONCENTRATIONS IN SPECIFIED RANGES

System size (population served)	Number of systems with average arsenic concentrations in specified ranges (µg/L; 43,749 systems total)								
	<2.0	>2.0 to 3.0	>3.0 to 5.0	>5.0 to 10.0	>10.0 to 15.0	>15.0 to 20.0	>20.0 to 30.0	>30.0 to 50.0	>50.0
25 to 500 .....	21,325	2,158	2,268	1,960	674	314	287	188	129
501 to 3,300 .....	7,616	771	810	700	241	112	103	67	46
3,301 to 10,000 .....	1,811	183	193	167	57	27	24	16	11
10,001 to 50,000 .....	933	94	99	86	29	14	13	8	6
>50,000 .....	154	16	16	14	5	2	2	1	1
Total .....	31,840	3,221	3,386	2,927	1,006	468	429	280	192
(% of systems) .....	(72.8%)	(7.4%)	(7.7%)	(6.7%)	(2.3%)	(1.1%)	(1.0%)	(0.6%)	(0.4%)

**Note:** Totals may not add up due to rounding of the number of systems to the nearest whole number. Systems serving fewer than 25 people are not included in this table. The estimates in this table do not take into account most treatment in place; in particular most of the systems in the ">50.0" column will have treated for arsenic in order to reduce their concentration below 50 µg/L. See text for more details.

In Tables V-3 and V-4, the estimated numbers of systems with mean concentrations above 50 µg/L do not represent the number of systems which are believed to be out of compliance with the current MCL of 50 µg/L; nor do they represent actual systems at all. Rather, they are statistical extrapolations above 50 µg/L, based

primarily on data below 50 µg/L. Since most data below 50 µg/L comes from systems which have not treated for arsenic, the ">50.0" columns in Tables V-3 and V-4 do not take into account most treatment currently in place. Therefore, the ">50.0" columns represent the estimated number of systems which would have mean

arsenic concentrations above 50 µg/L if they had not treated for arsenic. By comparison with Tables V-3 and V-4, during the three-year period from September 1994 through August 1997, EPA recorded a total of 14 samples from 10 public water systems in which arsenic concentrations exceeded 50 µg/L.

TABLE V-4.—STATISTICAL ESTIMATES OF NUMBER OF SURFACE WATER CWSs WITH AVERAGE ARSENIC CONCENTRATIONS IN SPECIFIED RANGES

System size (population served)	Number of systems with average arsenic concentrations in specified ranges (µg/L; 10,683 systems total)								
	<2.0	>2.0 to 3.0	>3.0 to 5.0	>5.0 to 10.0	>10.0 to 15.0	>15.0 to 20.0	>20.0 to 30.0	>30.0 to 50.0	>50.0
25 to 500 .....	2,794	122	94	69	11	4	4	2	2
501 to 3,300 .....	3,308	144	111	82	13	5	4	3	2
3,301 to 10,000 .....	1,656	72	56	41	6	3	2	1	1
10,001 to 50,000 .....	1,384	60	47	34	5	2	2	1	1
> 50,000 .....	477	21	16	12	2	1	1	0	0
Total .....	9,622	419	323	239	37	15	13	8	7
(% of systems) .....	(90.1%)	(3.9%)	(3.0%)	(2.2%)	(0.4%)	(0.1%)	(0.1%)	(0.1%)	(0.1%)

**Note:** Totals may not add up due to rounding of the number of systems to the nearest whole number. Systems serving fewer than 25 people are not included in this table. The estimates in this table do not take into account most treatment in place; in particular most of the systems in the ">50.0" column will have treated for arsenic in order to reduce their concentration below 50 µg/L. See text for more details.

*E. How Do EPA's Estimates Compare With Other Recent National Occurrence Estimates?*

In addition to EPA's national occurrence results presented in section V.D., two additional studies recently developed national occurrence estimates for arsenic in drinking water: the NAOS study (Frey and Edwards, 1997), and the USGS study of arsenic occurrence in ground water (USGS, 2000). The databases that supported the NAOS and USGS estimates are briefly described in section V.A., "What data did EPA evaluate?" Each of these occurrence estimates was developed in

a slightly different manner. Whereas EPA's occurrence estimates are based on compliance monitoring data from more than 19,000 CWSs in 25 states, the NAOS occurrence estimates are based on a stratified random sampling from representative groups defined by source type, system size, and geographic location. The NAOS database contains 435 predicted finished water arsenic data points (derived from raw water arsenic concentrations and treatment information), from more than 400 CWSs. The USGS analysis is based on arsenic ambient (untreated, or raw water) ground water data, providing 17,496 samples for 1,528 counties (with 5 or

more data points) in the United States (out of a total of 3,222 counties). USGS derived exceedance estimates for each county by calculating the percentage of data points in each county exceeding specific concentrations, from 1 µg/L to 50 µg/L. Then USGS associated the percentages for each county with the number of CWSs that use ground water in these counties, which was based on data derived from SDWIS. This information was aggregated for all of the appropriate counties to derive the national estimates for ground water CWSs. USGS did not have estimates for surface water CWSs.

TABLE V-5.—COMPARISON OF CWSs FROM EPA, NAOS, AND USGS ESTIMATES EXCEEDING ARSENIC CONCENTRATIONS

% CWS exceeding	EPA GW & SW (percent)	NAOS GW & SW (percent)	EPA GW (percent)	USGS GW (percent)
2 µg/L .....	24.1	21.7	27.2	25.0
5 µg/L .....	10.3	11.5	12.1	13.6
10 µg/L .....	4.5	4.5	5.4	7.6

Table V-5 compares the EPA, NAOS, and USGS estimates of the percent of samples exceeding various arsenic concentrations. At a concentration of 2 µg/L, the EPA national exceedance estimate for both surface water and ground water CWSs (24.1 percent) is higher than the NAOS estimate (21.7 percent). At 5 µg/L, the EPA and NAOS predicted exceedance probabilities are relatively similar (10.3 and 11.5 percent, respectively). These two estimates are the same at 10 µg/L (4.5 percent). For ground water CWSs, the USGS and EPA estimates are also relatively similar. At 2 µg/L, the EPA national ground water exceedance estimate (27.2 percent) is slightly higher than the USGS estimate (25.0 percent). At 5 and 10 µg/L, the USGS exceedance estimates (13.6

percent and 7.6 percent, respectively) are slightly higher than the EPA estimates (12.1 percent and 5.4 percent). This comparison of exceedance probabilities suggests that EPA's arsenic occurrence projections based on compliance monitoring data are relatively close to the NAOS and USGS projections through the range of this comparison. In addition, the USGS estimates are expected to be slightly higher than the EPA estimates for ground water, because they are based on raw water arsenic levels (untreated).

*F. What Are the National Occurrence Estimates of Arsenic in Drinking Water for Non-Transient, Non-Community Water Systems?*

The 25-States database contains data for non-transient, non-community water systems (NTNCWSs) in 15 States (two additional States only provided data from two systems). NTNCWSs are public water systems that regularly serve at least 25 of the same persons more than 6 months a year. Most NTNCWSs serve less than 3,300 people (99.5%) and use ground water (96%).

EPA calculated basic statistics for ground water CWSs and NTNCWSs in each of these States. EPA compared the data and found that arsenic distributions in NTNCWSs are quite

similar to arsenic distributions in CWSs. In general, the means, standard deviations, and level of censoring for CWSs in a particular State are very close to the levels observed in NTNCWSs in that State. In some States, mean levels are slightly higher in CWSs than in NTNCWSs, whereas in others, mean levels are slightly lower in CWSs. There is no clear pattern and the differences are relatively minor, suggesting that any differences are due to random variation, rather than systematic underlying differences between NTNCWSs and CWSs. As a result, the occurrence

distributions for CWSs were used to derive the occurrence distributions for NTNCWS systems. If the NTNCWSs data from the 15 States were used to derive the estimates, there would have been less spatial coverage of United States, which would have resulted in more uncertainty in the estimate. The NTNCWSs estimates are presented in Tables V-6 and V-7.

As in the case of Tables V-3 and V-4, the estimated numbers of systems in Tables V-6 and V-7 with mean concentrations above 50 µg/L do not represent the number of systems which

are believed to be out of compliance with the current MCL of 50 µg/L; nor do they represent actual systems at all. Rather they represent the estimated number of systems which would have mean arsenic concentrations above 50 µg/L if they had not treated for arsenic. By comparison with Tables V-6 and V-7, during the three-year period from September 1994 through August 1997, EPA recorded a total of 14 samples from 10 public water systems in which arsenic concentrations exceeded 50 µg/L.

TABLE V-6.—STATISTICAL ESTIMATES OF NUMBER OF GROUND WATER NTNCWSS WITH AVERAGE ARSENIC CONCENTRATIONS IN SPECIFIED RANGES

System size (population served)	Number of systems with average arsenic concentrations in specified ranges (µg/L; 19,293 systems total)								
	<2.0	>2.0 to 3.0	>3.0 to 5.0	>5.0 to 10.0	>10.0 to 15.0	>15.0 to 20.0	>20.0 to 30.0	>30.0 to 50.0	>50.0
25 to 500 .....	12,088	1,223	1,285	1,111	382	178	163	106	73
501 to 3,300 .....	1,902	192	202	175	60	28	26	17	11
3,301 to 10,000 .....	43	4	5	4	1	1	1	0	0
10,001 to 50,000 .....	8	1	1	1	0	0	0	0	0
> 50,000 .....	0	0	0	0	0	0	0	0	0
Total .....	14,041	1,421	1,493	1,291	444	206	189	123	85
(% of systems) .....	(72.8%)	(7.4%)	(7.7%)	(6.7%)	(2.3%)	(1.1%)	(1.0%)	(0.6%)	(0.4%)

**Note:** Totals may not add up due to rounding of the number of systems to the nearest whole number. Systems serving fewer than 25 people are not included in this table. The estimates in this table do not take into account most treatment in place; in particular most of the systems in the ">50.0" column will have treated for arsenic in order to reduce their concentration below 50 µg/L. See text for more details.

TABLE V-7.—STATISTICAL ESTIMATES OF NUMBER OF SURFACE WATER NTNCWSS WITH AVERAGE ARSENIC CONCENTRATIONS IN SPECIFIED RANGES

System size (population served)	Number of systems with average arsenic concentrations in specified ranges (µg/L; 764 systems total)								
	<2.0	>2.0 to 3.0	>3.0 to 5.0	>5.0 to 10.0	>10.0 to 15.0	>15.0 to 20.0	>20.0 to 30.0	>30.0 to 50.0	>50.0
25 to 500 .....	502	22	17	12	2	1	1	0	0
501 to 3,300 .....	163	7	5	4	1	0	0	0	0
3,301 to 10,000 .....	18	1	1	0	0	0	0	0	0
10,001 to 50,000 .....	4	0	0	0	0	0	0	0	0
50,000 .....	2	0	0	0	0	0	0	0	0
Total .....	688	30	23	17	3	1	1	1	0
(% of systems) .....	(90.1%)	(3.9%)	(3.0%)	(2.2%)	(0.4%)	(0.1%)	(0.1%)	(0.1%)	(0.1%)

**Note:** Totals may not add up due to rounding of the number of systems to the nearest whole number. Systems serving fewer than 25 people are not included in this table. The estimates in this table do not take into account most treatment in place; in particular most of the systems in the ">50.0" column will have treated for arsenic in order to reduce their concentration below 50 µg/L. See text for more details.

*G. How Do Arsenic Levels Vary From Source To Source and Over Time?*

EPA analyzed the variability of arsenic concentrations within a system, from well to well or entry point to entry point (sampling point). This analysis allows EPA to estimate the number of sampling points in a system that may be above the proposed MCL and to improve estimation of the treatment costs for systems with multiple sampling points. The result of the intrasystem analysis is a constant coefficient of variation (CV), which is one of the inputs to the cost-benefit

computer modeling. EPA analyzed six of the eight States that provided intrasystem data: California, Utah, New Mexico, Oklahoma, Illinois and Indiana. Arkansas and Alabama were not analyzed because these States had very little occurrence of arsenic and almost all of the arsenic values were below the detection limit. After statistical analysis of 127 systems with five or more sampling points, EPA derived an arithmetic average CV of 0.64 or 64%. The EPA document titled "Arsenic Occurrence in Public Drinking Water

Supplies," presents this statistical analysis (US EPA, 2000b).

USGS examined its raw water arsenic data to assess the variability of arsenic levels over time and to determine whether there are temporal trends (USGS, 2000). Data came from about 350 wells with 10 or more arsenic analyses collected over different time periods. These wells were used for various purposes, such as public supply, research, agriculture, industry, and domestic supply, and encompassed non-potable and potable water quality. USGS conducted a regression analysis

of arsenic concentration and time for each well and found that most of the wells had little or no change in concentration over time (low “r-squared” values when arsenic concentrations were regressed with time). Arsenic levels for most of the wells probably do not consistently increase or decrease over time. In addition, USGS found that well depth had no relationship to temporal variability. To determine the extent of the temporal variability, EPA analyzed the CVs for the mean arsenic level in the wells. More than 100 wells had a CV and standard deviation of zero. Most of these wells consistently had arsenic concentrations below the detection limit of 1 µg/L. EPA examined the CVs for the other wells in relation to the mean arsenic level and found a relatively constant CV on the lognormal scale. The geometric mean of the CVs, excluding CVs of zero, is 0.39 or 39%. The report (USGS, 2000) listed several factors that may contribute to this variability, including natural variability in geochemistry or source of contamination, sampling technique, and changes in pumping over time.

*H. How Did EPA Evaluate Co-Occurrence?*

Sections 1412(b)(3)(C)(i)(II), (III) and (VI) of the SDWA, as amended in 1996, require EPA to take into account activities under preceding rules which may have impacts on each new successive rule. To fulfill this need EPA began the analysis of the co-occurrence of drinking water contaminants. The information on co-occurrence will be used to determine the level of overlap in regulatory requirements. For example, this will include cases where treatment technologies applied for one regulation may resolve monitoring and/or additional treatment needs for another regulation or where water utilities may incur costs for installing

multiple treatments to address other co-occurring substances. This information may also be used to show where specific levels of one contaminant may interfere with the treatment technology for another.

1. Data

For the co-occurrence analysis, EPA relied on data from the National Water Information System (NWIS), a U.S. Geological Survey (USGS) database. The NWIS database was used for several reasons:

- It contains both ground and surface water data;
- It is national in scope, representing raw water samples from approximately 40,000 observation stations across the U.S.; and
- It provides latitude/longitude coordinates for monitoring stations, which can be used in subsequent analyses to associate with Public Water Supply Systems.

NWIS contains a water quality data storage retrieval system developed by the USGS Water Resources Division. NWIS is a distributed water database; data can be processed over a network of computers at USGS offices throughout the U.S. The system comprises the Automated Data Processing System, the Ground Water Site Inventory System, the Water-Quality System, and the Water-Use Data System. NWIS does not represent Public Water Supply Systems directly but can be associated with them because it provides latitude/longitude coordinates for monitoring stations.

Using the NWIS data, arsenic was analyzed with 18 other constituents. The other constituents included: Sulfate, radon, radium, uranium, nitrate, antimony, barium, beryllium, cadmium, chromium, cyanide, iron, manganese, mercury, nickel, nitrite, selenium, thallium, hardness, and total dissolved solids. An additional set of ancillary parameters were selected for use as indicators of the hydrogeologic and

geochemical conditions that could influence the co-occurrence of specific constituents. These ancillary parameters included: turbidity, conductance, dissolved oxygen, pH, alkalinity, well depth, and depth below land.

2. Results of the Co-occurrence Analysis (US EPA, 1999f)

Dissolved arsenic was observed to have 5442 detected counts and total arsenic was observed to have 1273 detected counts in the database at the minimal threshold level of 2 µg/L. The national co-occurrence estimates derived from the USGS NWIS data revealed several correlations between arsenic/sulfate and arsenic/iron at the threshold levels chosen by EPA as likely to affect treatment (see section VIII.). First, a significant correlation was observed between dissolved arsenic and sulfate in surface water and ground water samples at the national level. The analysis of the surface and ground water data from EPA Regions 1, 2, 4, 5, 6, 7, 8, 9 and 10 show 339 co-occurrence frequency counts of the data above the threshold values of dissolved arsenic >5 µg/L and sulfate >250 mg/L (Table V-8). For total arsenic and sulfate there are 143 co-occurrence frequency counts for the same threshold levels. There was no significant co-occurrence of arsenic and sulfate in EPA Region 3. Secondly, a correlation was observed between dissolved arsenic and iron and total arsenic and iron in surface and ground waters from EPA Regions 1, 2, 4, 5, 7, 8 and 9 (Table V-8). There are 562 co-occurrence frequency counts of the data above the threshold levels of dissolved arsenic >5 µg/L and iron >300 µg/L. There are 542 co-occurrence frequency counts of the data above the threshold values of total arsenic >5 µg/L and iron >300 µg/L. There was no significant co-occurrence of arsenic and iron in EPA Regions 3, 6 and 10.

TABLE V-8.—CORRELATION OF ARSENIC WITH SULFATE AND IRON (SURFACE AND GROUND WATERS)

EPA regions	Arsenic types (threshold levels >5 µg/L)	Correlation elements and their threshold level	Frequency counts
1, 2, 4, 5, 6, 7, 8, 9, 10.	Dissolved Arsenic .....	Sulfate (>250 mg/L) .....	339
	Total Arsenic .....	Sulfate (>250 mg/L) .....	143
1, 2, 4, 5, 7, 8, 9	Dissolved Arsenic .....	Iron (>300 µg/L) .....	562
	Total Arsenic .....	Iron (>300 µg/L) .....	542

The results also show some co-occurring pairs of arsenic with radon. This appears to occur in EPA Regions 5 and 6 for ground water. However, the co-occurrence of arsenic and radon at levels of concern is not significant

(Table V-9). At present, the analysis does not show significant co-occurring pairs between arsenic and radon in surface water in any EPA region. The impact from the co-occurrence of arsenic and radon is not a concern on

a national level because there was no significant co-occurring pairs in EPA Regions 1, 2, 3, 4, 7, 8, 9, and 10. EPA requests comments on whether the NWIS database and this analysis is appropriate to use to represent co-

occurrence of arsenic with other constituents.

TABLE V-9.—CORRELATION OF ARSENIC WITH RADON (GROUND WATER)

EPA regions	Arsenic types and threshold levels (µg/L)	Radon and threshold levels(pci/l)	Frequency counts
5 and 6 .....	Dissolved 2≤5 .....	100≤300	58
		300≤1000	140
	Dissolved 5≤10 .....	100≤300	124
		300≤1000	101
	Total 2≤5 .....	0≤100	2
		100≤300	2
	Total 5≤10 .....	0≤100	1
		100≤300	1

**VI. Analytical Methods**

*A. What Section of SDWA Requires the Agency To Specify Analytical Methods?*

Section 1401 of SDWA directs EPA to promulgate national primary drinking water regulations (NPDWRs) which specify either MCLs or treatment techniques for drinking water contaminants (42 U.S.C. 300g-1). EPA is required to set an MCL “if, in the judgement of the Administrator, it is economically and technologically feasible to ascertain the level of a contaminant in water in public water systems” (SDWA section 1401(1)(C)(i)). Alternatively, “if, in the judgement of the Administrator, it is not economically or technologically feasible to so ascertain the level of such contaminant,” the Administrator may identify known treatment techniques, which sufficiently reduce the contaminant in drinking water, in lieu of an MCL (SDWA section 1401(1)(C)(ii)). In addition, the NPDWRs are required to include “criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including accepted

methods for quality control and testing procedures to insure compliance with such levels \* \* \*” (SDWA section 1401(1)(D))

*B. What Factors Does the Agency Consider in Approving Analytical Methods?*

In deciding whether an analytical method is economically and technologically feasible to determine the level of a contaminant in drinking water, the Agency considers the following factors:

- Is the method sensitive enough to address the level of concern (i.e., the MCL)?
- Does the method give reliable analytical results at the MCL? What is the precision (or reproducibility) and the bias (accuracy or recovery)?
- Is the method specific? Does the method identify the contaminant of concern in the presence of potential interferences?
- Is the availability of certified laboratories, equipment and trained personnel sufficient to conduct compliance monitoring?
- Is the method rapid enough to permit routine use in compliance monitoring?

- What is the cost of the analysis to water supply systems?

*C. What Analytical Methods and Method Updates Are Currently Approved for the Analysis of Arsenic in Drinking Water?*

EPA approved analytical methods and method updates for the analysis of arsenic in drinking water in previous rulemakings. EPA took the factors listed in section VI.B into consideration when it approved these methods and updates. The methods and updates, listed in Table VI-1, are based on atomic absorption, atomic emission and mass spectroscopy methodologies and have been used for compliance monitoring of arsenic at the 0.05 mg/L MCL by State, Federal and private laboratories for many years. In this section on the discussion of analytical methods, and in the sections discussing the consumer confidence rule and public notification, EPA uses the mg/L units of measure, the units used in the regulatory language. Note that EPA’s drinking water analytical methods refer to mg/L instead of µg/L, and milligrams are 1,000 times larger than micrograms.

TABLE VI-1.—APPROVED ANALYTICAL METHODS (AND METHOD UPDATES) FOR ARSENIC (CFR 141.23)

Methodology	Reference method <sup>1</sup>	MDL <sup>2</sup> or EDL <sup>3</sup> (mg/L)
Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) .....	200.7 (EPA) 3120B (SM)	0.008 <sup>3</sup> 0.050
Inductively Coupled Plasma Mass Spectroscopy (ICP-MS) ICP-MS with Selective Ion Monitoring .....	200.8 (EPA)	0.0014 <sup>4</sup> (0.0001)
Stabilized Temperature Platform Graphite Furnace Atomic Absorption (STP-GFAA) STP-GFAA with Multiple Depositions. Graphite Furnace Atomic Absorption (GFAA) .....	200.9 (EPA)	0.0005 <sup>5</sup> (0.0001)
Gaseous Hydride Atomic Absorption (GHAA) .....	3113B (SM)	<sup>3</sup> 0.001
	D-2972-93C (ASTM)	<sup>3</sup> 0.005
	3114B (SM) D-2972-93B (ASTM)	<sup>3</sup> 0.0005 <sup>3</sup> 0.001

<sup>1</sup> The reference methods approved for measuring arsenic in drinking water are cited in 40 CFR 141.23. The reference methods include: EPA = “Methods for the Determination of Metals in Environmental Samples—Supplement I”, EPA/600/R-94-111, US EPA, May 1994. (US EPA, 1994b)

SM = Standard Methods for the Examination of Water and Wastewater, 18th and 19th eds., Washington, D.C., 1992 and 1995. (APHA, 1992 and 1995 respectively). The 19th edition of SM was approved in the December 1, 1999 final methods rule (64 FR 67450, US EPA 1999).

ASTM = Annual Book of ASTM Standards: Waster and Environmental Technology," Vol. 11.01 and 11.02, American Society for Testing and Materials, 1994 and 1996. (ASTM, 1994 and 1996). The 1996 edition of ASTM was approved in the December 1, 1999 final methods rule (64 FR 67450, US EPA 1999).

<sup>2</sup> MDL = Method Detection Limit = "the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero." (40 CFR Part 136 Appendix B).

<sup>3</sup> EDL = Estimated Detection Limit (EDL) is defined as either the MDL or a concentration of a compound in a sample yielding a peak in the final extract with a signal to noise ratio of 5, whichever value is greater. Although the ASTM GFAA method (D-2972-93C) has a reported EDL of 0.005 mg/L, this method is similar to other GFAA methods. EPA believes D-2972-93C is capable of detection limits similar to other GFAA methods.

<sup>4</sup> In 1994 (59 FR 62456; US EPA, 1994c), the Agency approved the use of the updated "Methods for the Determination of Metals in Environmental Samples—Supplement I," (US EPA, EPA/600/R-94/111, 1994). The revised manual allows the use of selective ion monitoring with ICP-MS. The determined MDL for the direct analysis of arsenic in aqueous samples was 0.1 µg/L.

<sup>5</sup> In 1994 (59 FR 62456; US EPA, 1994c), the Agency approved the use of the updated "Methods for the Determination of Metals in Environmental Samples—Supplement I," (US EPA, EPA/600/R-94/111, 1994). The revised manual allows the use of multiple depositions with STP-GFAA. The determined MDL for arsenic using multiple deposition with STP-GFAA is 0.1 µg/L.

#### *D. Will Any of the Approved Methods for Arsenic Analysis Be Withdrawn?*

EPA believes all of the analytical methods listed in Table VI-1, with the exception of EPA Method 200.7 and SM 3120B, are technically and economically feasible for compliance monitoring of arsenic in drinking water at the proposed MCL of 0.005 mg/L. EPA is proposing to withdraw approval for EPA Method 200.7 and SM 3120B because the detection limit for the first ICP-AES method, 0.008 mg/L, and the estimated detection limit for the second ICP-AES method, 0.050 mg/L, are inadequate to reliably determine the presence of arsenic at the proposed MCL of 0.005 mg/L. Analysis of the Water Supply (WS) studies used to derive the PQL (Analytical Methods Support Document, US EPA, 1999) indicates that ICP-AES technology was rarely used for low level arsenic analysis. Therefore, the Agency believes the removal of the methods that use ICP-AES technologies will not have an impact on laboratory capacity.

Even at the MCL options of 0.003, 0.010 mg/L, and 0.020 mg/L, the Agency would still withdraw both EPA Method 200.7 and SM 3120B. At these MCL options, these methods are still inadequate for compliance monitoring of arsenic in drinking water.

#### *E. Will EPA Propose Any New Analytical Methods for Arsenic Analysis?*

The Agency conducted a literature search to identify additional analytical methods which are capable of compliance monitoring of arsenic at the proposed MCL of 0.005 mg/L (Analytical Methods Support Document, US EPA, 1999). A large majority of the analytical techniques identified from the literature search were from EPA's Office of Solid Waste SW-846 methods manual, which can be accessed online at [www.epa.gov/epaoswer/hazwaste/test/index.html](http://www.epa.gov/epaoswer/hazwaste/test/index.html). Of the Solid Waste methods, the Agency evaluated:

- SW-846 Method 6020 (ICP-MS, MDL = 0.0004 mg/L; US EPA, 1994d);

- SW-846 Method 7060A (GFAA, MDL = 0.001 mg/L; US EPA, 1994e);
- SW-846 Method 7062 (GFAA, MDL = 0.001 mg/L; US EPA, 1994f);
- SW-846 Method 7063 (Anodic Stripping Voltammetry-ASV, MDL = 0.0001 mg/L; US EPA, 1996d);

In addition to the SW-846 method, the Agency also reviewed:

- EPA Method 1632 (a wastewater GHAA method with an MDL = 0.000002 mg/L or 0.002 µg/L; US EPA 1996a); and
- EPA Method 200.15 (an ICP-AES with ultrasonic nebulization as part of the written method, MDL = 0.003 mg/L or 0.002 mg/L; US EPA, 1994a).

Although the SW-846 methods and the EPA 1632 wastewater method are capable of reaching the detection limits needed at the proposed arsenic MCL, most of these techniques (with the exception of the method using ASV technology) are similar to methods that have already been approved for the analysis of arsenic in drinking water. The Agency does not believe approval of these methods for drinking water would provide additional analytical benefits. Moreover, the addition of the SW-846 methods could complicate the laboratory certification process because SW-846 methods are not mandatory procedures, but rather guidance. At this time, laboratories are certified at different times for different EPA programs. Therefore, laboratories certified for both drinking water methods and Office of Solid Waste methods may need to be certified separately under both programs to use SW-846 methods for drinking water.

While SW-846 Method 7063 (using ASV technology) is not similar to any technique approved thus far, this method will not be approved for the measurement of arsenic in drinking water because it only detects dissolved arsenic as opposed to total arsenic. Today's proposal would regulate total arsenic in drinking water not dissolved arsenic. The techniques currently approved for drinking water measure total arsenic (arsenic species in the

dissolved and suspended fractions of a water sample). A preliminary total metals digestion would be necessary with the ASV technique in order to determine the total arsenic concentration in a drinking water sample.

The Agency also reviewed but does not propose to approve EPA Method 200.15, an ICP-AES method which requires the use of ultrasonic nebulization to introduce the sample into the plasma. To provide uniform signal response using EPA Method 200.15, it is necessary for arsenic to be in the pentavalent state. The addition of hydrogen peroxide to the mixed acid solutions of samples and standards prior to ultrasonic nebulization is necessary to convert all of the arsenic species to the pentavalent state. Although EPA Method 200.15 is capable achieving a MDL of 0.003 mg/L using direct analysis and a MDL of 0.002 mg/L using a total recoverable digestion and a 2-fold concentration, these levels of detection are still insufficient for compliance monitoring at the proposed MCL of 0.005 mg/L.

At the MCL options of 0.010 mg/L and 0.020 mg/L, the Agency would approve the use of EPA Method 200.15 but only with the use of a total recoverable digestion and a 2-fold concentration (MDL = 0.002 mg/L). At an MCL option of 0.003 mg/L, EPA method 200.15 would not be approved.

#### *F. Other Method-Related Items*

##### *1. The Use of Ultrasonic Nebulization with ICP-MS*

In the September 3, 1998 Analytical Methods for Drinking Water Contaminants Proposed Rule (63 FR 47907; US EPA 1998d), EPA proposed the use of ultrasonic nebulization with EPA Method 200.7 (ICP-AES) and EPA Method 200.8 (ICP-MS). Because EPA Method 200.7 and SM 3120B will be withdrawn for the analysis of arsenic in drinking water under the proposed MCL of 0.005 mg/L, ultrasonic nebulization as a modification would not be allowed.

Even with the modification of ultrasonic nebulization, the ICP–AES method is not capable of compliance monitoring for arsenic at the proposed MCL of 0.005 mg/L. EPA Method 200.8 (ICP–MS) would still be allowed for compliance monitoring at the proposed MCL of 0.005 mg/L. The use of ultrasonic nebulization can enhance transport efficiency and lower the detection limits for ICP–MS by approximately 5 to 10 fold. The final methods update rule was published in the **Federal Register** on December 1, 1999 (64 FR 67450; US EPA 1999j).

2. 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; US EPA, 1997e). 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.

G. What Are the Estimated Costs of Analysis?

To obtain cost information on the analysis of arsenic in drinking water, the Agency collected price information from a random telephone survey of seven commercial laboratories, which were certified in drinking water analysis, and from price lists posted on the Internet (Analytical Methods Support Document, US EPA, 1999l). Table VI–2 summarizes the results of this survey, including the specific methodology and the associated cost range. The actual costs of performing an analysis may vary with laboratory, the analytical technique selected, and the total number of samples analyzed by a laboratory. The estimated cost range is only for the analysis of arsenic and does not include shipping and handling costs. The Agency solicits comments from the public on the cost estimates listed in Table VI–2.

TABLE VI–2.—ESTIMATED COSTS FOR THE ANALYSIS OF ARSENIC IN DRINKING WATER <sup>1</sup>

Methodology	Estimated cost range (\$)
Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP–AES) .....	15 to 25.
Inductively Coupled Plasma Mass Spectroscopy (ICP–MS) .....	10 to 15.
Stabilized Temperature Platform Graphite Furnace Atomic Absorption (STP–GFAA) .....	15 to 50.
Graphite Furnace Atomic Absorption (GFAA) .....	15 to 50.
Gaseous Hydride Atomic Absorption (GHAA) .....	15 to 50.

<sup>1</sup> Analytical Methods Support Document (US EPA, 1999l).

H. What Is the Practical Quantitation Limit?

Method detection limits (MDLs) and practical quantitation levels (PQLs) are two performance measures used by EPA’s drinking water program to estimate the limits of performance of analytic chemistry methods for measuring contaminants in drinking water. As cited in Table VI–1, EPA defines the MDL as “the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero (40 CFR part 136, appendix B).” MDLs can be operator, method, laboratory, and matrix specific. MDLs are not necessarily reproducible within a laboratory or between laboratories on a daily basis due to the day-to-day analytical variability that can occur and

the difficulty of measuring an analyte at very low concentrations. In an effort to integrate this analytical chemistry data into regulation development, EPA’s OGWDW uses the PQL to estimate or evaluate the minimum, reliable quantitation level that most laboratories can be expected to meet during day-to-day operations. EPA’s Drinking Water program defined the PQL as “the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions (50 FR 46906, November 13, 1985).”

1. PQL Determination

A PQL is determined either through the use of interlaboratory studies or, in absence of sufficient information, through the use of a multiplier of 5 to 10 times the MDL. The inter-laboratory data is obtained from water supply (WS)

performance evaluation (PE) studies that are conducted twice a year by EPA to certify drinking water laboratories (now referred to as the Performance Testing or PT program). In addition to certification of drinking water laboratories, WS studies also provide:

- Large-scale evaluation of analytical methods;
- A database for method validation;
- Demonstration of method utilization by a large number of laboratories; and
- Data for PQL determinations.

Using graphical or linear regression analysis of the WS data, the Agency sets a PQL at a concentration where at least 75% of the laboratories (generally EPA and State laboratories) could perform within an acceptable level of precision and accuracy. This method of deriving a PQL was used in the past for inorganics such as antimony, beryllium,

cyanide, nickel and thallium (57 FR 31776 at 31800; US EPA, 1992b).

2. PQL for Arsenic

In 1994, EPA derived a preliminary PQL for arsenic based on data collected by the Agency from WS studies 20 through 33 (WS 31 was excluded because the spiked samples were mixed

incorrectly). In response to concerns from the water utility industry, the results of this derivation and a separate evaluation conducted by the American Water Works Association (AWWA) were reviewed by the EPA Science Advisory Board (SAB) in 1995. The SAB noted that the acceptance limits of + 40% used

by EPA to derive the PQL in 1994 were wider than those for other SDWA metal contaminants. The acceptance limits and PQLs for several SDWA metals are shown in Table VI-3. The SAB recommended that EPA set the PQL using acceptance limits similar to those used for other inorganics.

TABLE VI-3.—ACCEPTANCE LIMITS AND PQLS FOR OTHER METALS (IN ORDER OF DECREASING PQL)

Contaminant	Acceptance limit <sup>1</sup> (percent)	PQL (mg/L) <sup>2</sup>
Barium .....	±15	0.15
Chromium .....	±15	0.01
Selenium .....	±20	0.01
Antimony .....	±30	0.006
Thallium .....	±30	0.002
Cadmium .....	±20	0.002
Beryllium .....	±15	0.001
Mercury .....	±30	0.0005

<sup>1</sup> Acceptance limits for the listed inorganics are found at CFR 141.23 (k) (3)(ii).  
<sup>2</sup> The PQL for antimony, beryllium and thallium was published in 57 FR 31776 at 31801 (July 17, 1992; US EPA, 1992b). The PQL for barium, cadmium, chromium, mercury and selenium was published in 66 FR 3526 at 3459 (January 30, 1991; US EPA, 1991a).

Subsequent to SAB's recommendation, EPA derived a new PQL for arsenic (Analytical Methods Support Document, US EPA, 1999l). The process employed by the Agency to determine the new PQL utilized:

- Data from six voluntary, low-level (<0.006 mg/L of arsenic) WS studies;
- Acceptance limits similar to other low-level inorganics; and
- Linear regression analysis to determine the point at which 75% of EPA Regional and State laboratories fell within the chosen acceptance range.

The derivation of the PQL for arsenic was consistent with the process used to determine PQLs for other metal contaminants regulated under SDWA and took into consideration the recommendations from the SAB. Using acceptance limits of + 30% and linear regression analysis of WS studies 30 through 36 (excluding 31) yielded a PQL of 0.00258 mg/L. The Agency rounded up to derive a PQL for arsenic of 0.003 mg/L at the ± 30% acceptance limit. While the PQL represents a stringent target for laboratory performance, the Agency believes most laboratories, using appropriate quality assurance and quality control procedures, will achieve this level on a routine basis.

I. What Are the Sample Collection, Handling and Preservation Requirements for Arsenic?

The manner in which samples are collected, handled and preserved is critical to obtaining valid data. Specific sample collection, handling and preservation procedures for SDWA analytes are outlined in the "Manual for

the Certification of Laboratories Analyzing Drinking Water" (US EPA, 1997a). For metals such as arsenic, the certification manual specifies the following:

- Nitric acid (HNO<sub>3</sub> at pH < 2) as the preservative;
- A maximum sample holding time of 6 months;
- And a sample size of 1 liter, collected in an appropriately cleaned plastic or glass container, is suggested.

Currently, arsenic does not have an entry for preservation, collection, and holding time. EPA is proposing in this rule, to revise the table following § 141.23(k)(2) to add "arsenic, Conc. HNO<sub>3</sub> to pH < 2, P or G, and 6 months." EPA requests comment on the appropriateness of this revision.

While 40 CFR 141.23(a)(4) allows compositing of up to 5 samples from the same PWS, the detection limit required for compositing must be 1/5 of the MCL. Also, compositing for inorganic samples must be done in the laboratory. Samples should only be held if the laboratory detection limit is adequate for the number of samples being composited. In any case, the composite is not to exceed five samples. EPA is adding the test methods and detection limits for the approved arsenic analytical methods to the table following § 141.23(a)(4)(i).

J. Laboratory Certification

1. Background

The ultimate effectiveness of today's regulation depends upon the ability of laboratories to reliably analyze arsenic at the proposed MCL. The existing

drinking water laboratory certification program (LCP), which was established by States with guidance and recommendations from EPA, requires that only certified laboratories analyze compliance samples. External checks of a laboratory's ability to analyze samples of regulated contaminants within specific limits is the one means of judging laboratory performance and determining whether or not to grant certification. Under a performance testing (PT) program (formerly known as the performance evaluation or PE program), laboratories are required to successfully analyze PT samples (contaminant concentrations are unknown to the laboratory being reviewed) that are prepared by appropriate third parties. Successful participation in a PT program is a prerequisite for a laboratory to achieve certification and to remain certified for analyzing drinking water compliance samples. Achieving acceptable performance in these studies of unknown test samples provides some indication that the laboratory is following proper practices. Unacceptable performance may be indicative of problems that could affect the reliability of the compliance monitoring data.

2. What Are the Performance Testing Criteria for Arsenic?

The Agency has historically identified acceptable performance using one of two different approaches:

- (a) Regressions from the performance of preselected laboratories (using 95 percent confidence limits), or

(b) Specified accuracy requirements.

Acceptance limits based on specified accuracy requirements are developed from past PE study data. EPA has traditionally preferred to use the second ("true value") approach because it is the better indicator of performance and provides laboratories with a fixed target. Under this approach, each laboratory demonstrates its ability to perform within pre-defined limits. Laboratory performance is evaluated using a constant "yardstick" independent of performance achieved by other laboratories participating in the same study. A fixed criterion based on a percent error around the "true" value reflects the experience obtained from numerous laboratories and includes relationships of the accuracy and precision of the measurement to the concentration of the analyte. It also assumes little or no bias in the analytical methods that may result in average reporting values different from the reference "true" value.

In today's rulemaking, the Agency is proposing that the laboratory certification criteria for arsenic be set at an acceptance limit of + 30 % at > 0.003 mg/L in § 141.23(k)(3)(ii). Analysis of water supply data indicate that laboratory capacity at this level should be sufficient for compliance monitoring. At this level, 75 % of EPA Regional and State laboratories and 62 % of non-EPA laboratories were capable of achieving acceptable results. As discussed in the Analytical Methods Support Document, (US EPA, 1999), setting an acceptance limit of ±20% would have decreased laboratory capacity. EPA requests comment on setting the acceptance limit at the upper range of SAB's recommendation.

3. How Often is a Laboratory Required To Demonstrate Acceptable PT Performance?

EPA requires that a PT (PE) sample for chemical contaminants be successfully analyzed at least once a year using each method which is used to report compliance monitoring results. For arsenic this would require that the laboratory successfully analyze a PT (PE) sample using the method which is used to report the results for compliance monitoring. Additional guidance on the minimum quality assurance requirements, conditions of laboratory inspections and other elements of laboratory certification requirements for laboratories conducting compliance monitoring measurements are detailed in the Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures Quality Assurance (US EPA, 1997a), which can be downloaded via the Internet at "http://www.epa.gov/ogwdw000/certlab/labindex.html."

4. Externalization of the PT Program (Formerly Known as the PE Program)

Due to resource limitations, on July 18, 1996 EPA proposed options for the externalization of the PT studies program (61 FR 37464; US EPA, 1996c). After evaluating public comment, in the June 12, 1997 final notice EPA (62 FR 32112; US EPA, 1997c):

"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, including the **Federal Register** notices mentioned in this paragraph. 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](http://www.epa.gov/safewater)).

**VII. Monitoring and Reporting Requirements**

The currently applicable monitoring requirements for arsenic are different than the other inorganic contaminants (IOCs). First of all, arsenic's MCL and compliance requirements are found in § 141.11, instead of in § 141.62(b). Monitoring, compliance, and reporting requirements for arsenic are also different than the standardized monitoring framework for the grouped IOCs (which does not include radon). EPA is proposing to move arsenic to the standardized monitoring framework for IOCs (antimony, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium, and thallium), including the State reporting and compliance requirements. Table VII-1 presents a comparison of the existing and proposed arsenic requirements, in abbreviated form. For a full picture of the regulations, you must look at the regulatory language.

In addition, EPA is proposing to clarify the regulatory language for sampling to determine compliance for inorganics, volatiles and synthetic organic contaminants.

TABLE VII-1.—COMPARISON OF SAMPLING, MONITORING, AND REPORTING REQUIREMENTS

[This table is not complete for compliance purposes, but provides an overview for readers.]

Requirement	Current rule	Proposed rule
Compliance with § 141.11(a) .....	MCL only applies to CWS and compliance is calculated using § 141.23.	Would link compliance with 50 µg/L with § 141.23(l) and would not add NTNCWS.
Compliance with § 141.11(b) .....	MCL is 0.05 mg/L .....	MCL will remain 50 µg/L for CWS serving 10,000 or less until 5 years after publication of final rule, and be effective for larger systems 3 years after publication of final rule. New lower MCL in § 141.62. NTNCWS will be subject to sampling, monitoring and reporting 3 years after publication of final rule, but not subject to increased monitoring after exceedances, nor to MCL violations.
Monitoring frequency .....	Groundwater §141.23(a)(1) One sample at each entry point to the distribution system (sampling point). Surface water §141.23(a)(2) One sample at every entry point to the distribution system (sampling point).	No change to § 141.23(a)(1). No change to § 141.23(a)(2).

TABLE VII-1.—COMPARISON OF SAMPLING, MONITORING, AND REPORTING REQUIREMENTS—Continued

[This table is not complete for compliance purposes, but provides an overview for readers.]

Requirement	Current rule	Proposed rule
Compositing inorganics .....	§ 141.23(a)(4) may composite up to 5 samples in the lab; detection limit <1/5 of the MCL.	Adding approved arsenic analytical methods and detection limits to the table following § 141.23(a)(4)(i).
Composite >1/5 MCL .....	§ 141.23(a)(4)(i) take follow-up samples within 14 days of each sampling point in the composite.	Same but § 141.23(a)(4)(i) table will list MCL and detection limits for arsenic.
Compositing by system size .....	§ 141.23(a)(4)(ii) State may permit compositing at sampling points within a system serving >3,300 people.	No change to § 141.23(a)(4)(ii).
	§ 141.23(a)(4)(ii) State may permit compositing among different systems, 5-sample limit, systems serving <3,300 people.	No change to § 141.23(a)(4)(ii).
Resampling composites .....	§ 141.23(a)(4)(iii) Can use duplicates of the original sample instead, must be analyzed and reported to State within 14 days of collection.	No change to § 141.23(a)(4)(iii).
Compliance with § 141.11 CWSs have same requirements, but arsenic monitoring would move from § 141.23(l) to § 141.23(c).	§ 141.23(l)(1) CWS surface water yearly .....	§ 141.23(c)(1) surface water one sample per compliance point annually.
	§ 141.23(l)(2) CWS ground water every three years..	§ 141.23(c)(1) groundwater one sample at each sampling point during each compliance period.
Monitoring waivers § 141.23(c) .....	None currently available for arsenic. ....	§ 141.23(c)(2) System may apply to the State. § 141.23(c)(3) Must take at least one sample during waiver, which cannot exceed one compliance period (9 years).
Minimum data for waivers: Surface water Ground water All results <MCL. New water source needs three rounds of monitoring.	.....	§ 141.23(c)(4) at least 3 years. At least 3 rounds of monitoring. At least one sample must be taken after January 1, 1990.
Once MCL exceeded sampling .....	§ 141.23(m) Supplier must report to State within 7 days and initiate three additional samples at the same sampling point within a month.	§ 141.23(c)(7) exceed MCL as calculated in (i), go to quarterly monitoring next quarter. § 141.31(d) within 10 days of giving public notice, contact primacy agency. § 141.203(b) Tier 2 public notice no later than 30 days after learning of violation and repeat every 3 months or at least once a year if allowed by primacy agency.
Compliance based on less than required number of samples.	Not currently specified. ....	§ 141.23(i)(1) for IOCs, § 141.24(f)(15)(i) for VOCs, and §§ 141.24(h)(11)(i) and (ii) for SOCs will average based on # samples collected.
Average that determines violation. .... State notice .....	§ 141.23(n) When the 4 analyses, rounded to the same number of significant figures as the MCL exceeds the MCL, supplier must notify the State § 141.31 and give notice to the public § 141.32. Monitoring frequency determined by the State must continue until < MCL in two consecutive samples or until a variance, exemption, or enforcement action schedule becomes effective.	§ 141.23(i)(5) arsenic will be reported to the nearest 0.001 mg/L. § 141.23(i)(1) monitoring > annually, running annual average at sampling point. If less samples taken than required, compliance is based on average of samples. Any sample below method detection limit is assigned zero for calculation.
Public notice .....		
Sampling frequency after MCL compliance monitoring begun.	.....	§ 141.23(i)(2) monitoring annually or less often if sampling point > MCL.
Confirmation sample .....	None currently specified for arsenic .....	If State requires a confirmation sample, then compliance based on average of the two samples. If State specifies additional monitoring, compliance based on running annual average. If less samples taken than required, compliance is based on average of samples.
Increased monitoring frequency .....	.....	§ 141.23(f)(1) State may require one within two weeks. § 141.23(c)(8) State can decrease monitoring after a minimum of 2 quarters for ground water and 4 quarters for surface water <MCL.

TABLE VII-1.—COMPARISON OF SAMPLING, MONITORING, AND REPORTING REQUIREMENTS—Continued  
 [This table is not complete for compliance purposes, but provides an overview for readers.]

Requirement	Current rule	Proposed rule
New system and new sources .....	Only mentions waiver eligibility in § 141.23(c)(4).	§ 141.23(f)(1) If >MCL, State can require a confirmation sample within two weeks. § 141.23(f)(3) Average used to determine compliance with (i). States can delete results with obvious sampling errors. § 141.23(g) State may require more frequent monitoring. § 141.23(c)(9) IOCs, § 141.24(f)(22) VOCs, § 141.24(h)(20) SOCs, Compliance demonstrated within State-specified time and sampling frequencies.
Subpart O Consumer Confidence Reports for CWS.	>50 µg/L annual report § 141.153(d)(6) length of violation, potential health effects using Appendix C, actions taken. 25–50 µg/L informational statement per § 141.154(b).	Lowers MCL & adds MCLG to Appendices A & B to Subpart O—effective 30 days after final arsenic rule is published, before compliance with lower MCL is in place.
Subpart Q Public Notification for PWS .....	>50 µg/L CWSs Tier 2 annual report § 141.203 required October 31, 2000 (if they are in jurisdictions where the program is directly implemented by EPA) or on the date a primacy State adopts the new requirements (not to exceed May 6, 2002)..	§ 141.203(b) Tier 2 public notice no later than 30 days after learning of violation and repeat every 3 months or at least once a year if allowed by primacy agency.  § 141.31(d) within 10 days of giving public notice, contact primacy agency. >5 µg/L CWSs & add NTNCWS to Table 1 of § 141.203 to require Tier 2 annual report § 141.203 after effective date of arsenic MCL (3–5 yrs).

*A. What Are the Existing Monitoring and Compliance Requirements?*

The arsenic monitoring requirements appear in 40 CFR 141.23(a). Surface water systems must collect routine samples annually and ground water systems must collect a routine sample every three years. However, § 141.11(a) currently only requires community water systems (CWS) to monitor for arsenic. EPA understands that some States also require their non-transient non-community water systems (NTNCWS) to collect samples for the analysis of arsenic as well. Under the proposal, CWSs would continue to be allowed to composite samples as specified in § 141.23(a)(3); however, the one-fifth arsenic MCL will no longer be 10 µg/L (It will be 1 µg/L).

Sections 141.23(l) through (q) are currently used to determine compliance for arsenic. That is, if arsenic is detected at a concentration greater than the maximum contaminant level (MCL), the community water system must collect 3 additional samples within one month at the entry point to the distribution system that exceeded the MCL (§ 141.23(n)). If the average of the four analyses performed, rounded to one significant figure, exceeds the MCL, the system must notify the State; and the system must provide public notice (§ 141.23(n)). After public notification, the monitoring continues at the

frequency designated by the State until the MCL “has not been exceeded in two successive samples or until [the State establishes] a monitoring schedule as a condition to a variance, exemption or enforcement action (§ 141.23(n)).” Monitoring waivers are not permitted to exclude a system from the sampling requirements under § 141.23(l)–(q) which currently apply to arsenic.

*B. How Does the Agency Plan To Revise the Monitoring Requirements?*

The Agency is proposing to require CWS and NTNCWSs to monitor for arsenic using § 141.23(c). This will make the arsenic monitoring requirements consistent with the inorganic contaminants (IOC’s) regulated under the standardized monitoring framework. EPA is proposing that NTNCWSs monitor and report arsenic results to the State and public, as a Tier 2 notice in subpart Q, Public Notification. However, the Agency is proposing that NTNCWSs not be required to meet the MCL, unlike the other inorganics listed in § 141.62(b). EPA’s analysis for not requiring NTNCWSs to comply with the MCL is based on the cost-benefit analysis discussed later in section XI.C. of this preamble.

If arsenic exceeds the MCL, the CWS will be triggered into quarterly monitoring for that sampling point “in the next quarter after the violation

occurred (§ 141.23(c)(7).” The State may allow the system to return to the routine monitoring frequency when the State determines that the system is reliably and consistently below the MCL. However, the State cannot make a determination that the system is reliably and consistently below the MCL until a minimum of 2 consecutive ground water or 4 consecutive surface water samples have been collected (§ 141.23(c)(8)). All systems must comply with the sampling requirements, unless a waiver has been granted in writing by the State (§ 141.23(c)(6)).

As shown in Table VI-1, the approved methods can measure to 0.001 mg/L or below. In order to use the analytical power of the methods, EPA is proposing that arsenic data be reported to the nearest 0.001 mg/L. Therefore, a result of 0.0055 mg/L would be rounded to 0.006 mg/L, and 0.0145 mg/L would be rounded to 0.014 mg/L (Figures ending in “5” rounded down to end on an even digit and up to an even digit.). During the writing of this regulation, some people had asked whether data above 0.01 mg/L could be rounded to one significant figure because the MCL is being proposed with one significant figure. EPA is issuing a clarification to arsenic reporting in § 141.23(i) to indicate that arsenic results will be reported to the nearest 0.001 mg/L. The significance for compliance purposes will be that values between 0.010 mg/

L and 0.014 mg/L will be averaged to the nearest 0.001 mg/L, and the yearly average will more closely reflect the values measured. EPA requests comment on these clarifications to reporting requirements.

### *C. Can States Grant Monitoring Waivers?*

As proposed, States will be able to grant a 9-year monitoring waiver to a system (§ 141.23(c)(3)). Waivers of arsenic sampling requirements must be based on all analytical results from previous sampling and a vulnerability assessment or the assessment from an approved source water assessment program (provided that the assessments were designed to collect all of the necessary information needed to complete a vulnerability assessment for a waiver). States issuing waivers must consider the requirements in 40 CFR 141.23(c)(2)–(6). In order to qualify for a waiver, there must be three previous samples from a sampling point (annual for surface water and three rounds for groundwater) with analytical results reported below the proposed MCL (*i.e.*, the reporting limit must be < 0.005 mg/L). The use of grandfathered data collected after January 1, 1990 that is consistent with the analytical methodology and detection limits of the proposed regulation may be used for issuing sampling point waivers. The existing § 141.23(l)–(q) regulations do not permit the use of monitoring waivers. However, a State could now use the analytical results from the three previous compliance periods (1993–1995, 1996–1998, and 1999–2001) to issue ground water sampling point waivers. Surface water systems must collect annual samples so a State could use the previous 3 years sampling data (1999, 2000, and 2001) to issue sampling point waivers. One sample must be collected during the nine-year compliance cycle that the waiver is effective, and the waiver must be renewed every nine years. Vulnerability assessments must be based on a determination that the water system is not susceptible to contamination and arsenic is not a result of human activity (*i.e.*, it is naturally occurring).

Although the approved analytical methods can measure to 0.005 mg/L, not all States have required systems to report arsenic results below 50 µg/L. In this case, the States would not have adequate data to grant waivers until enough data are available to make the determinations. EPA has compliance monitoring data from 25 States at 10 µg/L and below. On the other hand, one

State submitted data to EPA rounded to tens of µg/L, so some States may not be able to grant waivers until the data are reported below the proposed MCL.

EPA believes that some States may have been regulating arsenic under the standardized inorganic framework being proposed today. If so, those States will have to ensure that existing monitoring waivers have been granted using data reported below the new proposed MCL. Otherwise States will have to notify the systems of the new lower reporting requirements that need to be met to qualify for a waiver for the proposed MCL.

### *D. How Can I Determine if I Have an MCL Violation?*

For this proposal, violations of the arsenic MCL would be determined under § 141.23(f)–(i). If a system samples more frequently than annually (*e.g.*, quarterly), the system would be in violation if the running annual average at any sampling point exceeds the MCL or if any one sample would cause the annual average to be exceeded (§ 141.23(i)(1)). If a system conducts sampling at an annual or less frequent basis, the system would be in violation if one sample (or the average of the initial and State-required confirmation sample(s)), at any sampling point exceeds the MCL (§ 141.23(i)(2)). However, States can require more frequent monitoring per § 141.23(g) for systems sampling annually or less often. Therefore, the Agency is proposing to clarify this section for situations for IOCs in § 141.23(i)(2)) and the corresponding sections for volatile and synthetic organic contaminants (§§ 141.24(f)(15)(ii) and 141.24(h)(11)(ii), respectively). This proposal clarifies compliance for contaminants subject to §§ 141.23(i)(2)), 141.24(f)(15)(ii), and 141.24(h)(11)(ii) by pointing out that compliance will be based on the running annual average of the initial MCL exceedance and subsequent State-required confirmation samples. These confirmation samples may be required at State-specified frequencies (*e.g.*, quarterly or some other frequency depending on site-specific conditions).

In addition, the clarifications to §§ 141.23(i)(2)), 141.24(f)(15)(ii) and 141.24(h)(11)(ii) address calculation of compliance when a system fails to collect the required number of samples. Compliance (determined by the average concentration) would be based on the total number of samples collected. The Agency expects systems will conduct all required monitoring. However, some

systems have purposely not collected the required number of quarterly samples, and in doing so some avoided reporting an MCL violation. While these systems all incurred monitoring and reporting violations for the uncollected samples, some systems divided the sum of the samples taken by four, which lowered the annual average reported to below the MCL, avoiding an MCL violation. The Agency requests comment on this clarification of exceedances determined under a State-determined monitoring frequency.

For purposes of calculating MCL annual averages, § 141.23(i)(1) continues to set all non-detects equal to a value of zero. However, the Agency realizes that some States use the detection limit or a fraction of the detection limit to calculate an average.

### *E. When Will Systems Have To Complete Initial Monitoring?*

The rule becomes effective 3 years after promulgation (about January 1, 2004) for large PWS (serving over 10,000). This will require all GW and SW systems serving over 10,000 to complete the initial round of monitoring by December 31, 2004. However, States may allow systems, on a case-by-case basis, 2 additional years to comply with the MCL if capital improvements are necessary.

The Agency is proposing a national finding that capital improvements are necessary for public water systems serving less than 10,000, on the basis that existing treatments are not expected to be effective in arsenic removal. Table VII-2 shows the percentage of small systems with no treatment in place as well as the percentage of systems which currently have in place technologies that can remove arsenic. The data shows that capital improvements would be necessary for many systems. The rule would be effective 5 years after promulgation (about January 1, 2006) for systems serving under 10,000. This would require these small GW systems to complete the initial round of monitoring by the December 31, 2007 ('05-'07 compliance period), and small SW systems to complete the initial round of monitoring by December 31, 2006. EPA is requesting comment on whether it is appropriate to make a national finding that systems serving less than 10,000 people will need the two additional years to add capital improvements in order to comply with the proposed MCL. The alternative would require States to issue individual two-year extensions for these small systems.

TABLE VII-2.—TREATMENT IN-PLACE AT SMALL WATER SYSTEMS (US EPA, 1999E AND US EPA, 1999M)

System size	Percent of systems with no treatment in place		Percent of systems with ion exchange in place		Percent of systems with coagulation/filtration in place		Percent of systems with lime softening in place		Percent of systems with reverse osmosis in place	
	GW	SW	GW	SW	GW	SW	GW	SW	GW	SW
25–100 .....	50	7	1.7	0	1.7	21.7	2.6	4.3	0	0
101–500 .....	25	6	1.4	0	4.1	53.3	2.7	8.9	0.5	0
501–1K .....	25	0	2.9	0	2.4	73.0	2.4	18.9	0	0
1K–3.3K .....	27	0	1.6	0	2.7	76.4	2.7	16.4	0.4	0
3.3K–10K .....	26	0	2.1	0	8.1	85.3	3.3	7.4	0.6	0

References: Geometries and Characteristics of Public Water Systems, August 1999, (US EPA, 1999e) Drinking Water Baseline Handbook, February 24, 1999, (US EPA, 1999m)

The regulatory changes affected by the revised arsenic MCL are summarized in Table VII-3.

TABLE VII-3.—TABLE IDENTIFYING REGULATORY CHANGES

CFR citation	Topic or subpart
§ 141.23(a)(4) .....	Sample compositing allowed by the State.
141.23(a)(4)(i) .....	Detection limit for arsenic.
141.23(a)(5) .....	Frequency of monitoring for arsenic determined in § 141.23(c).
141.23(c) .....	Standard inorganic monitoring framework, with State waivers possible.
141.23(f)(1) .....	Confirmation sampling may be required by the State.
141.23(g) .....	More frequent monitoring may be required by the State.
141.23(i)(5) .....	Compliance determination reporting.
141.23(k)(1) .....	Approved methodology.
141.23(k)(2) .....	Container, preservation, and holding time.
141.23(k)(3)(ii) .....	Acceptance limit for certified laboratories.
141.62(b)(16) .....	MCL for arsenic.
141.62(c) .....	BATs for arsenic.
141.26(d) .....	Small system compliance technologies (SSCTs).
141.154(b) .....	Requires CWS to report exceedances of new MCL in CCR before lower MCL is effective, removing 25–50 µg/L informational statement requirement.
Appendix A to Subpart O of 141.	Converting lower MCL compliance values for CCRs and listing MCLG.
Appendix B to Subpart O of 141.	Changes MCLG and MCL values effective 30 days after MCL is final.
PN, Subpart Q, Table 1 to § 141.203.	Add NTNCWS exceeding MCL (not a violation) to Tier 2 reporting.
Appendix A to Subpart Q of 141.	Public notification regulatory citations revised.
Appendix B to Subpart Q of 141.	Standard Health Effects Language unchanged; revise MCLG, MCL.

In order to prevent the arsenic MCL of 5 µg/L from becoming effective immediately, EPA is proposing to delete the reference to § 141.11(a) in § 141.6(c), which provides effective dates. While examining § 141.6(c) for sections that affect arsenic, we found several sections that do not exist. Therefore, EPA is proposing to remove the reference to the following sections in § 141.6(c) listed in Table VII-4:

TABLE VII-4.—TABLE LISTING DELETED SECTIONS

CFR section	Topic or reason
141.11(a) .....	New arsenic MCL would be effective immediately.
141.11(e) .....	Section 141.11(e) does not exist

TABLE VII-4.—TABLE LISTING DELETED SECTIONS—Continued

CFR section	Topic or reason
141.14(a)(1) .....	Section 141.14 does not exist.
141.14(b)(1)(i) .....	Section 141.14 does not exist.
141.14(b)(2)(i) .....	Section 141.14 does not exist.
141.14(d) .....	Section 141.14 does not exist.
141.24(a)(3) .....	Section 141.24(a) is reserved.

The Agency requests comment on whether these deletions to § 141.6(c) are necessary and appropriate.

*F. Can I use Grandfathered Data To Satisfy the Initial Monitoring Requirement?*

Ground water systems may use grandfathered data collected after Jan 1, 2002 to satisfy the sampling requirements for the 2002–2004 compliance period. However, the detection limit must be less than the revised MCL. If the grandfathered data is used to comply with the 2002–2004 compliance period and the analytical result is between the current MCL and the revised MCL, then that system will be in violation of the revised MCL on the effective date of the rule. If the system chooses not to use the grandfathered data, then it must collect another sample by December 31, 2004 to demonstrate compliance with the revised MCL.

### *G. What Are the Monitoring Requirements for New Systems and Sources?*

The current regulations only address new systems and sources in the waiver provisions of § 141.23(c)(4), so the proposal specifically adds monitoring requirements for these systems for inorganic, volatile organic, and synthetic organics contaminants. All new systems or systems that use a new source of water that begin operation after the effective date of this rule would have to demonstrate compliance with the MCL within a period of time specified by the State. The State would also specify sampling frequencies to ensure a system can demonstrate compliance with the MCL. This requirement would be effective for all inorganic, volatile organic, and synthetic organic contaminants regulated in § 141.23 and § 141.24. The Agency recognizes that many States have established requirements for new systems and new sources, and these are part of the approved State primacy programs. Therefore EPA believes that recognizing State-determined compliance will be the most effective way to regulate new systems and sources. EPA requests comment on this proposed clarification.

### *H. How Does the Consumer Confidence Report Change?*

On August 19, 1998, EPA issued subpart O, the final rule requiring community water systems to provide annual reports on the quality of water delivered to their customers (63 FR 44512; US EPA, 1998e). The first Consumer Confidence Reports (CCRs) were required by October 19, 1999. The next reports are due by July 1, 2000, for calendar year 1999 data and every July 1 after that (§ 141.152(a)). In general, reports must include information on the health effects of contaminants only if there has been a violation of an MCL or a treatment technique. For such violations specific "health effects language" in subpart O must be included verbatim in the report. The arsenic health effects language is currently required when arsenic levels exceed 50 µg/L.

In addition, the Agency decided to require more information for certain contaminants because of concerns raised by commenters. One of these contaminants was arsenic. As explained in the preamble to the final rule (63 FR 44512 at 44514; US EPA, 1998e) because of concerns about the adequacy of the current MCL, EPA decided that systems that detect arsenic between 0.025mg/L and the current MCL must include some

information regarding arsenic (§ 141.154(b)). This informational statement is different from the health effects language required for an exceedance of the MCL. EPA noted that the requirement would be deleted upon promulgation of a revised MCL.

Another issue which affects handling of arsenic in the CCR is the provision in the statute which authorized the Administrator to require inclusion of language describing health concerns for "not more than three regulated contaminants" other than those detected at levels which constitute a violation of an MCL (section 1414(c)(4)(B)(vi)). Based on stakeholder and commenter input, the Agency decided in the final CCR rule that it would use this authority in future rulemaking to require health effects language when certain MCLs are promulgated or revised. The health effects language of Subpart O would have to be included in reports of systems detecting a contaminant above the level of the new or revised MCL, prior to the effective date of the MCL, although technically the systems are not in violation of the regulations. The Agency used this authority in the promulgation of the Disinfectants and Disinfection Byproducts for one contaminant, Total Trihalomethanes on December 16, 1998 (63 FR 69390). The Agency is now proposing to use this same authority to require inclusion of the health effects language in reports of systems which detect arsenic above the level of the revised MCL upon promulgation of these regulations. The Agency believes that it is important to provide this information to customers immediately. The systems have the flexibility to place this information in context and explain to customers that there is no on-going violation. Furthermore, the health advisory EPA is planning to issue in the near future will provide consumers with information about obtaining sources with lower arsenic prior to the effective date of the 5 µg/L arsenic MCL. EPA asks for comment on whether the consumer confidence report should notify customers of arsenic health effects starting with the report issued by July 1, 2002 for calendar year 2001.

After the promulgation date of the revised arsenic MCL and before the effective date, community water systems that detect arsenic above 5 µg/L but below 50 µg/L would include the arsenic health effects language. Those systems that detect arsenic above 50 µg/L would include the health effects language and also report violations as required by § 141.153(d)(6).

### *I. How Will Public Notification Change?*

On May 4, 2000, EPA issued the final Public Notification Rule (PNR) for Subpart Q (US EPA 2000c) to revise the minimum requirements public water systems must meet for public notification of violations of EPA's drinking water standards and other situations that pose a risk to public health from the drinking water. Water systems must begin to comply with the new PNR regulations on October 31, 2000 (if they are in jurisdictions where the program is directly implemented by EPA) or on the date a primacy State adopts the new requirements (not to exceed May 6, 2002). EPA's arsenic drinking water regulation affects public notification requirements and amends the PNR as part of its rulemaking.

The PNR divides the public notice requirements into three tiers, based on the seriousness of the violation or situation. Tier 1 is for 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 is for 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 is for 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 proposal will require community water systems (CWS) to provide a Tier 2 public notice for arsenic MCL violations and to provide a tier 3 public notice for violations of the monitoring and testing procedure requirements. Today's proposal would also require NTNCWS to provide a Tier 2 notice for exceedances of the MCL. As later explained in section XI.C., the Agency believes that overall risks from water ingested from NTNCWS cannot justify the costs of treatment. EPA believes that most States will, using their authority as described in § 141.203(b), require NTNCWS to issue repeat notices on a yearly basis rather than every three months. EPA requests comment on the implementation of arsenic public notification requirements by the effective date of the arsenic MCL and on the Tier 2 public notice requirement for quarterly repeat notices for continuing exceedances of the arsenic MCL for NTNCWS.

**VIII. Treatment Technologies**

Section 1412(b)(4)(E) of the Safe Drinking Water Act states that each NPDWR which establishes an MCL shall list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting the MCL. Technologies are judged to be a best available technology (BAT) when the following criteria are satisfactorily met:

- The capability of a high removal efficiency;
- A history of full scale operation;
- General geographic applicability;
- Reasonable cost;
- Reasonable service life;
- Compatibility with other water treatment processes; and
- The ability to bring all of the water in a system into compliance.

In order to fulfill this requirement set forth by SDWA, EPA has identified BATs in Section VIII.A. Their removal efficiencies and a brief discussion of the major issues surrounding the usage of each technology are also given in section VIII.A. Likely treatment trains, of which the BAT will be the integral part, are identified in section VIII. B. The costs associated with these treatment trains are also provided. More details about the treatment technologies and costs can be found in "Technologies and Costs for the Removal of Arsenic From Drinking Water" (US EPA,1999i).

Section 1412(b)(4)(E)(ii) of the Act also states that EPA shall list any affordable small systems compliance technologies that are feasible for the purposes of meeting the MCL. The general process by which EPA identifies compliance, and if necessary, variance technologies is described in section VIII.C. The Agency, for the revised arsenic regulation, is not proposing any variance technologies. Compliance technologies for arsenic are identified in section VIII.E. More details about the technologies and affordability determinations can be found in "Compliance Technologies for Arsenic" (US EPA,1999g).

Section VIII.F briefly discusses how other rules, presently being developed by the Agency, may impact the arsenic rule, or how the arsenic rule may impact these other regulations.

*A. What Are the Best Available Technologies (BATs) for Arsenic? What Are the Issues Associated With These Technologies?*

EPA reviewed several technologies as BAT candidates for arsenic removal: ion exchange, activated alumina, reverse osmosis, nanofiltration, electro dialysis reversal, coagulation assisted

microfiltration, modified coagulation/ filtration, modified lime softening, greensand filtration, conventional iron and manganese removal, and several emerging technologies. The Agency proposes that, of the technologies capable of removing arsenic from source water, only the technologies in Table VIII-1 fulfill the requirements of the SDWA for BAT determinations for arsenic. The maximum percent removal that can be reasonably obtained from these technologies is also shown in the table. These removal efficiencies are for arsenic (V) removal.

**TABLE VIII-1.—BEST AVAILABLE TECHNOLOGIES AND REMOVAL RATES**

Treatment technology	Maximum percent removal <sup>1</sup>
Ion Exchange .....	95
Activated Alumina .....	90
Reverse Osmosis .....	>95
Modified Coagulation/Filtration .....	95
Modified Lime Softening .....	80
Electrodialysis Reversal .....	85

<sup>1</sup>The percent removal figures are for arsenic (V) removal.

In water, the most common valence states of arsenic are As (V), or arsenate, and As (III), or arsenite. As (V) is more prevalent in aerobic surface waters and As (III) is more likely to occur in anaerobic ground waters. In the pH range of 4 to 10, As (V) species ( $H_2AsO_4^-$  and  $H_2AsO_4^{2-}$ ) are negatively charged, and the predominant As (III) compound ( $H_3AsO_3$ ) is neutral in charge. Removal efficiencies for As (V) are much better than removal of As (III) by any of the technologies evaluated, because the arsenate species carry a negative charge and arsenite is neutral under these pH conditions. To increase the removal efficiency when As (III) is present, pre-oxidation to the As (V) species is necessary.

*Pre-oxidation.* As (III) may be converted through pre-oxidation to As (V) using one of several oxidants. Data on oxidants indicate that chlorine, potassium permanganate, and ozone are effective in oxidizing As (III) to As (V). Pre-oxidation with chlorine may create undesirable concentrations of disinfection by-products and membrane fouling of subsequent treatments such as reverse osmosis. EPA has completed research on the chemical oxidants for As (III) conversion, and is presently investigating ultraviolet light disinfection technology (UV) and solid oxidizing media. For point-of-use and point-of-entry (POU/POE) devices, central chlorination may be required for oxidation of As (III).

*Coagulation/Filtration (C/F)* is an effective treatment process for removal of As (V) according to laboratory and pilot-plant tests. The type of coagulant and dosage used affects the efficiency of the process. Within either high or low pH ranges, the efficiency of C/F is significantly reduced. Below a pH of approximately 7, removals with alum or ferric sulfate/chloride are similar. Above a pH of 7, removals with alum decrease dramatically (at a pH of 7.8, alum removal efficiency is about 40%). Other coagulants are also less effective than ferric sulfate/chloride. Disposal of the arsenic-contaminated coagulation sludge may be a concern especially if nearby landfills are unwilling to accept such a sludge.

*Lime Softening (LS)*, operated within the optimum pH range of greater than 10.5 is likely to provide a high percentage of As removal. However, if removals greater than 80% are required, it may be difficult to remove consistently at that level by LS alone. Systems using LS may require secondary treatment to meet that goal (e.g., addition of an ion exchange unit as a polishing step). As with C/F, disposal of arsenic-contaminated sludge from LS may be an issue.

*Coagulation/Filtration and Lime Softening* are technologies primarily used for large systems. Package plants may make it more affordable for small systems to employ these technologies. Package plants are pre-engineered (i.e., the process engineering for the package plants has been done by the manufacturer). What remains for the water system's engineer to design is the specifics of the on-site application of the equipment. However, these technologies still require well trained operators. If it is not possible to keep a trained operator at the plant, an off-site contract operator may be able to monitor the process with a telemetry device. Because of these complexities, these technologies are not likely to be installed solely for arsenic removal. However, if they are already in place, modification of these two technologies to achieve higher arsenic removal efficiencies is a viable option.

*Activated Alumina (AA)* is effective in treating water with high total dissolved solids (TDS). However, the capacity of activated alumina to remove arsenic is very pH sensitive. High removals can be achieved at high pHs, but at shorter run lengths. The use of chemicals for pH adjustment and bed regeneration, storage of sulfuric acid and sodium hydroxide, and process oversight increase operator responsibilities and the need for advanced training. (Decisions on the certification of water operators will be

made at the State and local levels). Operators may have to add an acid to lower pH to an optimal range and then afterwards increase the pH to avoid corrosion. Sodium hydroxide and sulfuric acid are required in the regeneration process. Selenium, fluoride, chloride, sulfate, and silica, if present at high levels, may compete for adsorption sites. Suspended solids and precipitated iron can cause clogging of the AA bed. Systems containing high levels of these constituents may require pretreatment or periodic backwashing. AA is highly selective towards As (V), and this strong attraction results in regeneration problems, possibly resulting in 5 to 10 percent loss of adsorptive capacity after each run. As a result, AA may not be efficient in the long term. In addition, activated alumina produces highly concentrated waste streams, which can contain approximately 30,000 mg/L of total dissolved solids (TDS) content. Because of the high content of TDS in the waste stream, disposal of the brine must be taken into consideration.

The safety issue of handling corrosive and caustic chemicals associated with this technology may make it inappropriate for small systems. Therefore, in estimating national costs, it was assumed that small systems would not adjust pH and would not regenerate on site. Costs were estimated assuming systems operated a non-optimal pH and operation on a "throw-away" basis. Regenerating the media off-site instead of disposing of spent media is another possibility.

*Ion Exchange (IX)* can effectively remove arsenic as well. It is recommended as a BAT primarily for small, ground water systems with low sulfate and TDS, and as a polishing step after filtration. Sulfate, TDS, selenium, fluoride, and nitrate compete with arsenic for binding sites and can affect run length. Column bed regeneration frequency is a key factor in calculating costs. Recent research indicates that ion exchange may be practical up to approximately 120 mg/L of sulfate (Clifford 1994). Passage through a series of columns could improve removal and decrease regeneration frequency. As with AA, suspended solids and precipitated iron can cause clogging of the IX bed. Systems containing high levels of these constituents may require pretreatment. Suspended solids and precipitated iron may also be removed by backwashing.

Ion exchange also produces a highly concentrated waste by-product stream, and the disposal of this brine must be considered. Brine recycling can reduce the amount of waste for disposal and

lower the cost of operation. Recent research showed that the brine regeneration solution could be reused as many as 20 times with no impact on arsenic removal provided that some salt was added to the solution to provide adequate chloride levels for regeneration (Clifford 1998).

*Reverse Osmosis (RO)* can provide removal efficiencies of greater than 95 percent when operating pressure is ideal (e.g., pounds per square inch, psi). Water rejection (on the order of 20–25%) may be an issue in water-scarce regions. If RO is used by small systems in the western U. S., water recovery will likely need to be optimized due to the scarcity of water resources. Water recovery is the volume of water produced by the process divided by the influent stream (product water/influent stream). Increased water recovery can lead to increased costs for arsenic removal. Since the ability to blend with an MCL of 5 µg/L would be limited, the entire stream may have to be treated. Therefore, most of the alkalinity and hardness would also be removed. In that case, to avoid corrosion problems and to restore minerals to the water, post-treatment corrosion control may be necessary. Discharge of reject water or brine may also be a concern.

*Electrodialysis Reversal (EDR)* can produce effluent water quality comparable to reverse osmosis. EDR systems are fully automated, require little operator attention, and do not require chemical addition. EDR systems, however, are typically more expensive than nanofiltration and reverse osmosis systems. These systems are often used in treating brackish water to make it suitable for drinking. This technology has also been applied in the industry for wastewater recovery. The technology typically operates at a recovery of 70 to 80 percent. Few studies have been conducted to exclusively evaluate this process for the removal of arsenic, but a removal of approximately 85% can be expected (US EPA, 1999i).

#### **Other Technologies**

*Coagulation Assisted Microfiltration.* The coagulation process described previously can be linked with microfiltration to remove arsenic. The microfiltration step essentially takes the place of a conventional gravity filter. The University of Houston recently completed pilot studies at Albuquerque, New Mexico on iron coagulation followed by a direct microfiltration system. The results of this study indicated that iron coagulation followed by microfiltration is capable of removing arsenic (V) from water to yield concentrations which are consistently

below 2 µg/L. Critical operating parameters are iron dose, mixing energy, detention time, and pH (Clifford, 1997). However, since a full-scale operation history is one of the requirements to list a technology as a BAT, it is not presently being listed as one. It could be designated as such in the future if the technology meets that requirement.

*Oxidation/Filtration (including greensand filtration)* has an advantage in that there is not as much competition with other ions. However, the process has not been used very much for arsenic removal. In addition, similar to activated alumina, greensand filtration may require pH adjustment to optimize removal, which may be difficult for small systems. This technology is not recommended for high removals. The maximum removal percentage was assumed to be 50% when estimating national costs. The presence of iron in the source water is critical for arsenic removal. If the source water does not contain iron, oxidizing and filtering the water will not remove arsenic. In developing national cost estimates, it was assumed that systems would opt for this type of technology only if more than 300 µg/L of iron was present. Oxidation/Filtration is not being listed as a BAT because it does not meet the requirement of a high removal efficiency. However, since it is a relatively inexpensive technology, it may be appropriate for those systems that do not require much arsenic removal and have high iron in their source water.

#### **Emerging Technologies**

There are several emerging technologies for arsenic removal; however, these require more testing before they can be designated as a BAT. Iron-based media products include the following. Iron oxide coated sand removes arsenic using adsorption; the sand also doubles as a filtration media. The technology has only been tested at the bench-scale level and may have a high cost associated with it. Granular ferric hydroxide also employs an adsorption process and is being used in a number of full scale plants in Germany. Costs may be an issue with this technology as well. Iron filings are essentially a filter technology, initially developed for arsenic remediation. Though quite effective at remediation, this technology may have limited use as a drinking water treatment technology; the technology performs well when treating high influent arsenic levels typical of remediation, but needs to be proven in treating lower influent levels expected in raw drinking water to a finished level at the proposed MCL.

Sulfur-modified iron appears to remove total organic carbon (TOC) and disinfection byproducts (DBPs) as well as arsenic. However, it has only been tested at the bench scale. ADI Group, Inc.'s proprietary process also has an iron-based media that has been installed in a number of locations.

Nanofiltration is of interest because it can be operated at lower pressures than reverse osmosis, which translate into lower operation and maintenance costs. However, when nanofiltration is operated at realistic recoveries, the removal efficiency appears to be low.

Electrodialysis Reversal (EDR), although easier to operate than reverse osmosis and nanofiltration, does not appear to be competitive with respect to costs and process efficiency.

**Waste Disposal**

Waste disposal will be an important issue for both large and small plants. Costs for waste disposal have been added to the costs of the treatment technologies (in addition to any pre-oxidation and corrosion control costs), and form part of the treatment trains that are listed in Section VIII.B. A

sufficient volume of receiving water would be needed in order to directly discharge the contaminated brine stream from membrane technologies.

Otherwise, operators may have to pre-treat to meet Clean Water Act permit requirements prior to discharge. If the plant is discharging to a sanitary sewer because of the membranes, there may be a very high salinity in the discharge as well as high levels of arsenic that might, without pretreatment, exceed local sewer use regulations. Ion exchange and activated alumina treatment brines will be even more concentrated (on the order of 30,000 TDS), and more than likely will require pre-treatment prior to discharge to either a receiving body of water or the sanitary sewer.

Disposal of solid treatment residuals would be problematic if they fail the toxicity characteristic (TC) of the Resource Conservation and Recovery Act (RCRA). If they fail the TC, the residuals are regulated as hazardous waste because of the concentration of arsenic. For the purposes of the national cost estimate, it was assumed that solid residuals would be disposed of at nonhazardous landfills.

*B. What Are the Likely Treatment Trains? How Much Will They Cost?*

Likely treatment trains are shown in Table VIII-2. These trains represent a wide variety of solutions a facility may consider when complying with the proposed arsenic MCL. Not all solutions may be viable for a given system. For example, only those systems with coagulation/filtration in-place will be able to modify their existing treatment system. The treatment trains include BATs, waste disposal, and when necessary, pre-oxidation and corrosion control.

Table VIII-2 also contains two "non-treatment" options which may be appropriate if the source water is of very poor quality. "Regionalization" refers to connecting with another system and purchasing water, and "alternate source" refers to finding a new source of water (e.g. drilling a new well). However, since arsenic is a naturally occurring contaminant, it may be ubiquitous at a particular site, so drilling another well may not improve the situation.

TABLE VIII-2.—TREATMENT TECHNOLOGY TRAINS

Train No.	Treatment technology trains
1 .....	Regionalization.
2 .....	Alternate Source.
3 .....	Add pre-oxidation [if not in-place] and modify in-place Lime Softening.
4 .....	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration.
5 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
6 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
7 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and add evaporation pond/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
8 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and evaporation pond/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
9 .....	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH at 7.
10 .....	Add pre-oxidation [if not in-place] and add Reverse Osmosis and add direct discharge waste disposal and add corrosion control [if >90% removal required].
11 .....	Add pre-oxidation [if not in-place] and add Reverse Osmosis and add POTW waste disposal and add corrosion control [if >90% removal required].
12 .....	Add pre-oxidation [if not in-place] and add Reverse Osmosis and add chemical precipitation/non-hazardous landfill and add corrosion control [if >90% removal required].
13 .....	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration and add mechanical dewatering/non-hazardous landfill waste disposal.
14 .....	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration and add non-mechanical dewatering/non-hazardous landfill waste disposal.
15 .....	Add pre-oxidation [if not in-place] and add Oxidation/Filtration (Greensand) and add POTW for backwash stream.
16 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and add chemical precipitation/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
17 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and add chemical precipitation/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
18 .....	Add pre-oxidation [if not in-place] and add Activated Alumina and add POTW/non-hazardous landfill waste disposal. pH at 7.
19 .....	Add pre-oxidation [if not in-place] and add POE Activated Alumina.
20 .....	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
21 .....	Add pre-oxidation [if not in-place] and add POU Activated Alumina.

Costs for each of these treatment trains are given in Table VIII-3. These costs are a function of system size. Some individual systems may experience household costs higher than those estimated in this table. The pre-oxidation costs and corrosion control costs are given separately for each system size category because they will only be incurred by some of the systems. In estimating national costs, it was assumed that only systems without pre-oxidation in-place would add the necessary equipment. It is expected that

no surface water systems will need to install pre-oxidation for arsenic removal. Based on Table IX-4, it is expected that fewer than 50% of the ground water systems may need to install pre-oxidation for arsenic removal. Ground water systems without pre-oxidation should determine if pre-oxidation is necessary by determining if the arsenic is present as As (III) or As (V). Groundwater systems with predominantly As (V) will probably not need pre-oxidation to meet the MCL. Similarly, costs for corrosion control

were only added to systems that used ion exchange or reverse osmosis to remove more than 90% of the arsenic in the raw water. It is expected that fewer than 1% of the affected systems will need to install corrosion control due to installation of arsenic treatment. For ion exchange, different treatment trains were used for two levels of sulfate. As sulfate affects regeneration frequency, the high sulfate treatment train is more expensive than the low sulfate treatment train.

TABLE VIII-3.—ANNUAL COSTS OF TREATMENT TRAINS (PER HOUSEHOLD)\*

Treatment train	Size							
	25-100 (dollars)	101-500 (dollars)	501-1000 (dollars)	1001-3300 (dollars)	3301-10K (dollars)	10K-50K (dollars)	50K-100K (dollars)	100K-1M (dollars)
1 .....	\$ 1347	\$ 202	\$ 77	\$ 25	\$ 8	\$ 2	\$ 1	\$ 0
2 .....	96	14	5	2	1	0	0	0
3 .....	750	138	70	40	30	26	22	18
4 .....	462	82	40	22	49	60	38	18
5 .....	519	146	90	106	73	55	44	39
6 .....	883	248	160	160	78	60	49	44
7 .....	629	226	153	154	108	84	71	58
8 .....	1227	469	333	290	197	165	135	88
9 .....	384	227	201	182	168	152	144	143
10 .....	2136	800	555	429	300	256	225	206
11 .....	2136	800	555	429	300	256	225	206
12 .....	2819	892	572	409	293	237	204	186
13 .....	1282	293	195	125	72	50	32	18
14 .....	1218	281	187	117	80	54	35	21
15 .....	558	156	102	72	55	42	37	31
16 .....	1008	222	121	128	86	58	46	40
17 .....	1050	246	115	114	96	66	52	45
18 .....	427	243	212	192	177	161	153	152
19 .....	467	427	408	388	367	342	327	298
20 .....	325	289	272	254	236	214	202	178
21 .....	377	334	314	292	271	245	230	202
pre-ox** .....	416	66	26	9	4	2	1	1
corros** .....	63	17	11	6	5	3	3	3

\*These costs are based on a discount rate of 7%.

\*\*The costs for treatment trains 1-21 do not include pre-oxidation or corrosion control costs. For systems that need to add pre-oxidation or corrosion control, the costs for these additional treatments should be added to those of the trains shown in the table.

C. How Are Variance and Compliance Technologies Identified for Small Systems?

Section 1415(e)(1) of SDWA allows States to grant variances to small water systems (i.e., systems having fewer than 10,000 customers) in lieu of complying with an MCL if EPA determines that there are no nationally affordable compliance technologies for that system size/water quality combination. The system must then install an EPA-listed variance treatment technology (section 1412(b)(15)) that makes progress toward the MCL, if not necessarily reaching it. To list variance technologies, three showings must be made:

(1) EPA must determine, on a national level, that there are no compliance technologies that are affordable for the

given small system size category/source water quality combination.

(2) If there is no nationally affordable compliance technology, then EPA must identify a variance technology that may not reach the MCL but that will allow small systems to make progress toward the MCL (it must achieve the maximum reduction affordable). This technology must be listed as a small systems variance technology by EPA in order for small systems to be able to rely on it for regulatory purposes.

(3) EPA must make a finding on a national level, that use of the variance technology would be protective of public health and establish.

Primacy States must then make a site-specific determination for each system as to whether or not the system can afford to meet the MCL based on State-

developed affordability criteria. If the State determines that compliance is not affordable for the system, it may grant a variance, but it must establish terms and conditions, as necessary, to ensure that the variance is adequately protective of human health.

In the Agency's draft national-level affordability criteria published in the August 6, 1998 **Federal Register** (US EPA, 1998h), EPA discussed the affordable treatment technology determinations for the contaminants regulated before 1996. The national-level affordability criteria were derived as follows. First an "affordability threshold" (i.e., the total annual household water bill that would be considered affordable) was calculated. In developing this threshold value, EPA considered the percentage of median

household income spent by an average household on comparable goods and services such items as housing (28%), transportation (16%), food (12%), energy and fuels (3.3%), telephone (1.9%), water and other public services (0.7%), entertainment (4.4%) and alcohol and tobacco (1.5%).

Another of the key factors that EPA used to select an affordability threshold was cost comparisons with other risk reduction activities for drinking water. Section 1412(b)(4)(E)(ii) of the SDWA identifies both Point-of-Entry and Point-of-Use devices as options for compliance technologies. EPA examined the projected costs of these options. EPA also investigated the costs associated with supplying bottled water for drinking and cooking purposes. The median income percentages that were associated with these risk reduction activities were: Point-of-Entry (>2.5%), Point-of-Use (2%) and bottled water (>2.5%). The complete rationale for EPA's selection of 2.5% as the affordability threshold is described in Variance Technology Findings for Contaminants Regulated Before 1996 (US EPA, 1998f).

Based on the foregoing analysis, EPA developed an affordability criteria of 2.5% of median household income, or about \$750, for the affordability threshold (US EPA 1998f). The median water bill for households in each small system category was then subtracted from this threshold to determine the affordable level of household expenditures for new treatment. This difference is referred to as the "available expenditure margin." Based on EPA's 1995 Community Water System Survey, median water bills were about \$250 per year for small system customers. Thus, an average available expenditure margin of up to \$500 per year was considered affordable for the contaminants regulated before 1996. However, EPA expects the available expenditure margin may be lower than \$500 per household per year for the arsenic rule because EPA believes that water rates are currently increasing faster than median household income. Thus, the "baseline" for annual water bills will rise as treatment is installed for compliance with regulations promulgated after 1996, but before the arsenic rule is promulgated.

To account for this, EPA intends to adjust its calculation of the baseline for the affordability criteria as follows. The national median annual household water bills for each size category will be adjusted by averaging the total national costs for the size category over all of the systems within the size category. In other words, the costs incurred by these

rules at the affected water systems will be averaged over all of the systems in that size category. A revised available expenditure margin will be calculated by subtracting the new baseline from the affordability threshold. The affordable technology determinations will be made by comparing the projected costs of treatment against the lower available expenditure margin. If the projected costs of all treatment technologies for a given system size/source water quality exceed the revised available expenditure margin, then variance technologies could be considered for those systems. EPA requests comment on this method of accounting for new regulations in its affordability criteria.

Applying the affordability criterion to the case of arsenic in drinking water, EPA has determined that affordable technologies exist for all system size categories and has therefore not identified a variance technology for any system size or source water combination at the proposed MCL. (See Table IX-12, Total Annual Costs per Household.) In other words, annual household costs are projected to be below the available affordability threshold for all system size categories for the proposed MCL. EPA solicits comment on its determination in this case as well as its affordability criteria more generally.

EPA recognizes that individual water systems may have higher than average treatment costs, fewer than average households to absorb these costs, or lower than average incomes, but believes that the affordability criteria should be based on characteristics of typical systems and should not address situations where costs might be extremely high or low or excessively burdensome. EPA believes that there are other mechanisms that may address these situations to a certain extent, such as rates for disadvantaged communities and grants. For instance, many utilities extend special "lifeline" rates to disadvantaged communities.

EPA also notes that high water costs are often associated with systems that have already installed treatment to comply with a NPDWR. Such treatment facilities may also facilitate compliance with future standards. EPA's approach to establishing the national-level affordability criteria did not incorporate a baseline for in-place treatment technology. Assuming that systems with high baseline water costs would need to install a new treatment technology to comply with a NPDWR may thus overestimate the actual costs for some systems.

To investigate this issue, EPA examined a group of five small surface water systems with annual water bills

above \$500 per household per year during the derivation of the national-level affordability criteria. All of these systems had installed disinfection and filtration technologies to comply with the surface water treatment rule. If these systems exceeded the revised arsenic standard, modification of the existing processes would be much more cost-effective than adding a new technology to comply with the arsenic rule. These systems have already made the investment in treatment technology and that is reflected in the current annual household water bills.

In addition, systems that meet criteria established by the State could be classified as disadvantaged communities under section 1452(d) of the SDWA. They can receive additional subsidization under the Drinking Water State Revolving Fund (DWSRF) program, including forgiveness of principal. Under DWSRF, States must provide a minimum of 15% of the available funds for loans to small communities and have the option of providing up to 30% of the grant to provide additional loan subsidies to the disadvantaged systems, as defined by the State.

As previously noted in today's proposal, some technologies can interfere with treatment in-place or require additional treatment to address side effects which will increase costs over the arsenic treatment technology base costs. (An example is corrosion control for lead and copper, which may need to be adjusted to accommodate other treatment). While EPA tries to account for such interferences in its cost estimates for each new compliance technology, it is not possible to anticipate all the site specific issues which may arise. However, EPA has included a discussion of the co-occurrence of radon, sulfate, and iron in this proposal. EPA will also provide guidance identifying cost-effective treatment trains for ground water systems that need to treat for both arsenic and radon after the arsenic rule is finalized.

EPA encourages small systems to discuss their infrastructure needs for complying with the arsenic rule with their primacy agency to determine their eligibility for DWSRF loans, and if eligible, to ask for assistance in applying for the loans.

#### *D. When Are Exemptions Available?*

Under section 1416(a), the State may exempt a public water system from any MCL and/or treatment technique requirement if it finds that (1) due to compelling factors (which may include economic factors), the system is unable

to comply or develop an alternative supply, (2) the system was in operation on the effective date of the MCL or treatment technique requirement, or, for a newer system, that no reasonable alternative source of drinking water is available to that system, (3) the exemption will not result in an unreasonable risk to health, and (4) management or restructuring changes cannot be made that would result in compliance with this rule. Under section 1416(b), at the same time it grants an exemption the State is to prescribe a compliance schedule and a schedule for implementation of any required control measures. The final date for compliance may not exceed three years after the NPDWR effective date except that the exemption can be renewed for small systems for limited time periods.

*E. What Are the Small Systems Compliance Technologies?*

Section 1412(b)(4)(E)(ii) of SDWA, as amended in 1996, requires EPA to issue

a list of technologies that achieve compliance with MCLs established under the Act that are affordable and applicable to typical small drinking water systems. These small public water systems categories are: (1) Population of more than 25 but less than 500; (2) Population of more than 500, but less than 3,300; and (3) Population of more than 3,300, but less than 10,000. Owners and operators may choose any technology or technique that best suits their conditions, as long as the MCL is met.

Of the treatment trains identified in section VIII.B., the ones identified in Table VIII-4 are deemed to be affordable for systems serving 25-500 people and the ones identified in Table VIII-5 are deemed to be affordable for systems serving 501-3,300 and 3,301-10,000 people, as their annual costs are below the affordability threshold (US EPA, 1999g). Because affordable compliance technologies are available, the Agency does not propose to identify any variance technologies. EPA requests

comments on the affordable compliance technology determinations for the three size categories and the determination that there will be no variance technologies. Centralized compliance treatment technologies include ion exchange, activated alumina, modified coagulation/filtration, modified lime softening, and oxidation/filtration (e.g. greensand filtration) for source waters high in iron. In addition, point-of-use (POU) and point-of-entry (POE) devices are also compliance technology options for the smaller systems. EPA is aware that very few water systems have had experience with centrally managed POU or POE options in the past. EPA requests comments on implementation issues associated with a centrally managed POU or POE option for arsenic. The non-treatment alternatives are especially relevant for small systems. EPA is proposing to add the abbreviations "POU" and "POE" to the definitions in § 141.2 and asks for comment on the utility of adding them.

TABLE VIII-4.—AFFORDABLE COMPLIANCE TECHNOLOGY TRAINS FOR SMALL SYSTEMS WITH POPULATION 25-500

Train No.	Treatment technology trains
3	Add pre-oxidation [if not in-place] and modify in-place Lime Softening
4	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration
5	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
6	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
7	Add pre-oxidation [if not in-place] and add Anion Exchange and add evaporation pond/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
8	Add pre-oxidation [if not in-place] and add Anion Exchange and evaporation pond/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
9	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH at 7.
15	Add pre-oxidation [if not in-place] and add Oxidation/Filtration (Greensand) and add POTW for backwash stream.
16	Add pre-oxidation [if not in-place] and add Anion Exchange and add chemical precipitation/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
17	Add pre-oxidation [if not in-place] and add Anion Exchange and add chemical precipitation/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
18	Add pre-oxidation [if not in-place] and add Activated Alumina and add POTW/non-hazardous landfill waste disposal. pH at 7.
19	Add pre-oxidation [if not in-place] and add POE Activated Alumina.
20	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
21	Add pre-oxidation [if not in-place] and add POU Activated Alumina.

TABLE VIII-5.—AFFORDABLE COMPLIANCE TECHNOLOGY TRAINS FOR SMALL SYSTEMS WITH POPULATIONS 501-3,300 AND 3,301 TO 10,000

Train No.	Treatment technology trains
3	Add pre-oxidation [if not in-place] and modify in-place Lime Softening
4	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration
5	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
6	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
7	Add pre-oxidation [if not in-place] and add Anion Exchange and add evaporation pond/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
8	Add pre-oxidation [if not in-place] and add Anion Exchange and evaporation pond/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.

TABLE VIII-5.—AFFORDABLE COMPLIANCE TECHNOLOGY TRAINS FOR SMALL SYSTEMS WITH POPULATIONS 501–3,300 AND 3,301 TO 10,000—Continued

Train No.	Treatment technology trains
9 .....	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH at 7.
10 .....	Add pre-oxidation [if not in-place] and add Reverse Osmosis and add direct discharge waste disposal and add corrosion control [if >90% removal required].
11 .....	Add pre-oxidation [if not in-place] and add Reverse Osmosis and add POTW waste disposal and add corrosion control [if >90% removal required].
12 .....	Add pre-oxidation [if not in-place] and add Reverse Osmosis and add chemical precipitation/non-hazardous landfill and add corrosion control [if >90% removal required].
13 .....	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration and add mechanical dewatering/non-hazardous landfill waste disposal.
14 .....	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration and add non-mechanical dewatering/non-hazardous landfill waste disposal.
15 .....	Add pre-oxidation [if not in-place] and add Oxidation/Filtration (Greensand) and add POTW for backwash stream.
16 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and add chemical precipitation/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 25 mg/l.
17 .....	Add pre-oxidation [if not in-place] and add Anion Exchange and add chemical precipitation/non-hazardous landfill waste disposal and add corrosion control [if >90% removal required]. Sulfate level at 150 mg/l.
18 .....	Add pre-oxidation [if not in-place] and add Activated Alumina and add POTW/non-hazardous landfill waste disposal. pH at 7.
19 .....	Add pre-oxidation [if not in-place] and add POE Activated Alumina.
20 .....	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
21 .....	Add pre-oxidation [if not in-place] and add POU Activated Alumina.

Centralized treatment is not always a feasible option. When this is the situation, home water treatment devices can be effective and affordable compliance options for small systems in meeting the proposed arsenic MCL. Home water treatment can consist of either whole-house (point-of-entry) or single faucet (point-of-use) treatment.

Whole-house, or POE treatment, is necessary when exposure to the contaminant by modes other than consumption is a concern; this is not the case with arsenic. Single faucet, or POU treatment, is preferred when treated water is needed only for drinking and cooking purposes. POU devices are especially applicable for systems that have a large flow and only a minor part of that flow directed for potable use. POE/POU options include reverse osmosis, activated alumina, and ion exchange processes. POU systems are easily installed and can be easily operated and maintained. In addition, these systems generally offer lower capital costs and may reduce engineering, legal, and other fees associated with centralized treatment options.

Allowing the usage of POU devices is one of the new elements of the Safe Drinking Water Act; on June 11, 1998, EPA issued a **Federal Register** notice (US EPA, 1998i) to withdraw the prohibition on the use of POU devices as compliance technologies. The SDWA stipulates that POU/POE treatment systems “shall be owned, controlled and maintained by the public water system,

or by a person under contract with the public water system to ensure proper operation and compliance with the MCL or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems.”

Using POU/POE devices introduces some new issues. Adopting a POU/POE treatment system in a small community requires more record-keeping to monitor individual devices than does central treatment. POU/POE systems require special regulations regarding customer responsibilities and water utility responsibilities. Use of POU/POE systems does not reduce the need for a well-maintained water distribution system. On the contrary, increased monitoring may be necessary to ensure that the treatment units are operating properly.

Water systems with high influent arsenic concentrations (*i.e.*, greater than 1 mg/L) may have difficulty meeting the proposed MCL when POU/POE devices are used. As a result, influent arsenic concentration and other source water characteristics must be considered when evaluating POU/POE devices for arsenic removal.

EPA assumed that systems would more likely opt to use POU AA or RO (and not IX), and POE AA (and not IX nor RO), when developing national cost estimates (refer to Table VIII-4).

Activated alumina and ion exchange units face a breakthrough issue. If the media or resin is not replaced and/or regenerated on time, there is a potential

for significantly reduced arsenic removal. Activated alumina units have the advantage of longer run lengths and the option to use the media once and throw it away. However, if POE ion exchange units are regenerated on time, they would also be an effective treatment technology. Units with automatic regeneration are thus viable options. POE IX and RO units also have a potential for creating corrosion control problems. With ion exchange POE units, a reduction in pH can be expected initially with new resin, but the pH reduction should subside over time.

*F. How Does the Arsenic Regulation Overlap With Other Regulations?*

Several Federal rules are under development regarding treatment requirements that may relate to the treatment of arsenic for this drinking water rule. The following briefly describes each rule, the impact the Arsenic Rule may have on that rule, and/or how each rule may impact the arsenic standard. The Arsenic Rule is expected to be promulgated in a similar time frame as the Ground Water Rule, the Radon Rule, and the Microbial and Disinfection By-Product Rule (Final December, 1998). In addition, the disposal of residuals may be affected by the hazardous waste regulations of the Resource Conservation and Recovery Act (RCRA).

*Ground Water Rule (GWR).* The goals of the GWR are to: (1) Provide a consistent level of public health protection; (2) prevent waterborne

microbial disease outbreaks; (3) reduce endemic waterborne disease; and (4) prevent fecal contamination from reaching consumers. EPA has the responsibility to develop a ground water rule which not only specifies the appropriate use of disinfection, but also addresses other components of ground water systems to assure public health protection. This general provision is supplemented with an additional requirement that EPA develop regulations specifying the use of disinfectants for ground water systems as necessary. To meet these requirements, EPA worked with stakeholders to develop a Ground Water Rule proposal (US EPA, 2000d) and plans to issue a final rule by late Fall 2000.

The GWR will result in more systems using disinfection. Under the GWR, a system has options other than disinfection (e.g., protecting source water). However, if a system does add a disinfection technology, it may contribute to arsenic pre-oxidation. This largely depends on the type of disinfection technology employed. If a system chooses a technology such as ultraviolet radiation, it may not affect arsenic pre-oxidation. However, if it chooses chlorination, it will contribute to arsenic pre-oxidation. As discussed previously, arsenic pre-oxidation from As (III) to As (V) will enhance the removal efficiencies of the technologies. In addition, systems may use membrane filtration for the GWR. In that case, depending on the size of the membrane, some arsenic removal can be achieved. Thus, the GWR is expected to alleviate some of the burden of the Arsenic Rule.

**Radon.** In the 1996 Amendments to the SDWA, Congress (section 1412(b)(13)) directed EPA to propose an MCLG and NPDWR for radon by August, 1999 (proposed on December 21, 1999, US EPA 1999n) and finalize the regulation by August, 2000 (section 1412(b)(13)). Like the Ground Water Rule, the Radon Rule will also be finalized before the Arsenic Rule. Systems may employ aeration to comply with the radon rule. Aeration alone, however, will not likely be sufficient to oxidize arsenic (III) to arsenic (V). However, if systems do aerate, they may be required by State regulations to also disinfect. The disinfection process may oxidize the arsenic, depending on the type of disinfection employed. Ultraviolet disinfection may not assist in arsenic oxidation (still under investigation by US EPA), whereas chemical disinfection or oxidation is likely to. Thus, the Radon Rule is expected to alleviate some of the burden of the Arsenic Rule.

**Microbial and Disinfection By-product Regulations.** To control disinfection and disinfection byproducts and to strengthen control of microbial pathogens in drinking water, EPA is developing a group of interrelated regulations, as required by the SDWA. These regulations, referred to collectively as the Microbial Disinfection By-product (M/DBP) Rules, are intended to address risk trade-offs between the two different types of contaminants.

EPA proposed a Stage 1 Disinfectants/Disinfection By-products Rule (DBPR) and Interim Enhanced Surface Water Treatment Rule (IESWTR) in July 1994. EPA issued the final Stage 1 DBPR and IESWTR in November, 1998.

The Agency has finalized and is currently implementing a third rule, the Information Collection Rule, that will provide data to support development of subsequent M/DBP regulations. These subsequent rules include a Stage 2 DBPR and a companion Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR).

The IESWTR will primarily affect large surface water systems, so EPA does not expect much overlap with small systems treating for arsenic. However, the Stage 1 DBPR will affect both large and small sized systems and may overlap with small systems treating for arsenic. In addition, the Stage 2 DBPR and possibly the LT2ESWTR would have significance as far as arsenic removal is concerned. For systems removing DBP precursors, systems may use nanofiltration. The use of nanofiltration would also be relevant for removing arsenic, and as a result, would ease some burden when systems implement these later rules.

**Hazardous Waste.** The current toxicity characteristic (TC) regulatory level for designating arsenic as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) is 5 mg/L and is listed in 40 CFR 261.24(a). It is important to differentiate between the toxicity characteristic and the toxicity characteristic leaching procedure (TCLP). The TCLP is the method by which a waste is evaluated to determine if it exceeds the toxicity characteristic. It is also important to note that while the toxicity characteristic was based on multiplying the current drinking water MCL by a factor of 100, the TC is not directly linked to the drinking water MCL. Thus, lowering the drinking water MCL does not mean that the toxicity characteristic would be lowered. A separate RCRA rulemaking would be required to lower the toxicity characteristic regulatory level. The drinking water standards for

several inorganic contaminants have been lowered without any lowering of the toxicity characteristic. For example, the cadmium MCL was lowered from 10 µg/L to 5 µg/L in 1991, but the TC for cadmium still remains at 1.0 mg/L. The drinking water standard for lead was revised from an MCL of 50 µg/L to an action level of 15 µg/L. Both drinking water standards were lowered in 1991. The TC for lead remains at 5 mg/L. The studies summarized below show that arsenic residuals should be below the current TC of 5 mg/L and could be disposed in a non-hazardous landfill.

In one study, sludges from four different water treatment plants were evaluated. (Bartley *et al.* 1992). There are data from two lime softening plants, one plant with both lime softening and coagulation/filtration processes, and one arsenic removal plant utilizing coagulation/filtration. The raw water arsenic in the two lime softening plants and the one plant using both lime softening and coagulation/filtration were below 0.001 mg/L. The arsenic removal plant was removing arsenic from 1.1 mg/L to 0.42 mg/L using ferric sulfate coagulation. The product water was blended with water from another source to comply with the MCL. The TCLP extracts ranged from 0.007 to 0.039 mg/L, which is considerably below the current criterion for being designated a hazardous waste under RCRA.

In another study, TCLP tests were performed using the activated alumina from two activated alumina plants (Wang *et al.*, 2000). Both plants had similar setups (one is referred to as CS, the other is referred to as BES). Both systems consist of four tanks of activated alumina with two parallel sets of two tanks in series. The first set of tanks are used as roughing filters and the second set of tanks are used as polishing filters. The units were not regenerated, but replaced. For the CS system, the influent arsenic concentration ranged from 0.053 to 0.087 mg/L with an average of 0.062 mg/L. The effluent arsenic concentration was consistently below 0.005 mg/L. When the activated alumina media was removed from the roughing filters, three samples were taken. All three samples had arsenic TCLP test results of less than 0.05 mg/L. Again, these results were well below the regulatory limit.

The influent arsenic concentration of the activated alumina plant referred to as BES ranged from 0.021 to 0.076 mg/L, with an average of 0.049 mg/L. Effluent levels were also less than 0.005 mg/L. When the media was removed from the two roughing filters, TCLP tests were taken. The results were <0.05 mg/L.

L and 0.066 mg/L. Again, the results were below the regulatory limit.

Another study examined residuals produced by anion exchange and coagulation-microfiltration (Clifford, 1997). Experiments were performed at the University of Houston-US EPA Drinking Water Research Facility, a 10 ft x 40 ft customized trailer containing various unit processes, including ion exchange and coagulation-microfiltration, and a small analytical lab. The mobile research facility was set up at the West Mesa Pump Station in Albuquerque, NM. The mean arsenic concentration in the source water was 0.021 mg/L.

Ion exchange was field tested, and the media was regenerated. This initial waste stream was a brine from the regeneration process. The brine in the ion exchange process was reused 15 times. The average arsenic concentration in the product was below 0.002 mg/L during the 15 cycles. The process produced a highly concentrated spent brine, with arsenic concentrations

reaching 26.6 mg/L. It should be noted that the arsenic concentration in the brine would be lower if the brine was not used as many times. After 6 months of storage, the arsenic concentration reduced to 11.3 mg/L. The arsenic was then precipitated out of the brine using iron, resulting in a brine with approximately 0.037 mg/L of arsenic. The precipitated sludge was then subjected to the TCLP extraction procedure. The TCLP extract had an average arsenic concentration of 0.270 mg/L. This is below the current threshold for being designated a hazardous waste.

Coagulation-microfiltration was also field tested. Arsenic removal to below 0.002 mg/L could be achieved; 12,000 gallons of water were filtered over 3 days. The backwash water, which is the process waste, had less than 0.5% solids. According to the TCLP Method 1311, for a liquid waste containing less than 0.5% solids, the liquid portion of the waste after filtration, is defined as the TCLP extract. About 20 backwash

samples were collected, filtered, and analyzed for arsenic. The average concentration in the backwash water after filtration was 0.0026 mg/L and thus could be disposed as a nonhazardous waste. Additionally, the simulated sludge was subjected to the TCLP leaching procedure. The arsenic concentration in the TCLP extract was 0.0218 mg/L, which is also considerably lower than the regulatory limit.

The University of Colorado performed a series of tests of various arsenic treatment solid residuals using the TCLP test (Amy et al, 1999). The arsenic treatment processes included conventional plants utilizing lime softening, alum and ferric chloride coagulation, activated alumina, and membranes. The results of this analysis for the conventional plant residuals are presented in Table VIII-6. The data indicates that all the plants would pass the current TCLP test although the data from the iron coagulation plant do approach the limit.

TABLE VIII-6.—TCLP RESULTS FOR CONVENTIONAL PLANT ARSENIC RESIDUALS

Utility ID	Type of utility	TCLP extract Arsenic (mg/L)
F, coagulation sludge .....	Lime softening .....	0.0009
F, softening sludge .....	Lime softening .....	0.0039
F, filter sludge .....	Lime softening .....	0.0014
G .....	Lime softening .....	0.002
J .....	Lime softening .....	0.0284
L .....	Alum coagulation .....	0.0093
C .....	Fe/Mn removal .....	0.0444
O .....	Iron coagulation .....	1.5596

Table VIII-7 is a summary of TCLP data on liquid residuals prepared by the University of Colorado for activated alumina regenerant and a reverse osmosis reject water precipitated with ferric chloride. The activated alumina regenerant solution was neutralized to a pH of 6, which caused the aluminum to precipitate and adsorb the arsenic. The membrane reject water was treated with ferric chloride to remove the arsenic and the resulting ferric hydroxide residual was tested. The data indicates that solid residuals generated from the alumina regenerant and membrane residuals would pass the TCLP test.

TABLE VIII-7.—TCLP TEST RESULTS FOR ACTIVATED ALUMINA AND MEMBRANE RESIDUALS

Sample	TCLP extract as (mg/L)
Activated Alumina Column Regenerant .....	0.0242

TABLE VIII-7.—TCLP TEST RESULTS FOR ACTIVATED ALUMINA AND MEMBRANE RESIDUALS—Continued

Sample	TCLP extract as (mg/L)
Membrane Filter Reject Residuals .....	0.0179

All of the previous data is from residuals produced by central treatment. There is no TCLP data on spent activated alumina from POU or POE devices. The TCLP results of spent activated alumina media from POU and POE devices were simulated by assuming a worst-case scenario for 6-month and one year replacement frequencies (Kempic, 2000). To determine the amount of arsenic that could potentially leach into the extraction fluid during the toxicity characteristic leaching procedure, it was assumed that the influent arsenic concentration was 0.050 mg/L and that

the activated alumina column adsorbed all of the arsenic. The first assumption represents the upper bound for influent concentrations since it is the current maximum contaminant level (MCL) for arsenic. The second assumption means that there would be no leakage or any breakthrough of arsenic through the column, which is not realistic. To calculate the total adsorbed arsenic mass, it was assumed that the POU unit treated 24 liters per day. This is the upper bound consumption used in the replacement frequency calculations.

Two other assumptions were made to simulate the worst-case scenarios. In the TCLP, the solid phase is extracted with an amount of extraction fluid equal to 20 times the weight of the solid phase. The dry media mass was used for the solid phase for this calculation rather than the wet media mass. It was also assumed that all of the adsorbed arsenic would leach into the extraction fluid, which is not realistic. The estimates for the worst-case scenarios are provided in Table VIII-8.

TABLE VIII-8.—TCLP PROJECTIONS FOR ACTIVATED ALUMINA WORST-CASE SIMULATIONS

Replacement frequency	Max TCLP Conc. (mg/L)
POU & 6-months .....	2.6
POE & 6-months .....	0.8
POU & Annual .....	10.4
POE & Annual .....	3.2

The projections for three of the worst-case scenarios were below the TC of 5 mg/L. The worst-case maximum TCLP concentration for annual replacement for a POU activated alumina device was above the TC. However, despite this projection, activated alumina waste should be non-hazardous. The most unrealistic assumption was that all of the arsenic adsorbed onto the alumina would leach into the extraction fluid. The TCLP uses weak acetic acid (0.57%) at pH 5 for the extraction fluid. The optimal pH for arsenic adsorption onto activated alumina is between pH 5.5 and 6.0. Therefore, arsenic should be retained on the activated alumina at this pH. In fact, adsorbed arsenic is extremely difficult to remove under any conditions. A strong base (4% NaOH) is typically used to regenerate activated alumina. Arsenic is so strongly adsorbed to the activated alumina that only 50 to 70% of the arsenic is eluted during regeneration. Therefore, it is extremely unlikely that the spent activated alumina from POU and POE units would be considered hazardous.

All of the TCLP data from solid residuals were below the current TC of 5 mg/L. The arsenic concentrations in TCLP extracts from alum coagulation, activated alumina, lime softening, iron/manganese removal, and coagulation-microfiltration residuals were below 0.05 mg/L, which is two orders of magnitude lower than the current TC regulatory level. The TCLP data for iron coagulation was mixed—the residuals from the arsenic removal plant were below 0.05 mg/L, but the residuals from another iron coagulation plant were above 1 mg/L. For anion exchange, the TCLP data on the precipitated brine stream was 0.27 mg/L. As was noted, this was a highly concentrated brine stream which had been used for fifteen regenerations. Arsenic concentrations in the precipitate would be lower if the brine was used for fewer regeneration cycles. Based on this data, EPA does not believe that drinking water treatment plant residuals would be classified as hazardous waste. The TCLP data also indicate that most residuals could meet a much lower TC regulatory level. EPA

requests comment on whether it is appropriate to assume that all residuals can be disposed at a non-hazardous landfill.

#### IX. Costs

##### A. Why Does EPA Analyze the Regulatory Burden?

EPA is responsible for issuing regulations that improve the quality of the nation's drinking water and reduce the risk of illness from exposure to harmful contaminants via drinking water supplied by public water systems (PWSs). As part of the regulatory development process, the Agency is required to analyze the regulatory cost and burden imposed on all regulated and affected entities and the benefits associated with the regulation. The Regulatory Impact Analysis (RIA) document is the principal summary of these analyses. Assessing the impacts of proposed SDWA regulations is a complex process, involving many analyses specified by various federal mandates. In particular, EPA must conduct analyses for the following mandates:

- 1996 Safe Water Drinking Act (SDWA) Amendments
- Paperwork Reduction Act (PRA)
- Regulatory Flexibility Act (RFA)
- Small Business Regulatory Enforcement Fairness Act (SBREFA)
- Unfunded Mandates Reform Act (UMRA)
- Executive Order (EO) 12866, "Regulatory Planning and Review"
- EO 12989, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations"
- EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks."

Executive Order 12866 describes the requirements for and content of the national cost-benefit analyses. Section 1412(b)(3)(C) of SDWA, as amended in 1996, directs EPA to seek comment on a health risk reduction and cost analysis (HRRCA) that will be issued with proposed MCLs. The HRRCA must identify quantifiable and nonquantifiable costs and health benefits of each MCL considered, including the incremental costs and benefits of each MCL considered. In addition, the HRRCA must identify benefits resulting from reducing co-occurring contaminants and exclude costs that will result from other proposed or final regulations. The Paperwork Reduction Act (PRA) requires federal agencies to document the cost and labor burden associated with data collection, recordkeeping, and

reporting requirements of proposed regulations. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), mandates that federal agencies consider the impact imposed on small businesses, governments, and non-profit organizations. The objective of these mandates is to provide regulatory relief to small entities affected by SDWA regulations by identifying alternative or lower-cost compliance options. Finally, the Unfunded Mandates Reform Act (UMRA) seeks to assess the burden and costs of federal regulations to local and State governments, while Executive Order 12989 on environmental justice instructs federal agencies to evaluate the impact of proposed regulations on minority and low-income populations. Executive Order 13045 requires EPA to state how the regulation addresses risks for children.

An RIA attempts to estimate the possible outcomes in terms of costs and benefits of various levels of regulation. At the most basic level, an RIA is built on estimates of the distribution of arsenic occurrence among the various water systems, the costs of treatment technologies, and predictions of responses by systems above the regulatory level under consideration. Because actual compliance monitoring at the proposed MCL has not been required of all systems at the time of proposal development, projections are based on statistical estimates. EPA believes that the current estimates include appropriate conservative assumptions and on average actual costs are not likely to exceed the estimates. One conservative assumption is that equipment useful life is identical to financing life. The Agency has a long term effort in progress to better characterize how much this issue will affect cost estimations.

To be complete, accurate, and consistent, these analyses should be based on a single, integrated set of data and information that defines the baseline characteristics or conditions of the regulated community prior to implementation of the regulation. The regulated community is primarily the water supply industry and State, local, and tribal governments. However, it is the customers of public water systems, especially community water systems, that ultimately incur the cost burden and realize the intended health benefits of these regulations. Therefore, the baseline study identifies and, where possible, quantifies the universe (e.g., characteristics of water suppliers, their customers, and governmental entities) to

be used in the regulatory impact analysis (RIA).

The current RIA applied national occurrence information in the modeling effort as described earlier in section V.G. EPA requests comment on its analyses for developing cost projections, including household costs, as well as additional cost information. Most previous RIAs conducted for the drinking water program assumed that all the water going into a system was the same concentration. Actually, many water systems (especially those serving more than 500 people) have multiple points where water enters the distribution system. Each of these entry points generally will have a different level of arsenic. Consequently, water systems tend to be impacted by regulations in stages that increase with decreasing regulatory level. Because costs are spread across the entire system, individual household expenditures will vary according to regulatory level. Past RIAs were unable to incorporate this information, and for costing purposes, all entry points to the distribution system required treatment. The arsenic RIA is the first drinking water chemical RIA to incorporate monte carlo simulation of intra-system occurrence variability into the cost and benefits estimation. This simulation permits more accurate characterization of the relative household impacts of various alternatives. Several other changes have also been incorporated into the cost and benefit estimates for the arsenic RIA:

*Very Large Systems*—Very large water systems, those serving more than a million people, can contribute a significant portion to estimates of overall costs and benefits at select regulatory levels. On the other hand, because there are so few of these systems and given that they are of complex configuration, statistically based estimates of arsenic occurrence (especially at low levels of arsenic incidence) introduce very large uncertainty into the RIA. EPA addressed this issue by developing individually tailored estimates through the use of generally available occurrence information and Information Collection Rule data. Estimates were provided to the utilities and they were offered the opportunity to correct errors in the Agency assessment. While these estimates are a considerable improvement over past ones, it is important to keep in mind that they are merely projections and that individual compliance costs could actually still vary by a wide margin depending upon rule timing, interactions with other treatment or capital budget priorities,

regulatory commission decisions, or actual compliance sampling results.

*Inventory Based Modeling*—Past RIAs have generally developed benefit and cost estimates by estimating impacts for single representative community water systems within a limited number of size-based classes. Such an approach introduces a slight positive bias to total national cost estimates. This RIA has gone beyond the past approach in the modeling of community water system and non-transient non-community water system impacts. This RIA uses a monte carlo approach to simulate application of occurrence information to the actual SDWIS inventory. Through repeated simulations and assignments, the model is able to develop the most robust [statistically defensible] estimates of actual exposure levels and to better characterize the spread in household costs.

#### *B. How Did EPA Prepare the Baseline Study?*

EPA identified baseline characteristics as the first step in standardizing baseline profiles and information for use across all Agency drinking water RIAs and related analyses. The Agency has several efforts underway to develop improved technical approaches for cost and benefit analyses, including developing characteristic engineering unit costs of treatment plants, assessing financial and operational capacity, and considering the low-cost best available treatment (BAT) options for small systems. Then, EPA reviewed the analytical procedures, and data requirements needed to conduct the analyses.

Table IX-1 provides an overview of the overall approach for identifying and classifying specific baseline characteristics. This matrix organizes the baseline characteristics according to the various entities likely to be affected by SDWA regulations and the different categories of data analysis inputs. The affected entities include:

- State and Tribal Governments: Agencies at the State or local level (including certain Tribes and Alaskan Native Villages) responsible for implementing, administering, and enforcing drinking water programs, and other programs potentially affected by Federal drinking water mandates.
- Public Water Suppliers: Utilities and other entities that provide potable water to 25 or more persons, 15 or more service connections (includes community and transient/non-transient non-community water systems).
- Customers: All entities that purchase drinking water from public water systems (including residential,

commercial, industrial, wholesale, governmental, agricultural, and other users).

The corresponding categories of data analysis inputs shown in Table IX-1 include:

1. Technical/Operational: Characteristics relating to capital assets and operational processes, labor skills and training, and other variable inputs.
  2. Managerial/Organizational: Characteristics relating to ownership, control and authority, organizational structure and management approach.
  3. Financial/Economic: Characteristics relating to monetary factors, opportunity costs, and benefits.
  4. Socio-Economic/Demographic: Composition and characteristics of affected entities (who, where, how much) and demographic trends.
- Data to describe all the baseline conditions shown in Table IX-1 are contained in a comprehensive EPA document designed to be applicable to all drinking water regulatory impact analyses, "The Baseline Handbook." It is data from this document which is used in Chapter 4 of the RIA for Arsenic.

#### 1. Use of Baseline Data

Uses of baseline data include the following analyses:

- National and Sub-National Benefits, Costs, and Economic Impact Analyses:
- Occurrence Analysis
  - Exposure/Risk Assessment
  - Model Plants/System Configuration
  - Unit Engineering Cost Analysis
  - Compliance Decision Tree Analysis
  - Financial Analysis
  - Government Implementation
  - Reporting, Recordkeeping, and Monitoring Costs
  - Valuation of Health Benefits
  - Non-Health Benefits Assessment
  - Economic Impact Assessment
- Small Entity Impact Analyses:
- Small Entity Definition
  - Reporting and Recordkeeping Requirements for Small Entities
  - Financial Analysis for Small Entities
  - Socio-Economic Analysis for Small Entities
  - Regulatory Alternatives Analysis
- Other Special Analyses:
- Health Risks to Sensitive Subpopulations
  - Affordability Analyses
  - Government Budgetary Effects

These broad analytical requirements reflect the overlapping nature of the required analyses pursuant to the relevant statutory and administrative mandates. For example, various mandates, including EO 12866, SDWA,

UMRA, and PRA, require national cost and benefit analyses.

2. Key Data Sources Used in the Baseline Analysis for the RIA?

A number of different data sources were employed in the development of the tables included Chapter 4 of the arsenic RIA. The key data sources used included:

*1995 Community Water System Survey (CWSS).* This database was compiled by EPA from a survey conducted in 1995 to profile the operational and financial characteristics of community water systems of all source, size, and ownership types.

*WATER STATS, The Water Utility Database.* This database was compiled by the

American Water Works Association from a 1996 survey of its member utilities. Data on water system operations and finances were collected in two stages. The first stage involved a comprehensive census of the largest water utilities (i.e., those serving 50,000 or more persons). A second stage data collection involved a statistical sample of smaller water utilities.

*Safe Drinking Water Information System (SDWIS).* This database serves as the U.S. EPA's comprehensive database of public water system regulatory compliance and violation information. SDWIS contains the Agency's inventory of all public water supplies, both community and noncommunity systems and the populations they serve.

*Survey on State Program Staffing/Funding for FY-97.* The Association of State Drinking Water Administrators (ASDWA) conducted a survey of State drinking water programs to solicit estimates on the number of staff (i.e., full-time equivalents, FTEs) involved in drinking water regulatory implementation and enforcement activities by program area, as well as estimates of drinking water program revenues/funding and expenditures by major account categories.

*1990 Census of Population.* Data from the 1990 Census of Population was used in conjunction with water system data to develop estimates for various demographic characteristics of households and communities served by public water systems.

TABLE IX-1.—SUMMARY OF GENERAL BASELINE CATEGORIES OF AFFECTED ENTITIES

Affected entity	Baseline characteristics			
	1: Technical & operational	2: Managerial & organizational	3: Economic & financial	4: Socioeconomic & demographic
A: State Government .....	A1.1 PWS Inspections & Sanitary Surveys.	A2.1 Program Staffing .... A2.2 Laboratory Capacity/Facilities. A2.3 Division of Authority/Jurisdiction.	A3.1 Program Expenditures. A3.2 Program Funding/Revenues.	A4.1 State PWS Profile.
B: Public Water Suppliers	B1.1 Water Sources/Intakes. B1.2 Source Contamination/Protection. B1.3 Physical Configuration. B1.4 Plant Condition ..... B1.5 Plant Flow/Capacity B1.6 Treatment/Waste Processes In-Place. B1.7 Storage Capacity ... B1.8 Distribution System B1.9 Residence Time .... B1.1 Monitoring/Laboratory.	B2.1 Ownership/Organizational Structure. B2.2 Plant Operation/Operators.	B3.1 Operating Expenses B3.2 Operating Revenues. B3.3 Non-Operating Expenses. B3.4 Assets & Liabilities B3.5 Rate Structures/ User Burden. B3.6 Capital Investment Expenditure.	B4.1 PWS Type. B4.2 PWS Size/Customer Base. B4.3 PWS Source Water. B4.4 Geographic Location.
C: Customers .....	C1.1 POU/POE Systems In Use.	C2.1 Alternative Water Use. C2.2 Public Attitudes/Perceptions.	C3.1 Residential Income C3.2 Nonresidential Income. C3.3 Residential Water Costs. C3.4 Nonresidential Water Costs. C3.5 Cost of Drinking Water Alternatives. C3.6 Medical Costs ..... C3.7 Non-Medical Costs C3.8 Community Financial Information.	C4.1 Population Profile. C4.2 Customer Water Use.

C. How Were Very Large System Costs Derived?

EPA must conduct a thorough cost-benefit analysis, and provide comprehensive, informative, and understandable information to the public about its regulatory efforts. As part of these analyses, EPA evaluated the regulatory costs of compliance for very large systems, who would be subject to the new arsenic drinking

water regulation. The nation's 25 largest drinking water systems (i.e., those serving a million people or more) supply approximately 38 million people and generally account for about 15 to 20 percent of all compliance-related costs. Accurately determining these costs for future regulations is critical. As a result, EPA has developed compliance cost estimates for the arsenic and radon regulations for each individual system that serves greater than 1 million

persons. These cost estimates help EPA to more accurately assess the cost impacts and benefits of the arsenic regulation. The estimates also help the Agency identify lower cost regulatory options and better understand current water systems' capabilities and constraints.

The system costs were calculated for the 24 public water systems that serve a retail population greater than 1 million persons and one public water

system that serves a wholesale population of 16 million persons. Table IX-2 lists these 25 public water systems. The distinguishing characteristics of these very large systems include:

- (1) A large number of entry points from diverse sources;
- (2) mixed (*i.e.*, ground and surface) sources;
- (3) Occurrence not conducive to mathematical modeling;
- (4) Significant levels of wholesaling;
- (5) Sophisticated in-place treatment;
- (6) Retrofit costs dramatically influenced by site-specific factors; and
- (7) Large amounts of waste management and disposal which can contribute substantial costs.

TABLE IX-2.—LIST OF LARGE WATER SYSTEMS THAT SERVE MORE THAN 1 MILLION PEOPLE

	PWS ID #	Utility name
1 .....	AZ0407025	Phoenix Municipal Water System.
2 .....	CA0110005	East Bay Municipal Utility District.
3 .....	CA1910067	Los Angeles—City Dept. of Water and Power.
4 .....	CA1910087	Metropolitan Water District of Southern California.
5 .....	CA3710020	San Diego—City of.
6 .....	CA3810001	San Francisco Water Department.
7 .....	CA4310011	San Jose Water Company.
8 .....	CO0116001	Denver Water Board.
9 .....	FL4130871	Miami-Dade Water And Sewer Authority—Main System.
10 .....	GA1210001	City of Atlanta.
11 .....	IL0316000	City of Chicago.
12 .....	MA6000000	Massachusetts Water Resource Authority.
13 .....	MD0150005	Washington Suburban Sanitation Commission.
14 .....	MD0300002	Baltimore City.
15 .....	MI0001800	City of Detroit.
16 .....	MO6010716	St. Louis County Water County.
17 .....	NY5110526	Suffolk County Water Authority.
18 .....	NY7003493	New York City Aqueduct System.
19 .....	OH1800311	City of Cleveland.
20 .....	PA1510001	Philadelphia Water Department.
21 .....	PR0002591	San Juan Metropolitan.
22 .....	TX0570004	Dallas Water Utility.
23 .....	TX1010013	City of Houston—Public Works Department.
24 .....	TX150018	San Antonio Water System.
25 .....	WA5377050	Seattle Public Utilities.

Generic models cannot incorporate all of these considerations; therefore, in-depth characterizations and cost analyses were developed utilizing several existing databases and surveys.

The profile for each system contains information such as design and average daily flows, treatment facility diagrams, chemical feed processes, water quality parameters, system layouts, and intake and aquifer locations. System and treatment data were obtained from the following sources:

- (1) The Information Collection Rule (1997);
- (2) The Community Water Supply Survey (1995);
- (3) The Association of Metropolitan Water Agencies Survey (1998);
- (4) The Safe Drinking Water Information System (SDWIS); and
- (5) The American Water Works Association WATERSTATS Survey (1997).

While these sources contained much of the information necessary to perform cost analyses, the Agency was still missing some of the detailed arsenic occurrence data in these large water systems. Where major gaps existed, especially in groundwater systems, occurrence data obtained from the

States of Texas, California, and Arizona, the Metropolitan Water District of Southern California Arsenic Study (1993), the National Inorganic and Radionuclides Study (EPA, 1984), and utilities were used. Based on data from the studies, detailed costs estimates were derived for each of the very large water systems.

Cost estimates were generated for each system at several MCL options. The total capital costs and operational and maintenance (O & M) costs were calculated using the profile information gathered on each system, conceptual designs (*i.e.*, vendor estimates and RS Means), and modified EPA cost models (*i.e.*, Water and WaterCost models). The models were modified based on the general cost assumptions developed in the Phase I Water Treatment Cost Upgrades (EPA, 1998).

Preliminary cost estimates were sent to all of the systems for their review. Approximately 30% of the systems responded by submitting revised estimates and/or detailed arsenic occurrence data. Based on the information received, EPA revised the cost estimates for those systems. Based on the results, the majority of the very large systems will not have capital or

O&M expenditures for complying with a MCL of 5 µg/L (Table IX-3). More detailed costs estimates for each very large water system can be found in the water docket.

TABLE IX-3.—TOTAL ANNUAL COSTS FOR LARGE SYSTEMS FOR (SERVING MORE THAN 1 MILLION PEOPLE)

MCL option (µg/L)	Number systems treating	Cost [\$millions] <sup>1</sup>
3 .....	3	\$16-18
5 .....	3	11-12
10 .....	3	6.6-7.47
20 .....	3	2.6-2.7

<sup>1</sup> The lower number shows costs annualized at 3%; the higher number shows costs annualized at 7% capital costs. The 7% rate represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations.

*D. How Did EPA Develop Cost Estimates?*

EPA developed national cost estimates by using the occurrence data, unit cost curves, and a decision tree. The occurrence data provides a measure of the number of systems that would need to install treatment in each size

category (the occurrence data was described in Section V). The unit cost curves provide a measure of how much a technology will cost to install. Unit cost curves are continuous functions; they are a function of system size and provide an estimated cost for all design and average flows. The costs for a treatment train for the average flow in each size category were given previously in Table VIII-3. The unit cost curves can be found in "Technologies and Costs for the Removal of Arsenic From Drinking Water" (US EPA, 1999i).

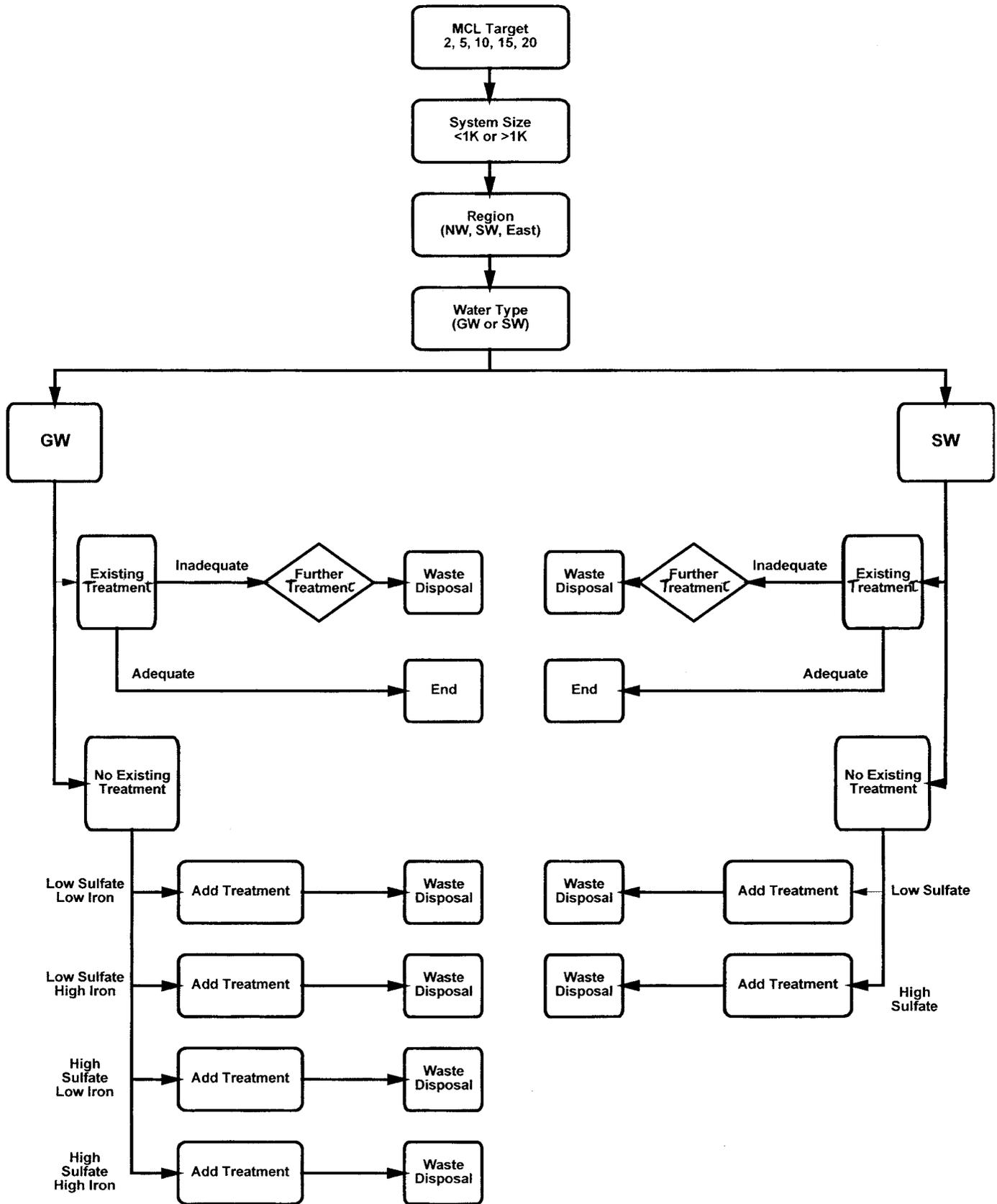
EPA then developed a decision tree, which is a prediction of what treatment technology trains facilities would likely install to comply with options

considered for the revised arsenic standard. A brief discussion of this decision tree follows. A copy of the full 300+ page flowchart and supporting documentation can be found in "Decision Tree for the Arsenic Rulemaking Process" (US EPA, 1999d). The following figure is a brief representation of this flowchart. As shown in the flowchart, EPA considered the impact of (1) MCL option and influent arsenic concentration; (2) system size; (3) regional effects (water scarcity); (4) source water type (that is, ground water or surface water); (5) existing treatment in-place; (6) waste disposal issues and costs; and (7) co-occurrence of iron and sulfate, to

estimate what systems are likely to install.

Ultimately, the decision tree was expressed in decision matrices, in which EPA assigned probabilities as to how often each of the treatment trains in Table VIII-2 will likely be used. EPA developed a different decision matrix for the eight system size categories, for three different removal efficiencies (<50%, 50-90% and >90%), and for two source waters (ground and surface). In general, to the extent possible (*e.g.*, based on source water quality), EPA assumed that systems would employ the least-cost technology that can meet the MCL option.

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*MCL option.* EPA developed a decision tree that accounted for treatment technology limitations, and only assigned non-zero probabilities in the matrices to those technologies capable of reaching each MCL option. The maximum removal percentages are given in Table VIII-1. For instance, since greensand filtration is only assumed capable of removing 50% of the influent arsenic, for an influent level of 20 µg/L, the technology is assumed to be capable of only producing product water with 10 µg/L of arsenic. Therefore, for an MCL option of 5 µg/L, no usage was assumed for greensand filtration at a 20 µg/L level of influent arsenic.

*System size.* The decision tree also depends on system size. For instance, small systems are assumed to operate activated alumina on a throw-away basis, and thus the probability of using a treatment train that employs on-site regeneration is assumed to be zero. The converse is true for large systems; non-zero probabilities are assumed only for those trains that employ regeneration on-site.

*Water scarcity.* Water scarcity was also taken under consideration when developing the decision tree. It was assumed that this issue would adversely affect the selection of reverse osmosis, since the technology rejects a significant

portion of the influent water. However, the costs for reverse osmosis treatment trains are much higher than others (refer to Table VIII-3), and systems would likely opt for other, less expensive, treatment options. For the range of MCL options considered, it was assumed that ion exchange would be capable of delivering the required removal efficiencies. Thus, water scarcity, though considered in the decision tree, did not affect percentages assigned to reverse osmosis.

*Source water type.* Source water type is also a factor in the decision tree. It affects the unit cost curves; one set of curves were developed for surface water, and another was developed for ground water. The treatment-in-place data and co-occurrence data (as shown below) are sorted by source water type. Also, certain technologies are considered appropriate for one source water type, but not the other. For instance, greensand filtration is considered relevant only for ground waters.

*Existing treatment in-place.* Treatments that may already exist at facilities were taken into account in the decision tree. It was assumed that systems would need to pre-oxidize, if they weren't doing so already. Table IX-4 shows the number of systems that

were assumed to require addition of pre-oxidation (Source: US EPA,1999e).

TABLE IX-4.—SYSTEMS NEEDING TO ADD PRE-OXIDATION

System size	Percent of ground water systems	Percent of surface water systems
25-100 .....	54	9
101-500 .....	30	4
501-1K .....	24	0
1,001-3.3K .....	24	0
3,301-10K .....	27	3
10,001-50K .....	13	1
50,001-100K .....	41	2
100,001-1 M .....	16	0

It was also assumed that those systems that had coagulation/filtration in place, or lime softening in place, would modify those treatments to optimize for arsenic removal, since it is a relatively inexpensive option. The percent of systems with these treatments in place is given in Table IX-5 (Source: US EPA,1999e). However, for higher removals (>90%), it was assumed that only half of the systems would be able to achieve the desired removal with a modification. For those systems, an additional cost of a polishing step, such as ion exchange, was added.

TABLE IX-5.—PERCENT OF SYSTEMS WITH COAGULATION-FILTRATION AND LIME-SOFTENING IN PLACE

System size	Percent of ground water systems with CF in place	Percent of surface water systems with CF in place	Percent of ground water systems with LS in place	Percent of surface water systems with LS in place
25-100 .....	2	22	3	4
101-500 .....	4	53	3	9
501-1K .....	2	73	2	19
1,001-3.3K .....	3	76	3	16
3,301-10K .....	8	85	3	7
10,001-50K .....	4	92	5	8
50,001-100K .....	4	85	3	5
100,001-1 M .....	5	94	10	5

*Waste disposal issues and costs.* Waste disposal of arsenic contaminated sludges and brines was also factored into the decision tree, and waste costs were added to the treatment trains. The waste disposal options for each of the technologies considered are given in Table IX-6. For ion exchange and activated alumina, it was assumed that the waste streams would be too concentrated to discharge directly. For these technologies, it was assumed that some of the smallest systems would be able to take advantage of evaporation

ponds, but that this option would be cost prohibitive in medium and large systems. It was assumed that most systems would opt for either chemical precipitation or discharge to a sanitary sewer. EPA also assumed that systems would dispose of spent activated alumina media in non-hazardous landfills. Costs for reverse osmosis are prohibitive (In Table VIII-3, Annual Costs of Treatment Trains, compare lines 11, 12, and 13 against other technologies), but if used, EPA assumed the relatively large amount of reject

water would be discharged directly (because it would not be as concentrated as ion exchange and activated alumina waste streams), to a sanitary sewer or by chemical precipitation. For coagulation assisted microfiltration, modified coagulation filtration, and modified lime softening, EPA assumed the waste would be discharged to non-hazardous landfills after the sludge is mechanically or non-mechanically dewatered. For greensand filtration, it was assumed that the spent media would be disposed of in a non-hazardous landfill.

TABLE IX-6.—WASTE DISPOSAL OPTIONS

Treatment tech	POTW waste disposal	Evap pond	Non-haz landfill	Direct discharge	Chemical precip	Mech dewater	Non-mech dewater
Ion Exchange .....	✓	✓			✓		
Activated Alumina .....	✓	✓	✓		✓		
Reverse Osmosis .....	✓			✓	✓		
Coag Assisted Micro-filtration .....			✓			✓	✓
Greensand .....			✓				
Modify CF .....			✓			✓	✓
Modify LS .....			✓			✓	✓

*Co-occurrence of iron and sulfate.* EPA also factored into the decision tree co-occurrence data on iron and sulfate (shown in Tables IX-7 to IX-10, Source: US EPA, 1999f). Co-occurrence of sulfate in water adversely affects the performance of ion exchange, and increases operation and maintenance costs. Three sulfate-level treatment trains were costed for ion exchange: one

low-level, one mid-level and one high-level. The percentages in Tables IX-7 to IX-8 were used as ceilings in national cost estimates and limited the number of systems that could be placed in the decision matrices in the low-level and mid-level sulfate ranges. For example, the co-occurrence data shows that the maximum number of systems that can be costed at the low-level sulfate

treatment train for an influent level of arsenic between 10 and 20 µg/L is 35%. If more systems were to be placed in the decision matrices under ion exchange, no more than 39% were assumed to face a sulfate level between 25 and 120 mg/L. Any more systems assigned to ion exchange in the decision matrices were assumed to face high sulfate levels.

TABLE IX-7.—GROUND WATER: ARSENIC AND SULFATE

Influent arsenic	Likelihood of sulfate (percent)		
	<25 mg/L	25-120 mg/L	>120 mg/L
<10 µg/L .....	48	33	19
10-20 µg/L .....	35	39	26
>20 µg/L .....	33	38	30

TABLE IX-8.—ARSENIC WATER: ARSENIC AND SULFATE

Influent arsenic	Likelihood of sulfate (percent)		
	<25 mg/L	25-120 mg/L	>120 mg/L
<10 µg/L .....	28	32	40
10-20 µg/L .....	20	30	51
>20 µg/L .....	12	28	60

TABLE IX-9.—GROUND WATER: ARSENIC AND IRON

Influent arsenic	Likelihood of sulfate (percent)	
	<300 µg/L	>300 µg/L
<10 µg/L .....	82	18
10-20 µg/L .....	81	19
>20 µg/L .....	71	29

TABLE IX-10.—SURFACE WATER: ARSENIC AND IRON

Influent arsenic	Likelihood of sulfate (percent)	
	<300 µg/L	>300 µg/L
<10 µg/L .....	91	9
10-20 µg/L .....	92	8
>20 µg/L .....	90	10

Co-occurrence of iron in water improves the performance of greensand filtration. Greensand is relatively inexpensive for small systems to use, but not as effective as other treatment technologies. It was assumed that systems would opt for greensand filtration only if the level of iron was greater than 300 µg/L. EPA used the co-occurrence data in Tables IX-9 to IX-10

to determine the ceiling on the number of systems that could use greensand filtration in the decision matrices.

*E. What Are the National Treatment Costs of Different MCL Options?*

Under the proposed option of 5 µg/L, the Agency estimates that annual treatment costs to community water systems will be \$374 million per year. If required to treat at the proposed level,

treatment costs to non-community non-transient systems would be \$15 million per year. National annual costs for the MCL options considered (3, 5, 10, and 20 µg/L) are provided in Table IX-11.

TABLE IX-11.—NATIONAL ANNUAL TREATMENT COSTS  
[Dollars in millions]

MCL option (µg/L)	Community water systems	Non-community Non-transient systems	Total treatment costs
3 .....	\$639	\$25	\$664
5 .....	374	15	389
10 .....	160	6	166
20 .....	59	2	61

Total annual costs per household are given in Table IX-12. Due to economies of scale, costs per household are higher in the smaller size categories, and lower in the larger size categories. For the proposed option of 0.005 µg/L, costs are expected to be \$364 per household for systems serving 25-100 people, and \$254 per household for systems serving

101-500 people. Costs per households in systems larger than those are substantially lower: from \$104 to \$21 per household. Costs per household do not vary dramatically across MCL options. This is because of the fact that once a system installs a treatment technology to meet an MCL target, costs do not vary significantly based upon the

removal efficiency it will be operated under. Costs are, however, somewhat lower at less stringent MCL options. This is because it was assumed that some systems would blend water at these options, and treat only a portion of the flow.

TABLE IX-12.—TOTAL ANNUAL COSTS PER HOUSEHOLD  
[Dollars]

System size	3 µg/L	5 µg/L	10 µg/L	20 µg/L
25-100 .....	\$368	\$364	\$357	\$349
101-500 .....	259	254	246	238
501-1K .....	106	104	98	93
1K-3.3K .....	64	60	57	52
3.3K-10K .....	44	41	37	33
10K-50K .....	36	33	29	25
50K-100K .....	30	27	23	19
100K-1M .....	23	21	18	15

Incremental costs are given in Tables IX-13 and IX-14. Incremental costs refer to the dollars that must be spent to obtain the next, more stringent, level of control. The national and household

costs under 20 µg/L refer to the amount that must be spent to reach 20 µg/L starting from the baseline of 50 µg/L. The dollar value under 10 µg/L represents the cost differential between

20 µg/L and 10 µg/L. The values under 5 µg/L and 3 µg/L were derived similarly.

TABLE IX-13.—INCREMENTAL NATIONAL ANNUAL COSTS  
[Dollars in millions]

MCL option (µg/L)	Community water systems	Non-community non-transient water systems	Total
20 .....	\$59	\$2	\$61
10 .....	101	4	105
5 .....	214	9	223
3 .....	265	19	275

TABLE IX-14.—INCREMENTAL ANNUAL COSTS PER HOUSEHOLD  
[Dollars]

System size	20 µg/L	10 µg/L	5 µg/L	3 µg/L
25-100 .....	\$349	\$8	\$7	\$4
101-500 .....	238	8	8	5
501-1K .....	93	5	6	2
1K-3.3K .....	52	5	3	4
3.3K-10K .....	33	4	4	3

TABLE IX-14.—INCREMENTAL ANNUAL COSTS PER HOUSEHOLD—Continued  
[Dollars]

System size	20 µg/L	10 µg/L	5 µg/L	3 µg/L
10K-50K .....	25	4	4	3
50K-100K .....	19	4	4	3
100K-1M .....	15	3	3	2

In the process of analyzing treatment technologies and developing cost estimates, EPA held several meetings with stakeholders to obtain input on assumptions made. Several of the key assumptions agreed to by stakeholders are given below.

#### 1. Assumptions Affecting the Development of the Decision Tree

- EPA assumed that ion exchange usage would be prohibited above 120 mg/L of sulfate and 500 mg/L of TDS.
- EPA assumed that greensand filtration would be used only if iron in the raw water was above 300 µg/L.
- EPA assumed that systems would pre-oxidize, when existing chlorination or other oxidants are not already present.
- EPA assumed that systems would not likely use POE-RO nor POE-IX because of corrosion control problems. Also, with IX, if the resin is not replaced and/or regenerated on time, there is a potential for arsenic peaking. EPA assumed that systems will most likely use POE-AA.
- The breakthrough issue also exists with POU-IX. POU-AA has the advantage of a longer run length. EPA assumed that systems would use either POU-AA or POU-RO.

#### 2. Assumptions Affecting Unit Cost Curves

- There are significant safety and operating efficiency risks to small systems when adjusting downward. This pH adjustment would require much more oversight than most small systems will have. EPA, in calculating unit costs for activate alumina assumed that systems would not adjust pH downward; thus, AA will be operated at a sub-optimal pH.
- There is a danger of operating technologies such as ion exchange near breakthrough. EPA incorporated a safety factor, and used 80% of the MCL as the target when calculating costs for all technologies.
- EPA assumed that small systems would not regenerate Activated Alumina on site—AA will likely be operated on a “throw-away” basis.
- For modifying coagulation/filtration, EPA considered the cost of a new chemical feed system when

switching to iron. EPA costed out switching coagulants for high removals. For lower removals, EPA costed out optimizing alum usage.

- EPA assumed 75% for RO recovery.
- For Activated Alumina, EPA assumed that there will not be any systems with raw water in the optimal range for arsenic removal (pH between 5.5–6.0).
- For iron-coagulation-micro-filtration EPA assumed systems would apply a stronger iron dose rather than adjusting to optimum pH.
- For ion exchange, one or more regenerations per day is not problematic. Regeneration in Ion Exchange can be done automatically. EPA examined cost models on regeneration frequency, volume of waste generated and considered computer-automation for regeneration.

#### X. Benefits of Arsenic Reduction

The benefits associated with reductions of arsenic in drinking water arise from a reduction in the risk of adverse human health effects, and a corresponding decrease in the number of expected cases and premature deaths of people experiencing these effects. The various adverse health effects associated with arsenic are known with different levels of certainty. Presently some can be quantified and some cannot. The best characterized benefits can be both quantified and monetized (*i.e.*, a dollar value is attached to the expected decrease in number of cases), while other benefits may be only known well enough to describe. The latter are known as qualitative benefits. The Safe Drinking Water Act (SDWA) amendments of 1996 require that EPA fully consider both quantifiable and non-quantifiable benefits that result from drinking water regulations.

The first step in the benefits evaluation process is to consider the adverse health effects that may be expected to decrease with a reduction in the concentrations of arsenic in drinking water. Arsenic has many health effects, both cancer and non-cancer. Section III. discusses these health effects.

As discussed in section VIII.A., treatment for arsenic removal may add or remove other contaminants. Using chlorine or other oxidants may increase

risk from disinfection by-products. On the other hand, treatments put in place for arsenic may incidentally reduce the risk from other co-occurring contaminants.

#### A. Monetized Benefits of Avoiding Bladder Cancer

Reducing arsenic levels in tap water will reduce the risks of suffering the adverse health effects described in the previous sections. In 1999 the National Research Council examined several risk distributions for male bladder cancer in 42 villages in Taiwan with arsenic ranging from 10 to 934 µg/L, grouping arsenic exposure by village. Previous scientific studies analyzed risk using less specific exposure categories, which can obscure “the true shape of the dose response curve (NRC 1999, page 273).” Risk assessments for other adverse health effects have not been as thoroughly addressed.

To monetize bladder cancer benefits, EPA calculated the number of cases potentially avoided based on the NRC bladder cancer risk analyses. The cases are evaluated in terms of the economic benefits associated with avoiding the cancer cases.

In addition to the monetized benefits of avoiding bladder cancer, EPA has chosen to monetize the potential benefits of avoided lung cancer, using a “What If” analysis based on statements in the NRC report (see section X.B for applying the “what-if” scenario to lung cancer).

#### 1. Risk Reductions: The Analytic Approach

EPA applied the 1999 NRC bladder cancer risk assessment to U.S. males and females. The following sections explain how we calculated risk reductions for populations exposed to MCL options of 3 µg/L and above. The approach for this analysis included five components. First, EPA used data from the recent EPA water consumption study. This study is described in section X.A.2. Second, Monte Carlo simulations (section X.A.3) were used to develop relative exposure factors (section X.A.4). Third, arsenic occurrence estimates were used to identify the population exposed to levels above 3 µg/L. Fourth, NRC risk distributions were chosen for

the analysis. Fifth, EPA developed estimates of the risks faced by exposed populations using Monte Carlo simulations, using the relative exposure factors, occurrence, and NRC risk distributions mentioned above. These components of the analysis are described in the following sections.

2. Water Consumption

EPA recently updated its estimates of personal (per capita) daily average estimates of water consumption (“Estimated per Capita Water

Consumption in the United States,” EPA 2000a). The estimates used data from the combined 1994, 1995, and 1996 Continuing Survey of Food Intakes by Individuals (CSFII), conducted by the U.S. Department of Agriculture (USDA). The CSFII is a complex, multistage area probability sample of the entire U.S. and is conducted to survey the food and beverage intake of the U.S. Estimates of water consumed include direct water, indirect water and total water (Table X-1). “Direct” water is tap water consumed directly as a beverage.

“Indirect” water is defined as water added to foods and beverages during final preparation at home or by food service establishments such as school cafeterias and restaurants. For the purpose of the report, indirect water did not include “intrinsic” water which consists of water found naturally in foods (biological water) and water added by commercial food and beverage manufactures (commercial water). “Total” water refers to combined direct and indirect water consumption.

TABLE X-1.—SOURCE OF WATER CONSUMED

Source	Direct (drinking)	Indirect (from food and beverages)	Bottled water
Community Tap .....	X	X	
Well Tap .....	X	X	
Total .....	X	X	X

Per capita water consumption estimates are reported by source. Sources include community/tap water, bottled water, and water from other sources, including water from household wells and rain cisterns, and household and public springs. For each source, the mean and percentiles of the distribution of average daily per capita consumption are reported. The estimates are based on an average of 2 days of reported consumption by survey respondents.

The estimated mean daily average per capita consumption of community/tap water by individuals in the U.S. population is 1 liter/person/day. For total water, which includes bottled water, the estimated mean daily average per capita consumption is 1.2 liters per person/day. These estimates of water consumption are based on a sample of 15,303 individuals in the 50 States and the District of Columbia. The sample was selected to represent the entire population of the U.S. based on 1990 census data.

The estimated 90th percentile of the empirical distribution of daily average per capita consumption of community/tap water for the U.S. population is 2.1 liters/person/day; the corresponding number for daily average per capita consumption of total water is 2.3 liters/person/day. In other words, current consumption data indicate that 90 percent of the U.S. population consumes up to approximately 2 liters/person/day, which is the amount many federal agencies use as a standard consumption value.

Water consumption estimates for selected subpopulations in the U.S. are

described in the analysis, including per capita water consumption by source for gender, region, age categories, economic status, race, and residential status and separately for pregnant women, lactating women, and women in childbearing years. The water consumption estimates by age were used in the computation of the relative exposure factors discussed in the section X.A.4.

These water consumption numbers differ somewhat from previous estimates reported in earlier studies. The mean per capita daily intake of total tap water, as estimated from the 1977–78 USDA’s Nationwide Food Consumption Survey, was 1.193 liters/person/day (reported by Ershow and Cantor in 1989). Based on the 1977–78 study, the estimated percentile corresponding to 2 liters per day consumed is the 88th.

3. Monte Carlo Analysis

Monte Carlo analysis is a technique for analyzing problems where there are a large number of combinations of input values that are too large to calculate for every possible result. A random number generator is used to generate numbers that correspond to assumptions about the distribution or likelihood of various input values. For each set of random input values a single outcome is calculated. As the simulation runs, the outcome is recalculated for each new set of input values and continues until a stopping criterion is reached. The accuracy of this technique, like other statistical techniques, depends on the accuracy of the underlying assumptions about the distribution of input values; it

does not resolve the uncertainty behind the assumptions. For the risk distributions calculated in this report, the simulations were carried out 2,000 times. For each simulation, a relative exposure factor, occurrence estimate, and individual risk estimate were calculated. These calculations resulted in estimates of the risks faced by populations exposed to arsenic concentrations in their drinking water. The underlying risk distribution are described in the following sections.

4. Relative Exposure Factors

EPA used models to integrate the new drinking water consumption study information into the benefits analysis. We used distributions for both community/tap water and total water consumption because the community water/tap water estimates may underestimate actual tap water consumption. In this analysis, we combined the water consumption data with data on population weight from the U.S. Census. The weight data included a mean and a distribution of weight for male and females on a year-to-year basis throughout a lifetime. Monte Carlo analysis generated male and female relative exposure factors (REFs) for each of the broad age categories used in the water consumption study. Lifetime male and female relative exposure factors were then estimated, where the factors show the sensitivity of exposure to an individual weighing 70 kilograms and consuming 2 liters of water per day. These life-long REFs can be directly multiplied by the average drinking water consumption to provide estimates of individual lifetime consumption

practices. The REFs provide a means to incorporate information on various age groups, for example children, into the analysis, as weight and water consumption vary among age groups. The means and variances of the REFs derived from this analysis were: for community water consumption (0.60, 0.37 males; 0.64, 0.36 females), for total water consumption (0.73, 0.39 males; 0.79, 0.37 females).

##### 5. NRC Risk Distributions

While the NRC's work did not constitute a formal risk analysis, they did examine many statistical issues (e.g., measurement errors, age-specific probabilities, body weight, water consumption rate, comparison populations, mortality rates, choice of model) and provided a starting point for additional EPA analyses. The report noted that "poor nutrition, low selenium concentrations in Taiwan, genetic and cultural characteristics, and arsenic intake from food" were not accounted for in their analysis (NRC, 1999, pg. 295).

In its 1999 report, "Arsenic in Drinking Water," the NRC analyzed bladder cancer risks using data from Taiwan. In addition, NRC examined evidence from human epidemiological studies in Chile and Argentina, and concluded that risks of bladder and lung cancer were comparable to those "in Taiwan at comparable levels of exposure (NRC 1999, page 7)." The NRC also examined the implications of applying different mathematical procedures to the newly available Taiwanese data for the purpose of characterizing bladder cancer risk. These risk distributions are based on bladder cancer mortality data in Taiwan, in a section of Taiwan where arsenic concentrations in the water are very high by comparison to those in the U.S. It is also an area of very low incomes and poor diets, and the availability and quality of medical care is not of high quality, by U.S. standards. In its estimate of bladder cancer risk, the Agency assumed that within the Taiwanese study area, the risk of contracting bladder cancer was relatively close to the risk of dying from bladder cancer (that is, that the bladder cancer incidence rate was equal to the bladder cancer mortality rate). At the time the study data were collected the chances of surviving were probably poor for individuals diagnosed with bladder cancer. We do not have data, however, on the rates of survival for bladder cancer in the Taiwanese villages in the study and at the time of data collection. We do know that the relative survival rates for bladder cancer in developing

countries overall ranged from 23.5% to 66.1% in 1982–1992 ("Cancer Survival in Developing Countries," International Agency for Research on Cancer, World Health Organization, Publication No. 145, 1998). We also have some information on annual bladder cancer mortality and incidence for the general population of Taiwan in 1996. The age-adjusted annual incidence rates of bladder cancer for males and females, respectively, were 7.36 and 3.09 per 100,000, with corresponding annual mortality rates of 3.21 and 1.44 per 100,000 (correspondence from Chen to Herman Gibb, January 3, 2000).

Assuming that the proportion of males and females in the population is equal, these numbers imply that the mortality rate for bladder cancer in the general population of Taiwan, at present, is 45%. Since survival rates have most likely improved over the years since the original Taiwanese study, this number represents a lower bound on the survival rate for the original area under study (that is, one would not expect a higher rate of survival in that area at that time). This has implications for the bladder cancer risk estimates from the Taiwan data. For this estimate we have made the assumption that all bladder tumors in the study area in Taiwan were fatal. If there were any persons with bladder cancer who recovered and died from some other cause, then our estimate underestimated risk; that is, there were more cancer cases than cancer deaths. Based on the above discussion, we think bladder cancer incidence could be no more than 2 fold bladder cancer mortality; and that an 80% mortality rate would be plausible. In the benefits analysis we include estimates using an assumed mortality rate ranging from 80% to 100%.

In the U.S. approximately one out of four individuals who is diagnosed with bladder cancer actually dies from bladder cancer. The mortality rate for the U.S. is taken from a cost of illness study recently completed by EPA (US EPA, 1999a). For those diagnosed with bladder cancer at the average age of diagnosis (70 years), the probability for dying of that disease during each year post-diagnosis were summed over a 20-year period to obtain the value of 26 percent. Mortality rates for U.S. bladder cancer patients have decreased overall by 24 percent from 1973 to 1996.

In the NRC report, Table 10–11 shows excess risk estimates based on the Taiwanese male bladder cancer, using a Poisson regression model; a risk at the current MCL of 50 µg/L is in the range of 1 to 1.347 per 1,000. Table 10–12 presents excess lifetime risk estimates

for bladder cancer in males calculated using EPA's 1996 proposed revisions to the cancer guidelines (US EPA 1996b). EPA selected four of these distributions as representative of the risks and uncertainty involved (selecting relatively high and relatively low estimates). These distributions (mean 1.049, 95% upper confidence limit 1.347; mean 0.731, 95% upper confidence limit 0.807; mean 1.237, 95% upper confidence limit 1.548; and mean 1.129, 95% upper confidence limit 1.229), were used in the EPA Monte Carlo simulations. All of these risk distributions are linear in the mean, and thus may be conservative assumptions, as the NRC report suggested the true relationship may be sublinear. If the true relationship is sublinear, *i.e.*, lower than the straight line from 50 µg/L to zero, the true risks at levels below 50 µg/L are being overestimated. Other factors which might lower the true risk include the use of grouped data, the high Taiwanese dietary intake of arsenic, and the amount of selenium in the Taiwanese diet.

NRC concluded that the present MCL in drinking water of 50 µg/L does not achieve EPA's goal for public health and requires downward revision. EPA did not request nor did NRC recommend a specific new MCL level.

##### 6. Estimated Risk Reductions

Estimated risk reductions for bladder cancer at various MCL levels were developed using Monte Carlo simulations. The inputs to the simulations were the distributions of relative risk factors (described in section X.A.4.), distributions of occurrence for arsenic levels at 3 µg/L and above, and bladder cancer risk distributions from the National Research Council report. The relative risk factor and occurrence distributions represent primarily population and occurrence variability, while the cancer risk distributions represent primarily uncertainty about the true risk. Thus the combined distributions reflect both variability and uncertainty. These combined distributions provide our best estimate of the actual risks faced by the exposed population, including the percentiles of the population facing various levels of risk.

Estimated risk reductions for bladder cancer at various MCL levels are shown in Tables X–2a and X–2b. Table X–2a uses data on community water consumption from the new EPA study; Table X–2b uses data on total water consumption from the study. Populations at or above 10<sup>-4</sup> risk levels are shown in Tables X–3a and X–3b.

The after treatment occurrence distributions were assumed to reflect treatment to 80% of the MCL level. The latter assumption is made since water systems tend to treat below the MCL level in order to provide a margin of safety.

As shown in Table X-2a, bladder cancer risks at the 90th percentile of water intake, for the various MCL options under consideration, range from a multiple of  $10^{-5}$  at 3 µg/L ( $4-6 \times 10^{-5}$ ) to a multiple of  $10^{-4}$  at 20 µg/L ( $1.2-2.4 \times 10^{-4}$ ). At 5 µg/L, the 90th percentile level is  $6-11 \times 10^{-5}$ ; at 10 µg/L the 90th percentile is  $1.0-1.7 \times 10^{-4}$ . Table X-2b presents similar

information. The risk estimates in Table X-2b are somewhat higher than those in Table X-2a because total water consumption is higher than community water consumption. Since there is uncertainty about these numbers, it is assumed that the range  $1-1.5 \times 10^{-4}$  represents a risk level of essentially  $10^{-4}$ . It is then assumed that risks above  $1.5 \times 10^{-4}$  represent risks greater than  $10^{-4}$ . Table X-3a gives information about percentages of the exposed populations and the number of people exposed at  $10^{-4}$  risk levels and above, and, using the stated definition for an over  $10^{-4}$  risk level, above  $10^{-4}$ . The numbers in this table show that at an

MCL of 3 µg/L, only a small number (not quantifiable) face a risk level of greater than  $10^{-4}$ . At an MCL of 5 µg/L, about 0.3 to 0.8 million face such risk levels, at an MCL of 10 µg/L, 0.8 to 4 million, and at an MCL of 20 µg/L, about 2.4 to 6.4 million would be at such levels. Table X-3b gives similar information using total water consumption data. The mean bladder cancer risks for the exposed population at the various MCL options, after treatment, are shown in Tables X-4a and X-4b. These mean risks are used in the computation of the number of cases avoided, used later in the benefits evaluation section.

TABLE X-2A.—BLADDER CANCER INCIDENCE RISKS<sup>1</sup> FOR HIGH PERCENTILE U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT<sup>2</sup> (COMMUNITY WATER CONSUMPTION DATA<sup>3</sup>)

MCL (µg/L)	85th	90th	95th
3	$3.2-5.4 \times 10^{-5}$	$4-6 \times 10^{-5}$	$4.3-7.5 \times 10^{-5}$
5	$5.3-9.3 \times 10^{-5}$	$6-11 \times 10^{-5}$	$7.5-13.0 \times 10^{-5}$
10	$.88-1.49 \times 10^{-4}$	$1.0-1.7 \times 10^{-4}$	$1.26-2.12 \times 10^{-4}$
20	$1.2-1.96 \times 10^{-4}$	$1.4-2.4 \times 10^{-4}$	$1.9-3.2 \times 10^{-4}$

<sup>1</sup> See Sections III.C. and D. for a description of other health effects, and Section X.B. for "What-if?" estimates of magnitude for lung cancer risks.

<sup>2</sup> The bladder cancer risks presented in this table provide our "best" estimates at this time. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

<sup>3</sup> Discussed in Section X.A.2.

TABLE X-2B.—BLADDER CANCER INCIDENCE RISKS<sup>1</sup> FOR HIGH PERCENTILE U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT<sup>2</sup> (TOTAL WATER CONSUMPTION DATA<sup>3</sup>)

MCL (µg/L)	85th	90th	95th
3	$3.8-6.4 \times 10^{-5}$	$4-7 \times 10^{-5}$	$5-8.7 \times 10^{-5}$
5	$6.3-10.5 \times 10^{-5}$	$7-12 \times 10^{-5}$	$8.5-14.5 \times 10^{-5}$
10	$1.02-1.8 \times 10^{-4}$	$1.2-2.0 \times 10^{-4}$	$1.39-2.56 \times 10^{-4}$
20	$1.4-2.34 \times 10^{-4}$	$1.7-2.8 \times 10^{-4}$	$2.17-3.56 \times 10^{-4}$

<sup>1</sup> See Sections III.C. and D. for a description of other health effects, and Section X.B. for "What-if?" estimates of magnitude for lung cancer risks.

<sup>2</sup> The bladder cancer risks presented in this table provide our "best" estimates at this time. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

<sup>3</sup> Discussed in Section X.A.2.

TABLE X-3A.—PERCENT OF EXPOSED POPULATION AT  $10^{-4}$  RISK OR HIGHER FOR BLADDER CANCER INCIDENCE<sup>1</sup> AFTER TREATMENT<sup>2</sup> (COMMUNITY WATER CONSUMPTION DATA<sup>3</sup>)

MCL (µg/L)	Percent at $10^{-4}$ risk or higher	Population at $10^{-4}$ risk or higher (millions)	Percent over $10^{-4}$ *	Population over $10^{-4}$ (millions)
3	<1-2.6	<0.3-0.7	<1	‡
5	1.5-12	0.4-3.2	<1-3	<0.3-0.8
10	11-34	2.9-9.1	3-15	0.8-4
20	19.5-41	5.2-11	9-24	2.4-6.4

<sup>1</sup> See Sections III.C. and D. for a description of other health effects, and Section X.B. for "What-if?" estimates of magnitude for lung cancer risks.

<sup>2</sup> The percents presented in this table provide our "best" estimates at this time. Actual percents could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

<sup>3</sup> Discussed in Section X.A.2.

\* Where over  $10^{-4}$  means  $1.5 \times 10^{-4}$  or above.

‡ Too low to calculate.

TABLE X-3B.—PERCENT OF EXPOSED POPULATION AT 10<sup>-4</sup> RISK OR HIGHER FOR BLADDER CANCER INCIDENCE <sup>1</sup> AFTER TREATMENT <sup>2</sup> (TOTAL WATER CONSUMPTION DATA <sup>3</sup>)

MCL (µg/L)	Percent at 10 <sup>-4</sup> risk or higher	Population at 10 <sup>-4</sup> risk or higher (millions)	Percent over 10 <sup>-4</sup> *	Population over 10 <sup>-4</sup> (millions)
3	<1-3	<0.3-0.8	<1	‡
5	3-18	0.8-4.8	<1-4	0.3-1.1
10	16-50	4.3-13.4	4-23	1.1-6.2
20	26-53	7-14.2	13-33	3.5-8.9

<sup>1</sup> See Sections III.C. and D. for a description of other health effects, and Section X.B. for "What-if?" estimates of magnitude for lung cancer risks.

<sup>2</sup> The percents presented in this table provide our "best" estimates at this time. Actual percents could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

<sup>3</sup> Discussed in Section X.A.2.

\* Where over 10<sup>-4</sup> means 1.5 × 10<sup>-4</sup> or above.

‡ Too low to calculate.

TABLE X-4A.—MEAN BLADDER CANCER INCIDENCE RISKS <sup>1</sup> FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT <sup>2</sup> (COMMUNITY WATER CONSUMPTION DATA <sup>3</sup>)

MCL (µ/L)	Mean exposed population risk
3	2.1-3.6 × 10 <sup>-5</sup>
5	3.6-6.1 × 10 <sup>-5</sup>
10	5.5-9.2 × 10 <sup>-5</sup>
20	6.9-11.6 × 10 <sup>-5</sup>

<sup>1</sup> See Sections III.C. and D. for a description of other health effects, and Section X.B. for "What-if?" estimates of magnitude for lung cancer risks.

<sup>2</sup> The bladder cancer risks presented in this table provide our "best" estimates at this time. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

<sup>3</sup> Discussed in Section X.A.2.

TABLE X-4B.—MEAN BLADDER CANCER INCIDENCE RISKS <sup>1</sup> FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT <sup>2</sup> (TOTAL WATER CONSUMPTION DATA <sup>3</sup>)

MCL (µ/L)	Mean exposed population risk
3	2.6-4.5 × 10 <sup>-5</sup>
5	4.4-7.5 × 10 <sup>-5</sup>
10	6.7-11.4 × 10 <sup>-5</sup>
20	8.4-13.9 × 10 <sup>-5</sup>

<sup>1</sup> See Sections III.C. and D. for a description of other health effects, and Section X.B. for "What-if?" estimates of magnitude for lung cancer risks.

<sup>2</sup> The bladder cancer risks presented in this table provide our "best" estimates at this time. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

<sup>3</sup> Discussed in Section X.A.2.

*B. "What if?" Scenario for Lung Cancer Risks*

The NRC report "Arsenic in Drinking Water" states that "some studies have shown that excess lung cancer deaths attributed to arsenic are 2-5 fold greater than the excess bladder cancer deaths (NRC, 1999, pg. 8)." Two-to-five fold greater would be 3.5 fold greater on average. Also in the U.S. the mortality rate from bladder cancer is 26% and the mortality rate of lung cancer is 88%. This suggests that if the risk of contracting lung cancer were identical to the risk of contracting bladder cancer, one would expect 3.4 times the number of deaths from lung cancer as from bladder cancer. Since these numbers are essentially the same, it seems reasonable to assume that the risk of contracting lung cancer is essentially the same as the rate of contracting bladder cancer,<sup>1</sup> in the context of this "what-if" scenario. If the risk of contracting lung cancer from arsenic in drinking water is approximately equal to the risk of contracting bladder cancer, then the combined risk estimates of contracting either bladder or lung cancer would be approximately double the risk estimates presented in the previous tables.

EPA anticipates that a peer-reviewed quantification of lung cancer risk from arsenic exposure may be available between the time of proposal and

<sup>1</sup> If "X" is the probability of contracting bladder cancer, then 0.26X is the probability of mortality from bladder cancer. If lung cancer deaths are 2 to 5 times as high as bladder cancer, then they are, on average, 3.5 times as high and the average probability of mortality from lung cancer would be 3.5 times 0.26X, or 0.91X. Since we also know that there is a 88% mortality rate from lung cancer, then if the probability of contracting lung cancer is "Y," the probability of mortality from lung cancer can also be represented as 0.88Y. Setting the two ways of deriving the probability of mortality from lung cancer equal, or 0.91X = 0.88Y, one can solve for Y (Y = (0.91/0.88) X). Thus Y is approximately equal to X, and the rate of contracting lung cancer is approximately the same as the rate of contracting bladder cancer.

promulgation. If so, EPA will make this information available for public comment through a Notice of Data Availability (NODA) and consider the analysis and public comment for the final rulemaking.

*C. Evaluation of Benefits*

The evaluation stage in the analysis of risk reductions involves estimating the value of reducing the risks. Background information on the economic concepts that provide the foundation for benefits valuation, and the methods that are typically used by economists to monetize the value of risk reductions, such as wage-risk, cost of illness, and contingent valuation studies are provided in the RIA. The following sections describe the use of these techniques to estimate the value of the risk reductions attributable to the regulatory options for arsenic in drinking water. Described first is the approach for valuing the reductions in fatal risks; described next is the approach for valuing the reductions in nonfatal risks.

The benefits calculated for this proposal are assumed to begin to accrue on the effective date of the rule and are based on a calculation referred to as the "value of a statistical life" (VSL), currently estimated at \$5.8 million. The VSL is an average estimate derived from a set of 26 studies estimating what people are willing to pay to avoid the risk of premature mortality. Most of these studies examine willingness to pay in the context of voluntary acceptance of higher risks of immediate accidental death in the workplace in exchange for higher wages. This value is sensitive to differences in population characteristics and perception of risks being valued.

For the present rulemaking analysis, which evaluates reduction in premature mortality due to carcinogen exposure, some have argued that the Agency

should consider an assumed time lag or latency period in these calculations. Latency refers to the difference between the time of initial exposure to environmental carcinogens and the onset of any resulting cancer. Use of such an approach might reduce significantly the present value estimate. EPA is interested in receiving comments on the extent to which the presentation of more detailed information on the timing of cancer risk reductions would be useful in evaluating the benefits of the proposed rule.

Latency is one of a number of adjustments or factors that are related to an evaluation of potential benefits associated with this rule, how those benefits are calculated, and when those economic benefits occur. Other factors which may influence the estimate of economic benefits associated with avoided cancer fatalities include (1) a possible "cancer premium" (*i.e.*, the additional value or sum that people may be willing to pay to avoid the experiences of dread, pain and suffering, and diminished quality of life associated with cancer-related illness and ultimate fatality); (2) the willingness of people to pay more over time to avoid mortality risk as their income rises; (3) a possible premium for accepting involuntary risks as opposed to voluntary assumed risks; (4) the greater risk aversion of the general population compared to the workers in the wage-risk valuation studies; (5) "altruism" or the willingness of people to pay more to reduce risk in other sectors of the population; and (6) a consideration of health status and life years remaining at the time of premature mortality. Use of certain of these factors may significantly increase the present value estimate. EPA therefore believes that adjustments should be considered simultaneously. The Agency also believes that there is currently neither a clear consensus among economists about how to simultaneously analyze each of these adjustments nor is there adequate empirical data to support definitive quantitative estimates for all potentially significant adjustment factors. As a result, the primary estimates of economic benefits presented in the analysis of this proposed rule rely on the unadjusted estimate. However, EPA solicits comment on whether and how to conduct these potential adjustments to economic benefits estimates together

with any rationale or supporting data commenters wish to offer. Because of the complexity of these issues, EPA will ask the Science Advisory Board (SAB) to conduct a review of these benefits transfer issues associated with economic valuation of adjustments in mortality risks. Consistent with the recommendations of the SAB, and subject to resolution of any technical problems, EPA will attempt to develop and present an estimate of the latency structure as a part of the analysis of the final rule, with prior solicitation of comment, if appropriate.

#### 1. Fatal Risks and Value of a Statistical Life (VSL)

To estimate the monetary value of reduced fatal risks (*i.e.*, risks of premature death from cancer) predicted under different regulatory options, value of a statistical life (VSL) estimates are multiplied by the number of premature fatalities avoided. VSL does not refer to the value of an identifiable life, but instead to the value of small reductions in mortality risks in a population. A "statistical" life is thus the sum of small individual risk reductions across an entire exposed population.

For example, if 100,000 people would each experience a reduction of 1/100,000 in their risk of premature death as the result of a regulation, the regulation can be said to "save" one statistical life (*i.e.*,  $100,000 \times 1/100,000$ ). If each member of the population of 100,000 were willing to pay \$20 for the stated risk reduction, the corresponding value of a statistical life would be \$2 million (*i.e.*,  $\$20 \times 100,000$ ). VSL estimates are appropriate only for valuing small changes in risk; they are not values for saving a particular individual's life.

Of the many VSL studies, the Agency recommends using estimates from 26 specific studies that have been peer reviewed and extensively reviewed within the Agency (US EPA, 1997f). These estimates, which are derived from wage-risk and contingent valuation studies, range from \$0.7 million to \$16.3 million and approximate a Weibull distribution with a mean of \$5.8 million (in 1997 dollars). To value the changes in fatal risks associated with the arsenic regulation, the mean estimate of \$5.8 million is used.

Use of these estimates to value the averted risks of premature death associated with the regulatory options for arsenic is an example of the benefit

transfer technique, since the subject of most of the studies (*i.e.*, job-related risks) differs from the fatal cancer risks averted by the regulatory options. Applying these studies results in several sources of potential bias (see latency discussion in section X.C.); however, quantitative adjustments to address these biases generally have not been developed or adequately tested and may be counterbalancing.<sup>2</sup> EPA notes the uncertainties in the cost-benefit analyses, as required by section 1412(b)(3)(C)(i)(VII) of SDWA, and requests comment on alternate approaches.

#### 2. Nonfatal Risks and Willingness To Pay (WTP)

Estimates of the willingness to pay to avoid treatable, nonfatal cancers are the ideal economic measures used for evaluation of the reduction in nonfatal risks. However this information is not available for bladder cancer. Willingness to pay (WTP) data to avoid chronic bronchitis is available, however, and has been used before by EPA (the microbial/disinfection by-product (MDBP) rulemaking) as a surrogate to estimate the WTP to avoid non-fatal bladder cancer. The use of such WTP estimates is supported in the SDWA, as amended, at section 1412(b)(3)(C)(iii): "The Administrator may identify valid approaches for the measurement and valuation of benefits under this subparagraph, including approaches to identify consumer willingness to pay for reductions in health risks from drinking water contaminants." The WTP central tendency estimate of \$536,000, to avoid chronic bronchitis, is used to monetize the benefits of avoiding non-fatal bladder cancers (Viscusi *et al.*, 1991).

EPA has also developed cost of illness estimates for bladder cancer, as reported in Table X-5. These estimates of direct medical costs are derived from a study conducted by Baker *et al.*, (as cited in US EPA, 1997f) which uses data from a sample of Medicare records for 1974-1981. These data include the total charges for inpatient hospital stays, skilled nursing facility stays, home health agency charges, physician services, and other outpatient and medical services. EPA combined these data with estimates of survival rates and treatment time periods to determine the average costs of initial treatment and maintenance care for patients who do not die of the disease.

<sup>2</sup> Some of the key sources of bias include the characteristics of the averted risks (whether they are voluntary or involuntary, ordinary or catastrophic, delayed or immediate, natural or man-made, *etc.*); the demographic characteristics of the group

affected (*e.g.*, age, income); the lag between exposure and diagnosis or incidence of the disease (latency) as well as between incidence and death; the baseline health status (*i.e.*, whether a person is currently in good health) of affected individuals;

and the presence of altruism (*i.e.*, individual's willingness to pay to reduce risks incurred by others) (US EPA, 1997f).

TABLE X-5.—LIFETIME AVOIDED MEDICAL COSTS FOR SURVIVORS (PRELIMINARY ESTIMATES, 1996 DOLLARS <sup>1</sup>)

Type of cancer	Date data collected	Number of cases studied	Estimated survival rate	Mean value per nonfatal case <sup>2</sup>
Bladder .....	1974-1981	5% of 1974 Medicare patients (sample from national statistics).	26 percent (after 20 years) .....	\$179,000 (for typical individual diagnosed at age 70)

<sup>1</sup> These costs increase by 2.8 percent when inflated to 1997 dollars, based on the consumer price index for the costs of medical commodities and services.

<sup>2</sup> Undiscounted costs.

Source: US EPA, 1999a.

*D. Estimates of Quantifiable Benefits of Arsenic Reduction*

Benefits estimates for avoided cases of bladder cancer were calculated using mean population risk estimates at various MCL levels. Table X-6 gives the mean populations risk estimates used, which are a composite of the mean population risk estimates discussed earlier. Lifetime risk estimates were converted to annual risk factors, and applied to the exposed population to determine the number of cases avoided. These cases were divided into fatalities and non-fatal cases avoided, based on survival information. The avoided premature fatalities were valued based on the VSL estimates discussed earlier, as recommended by EPA current guidance for cost/benefit analysis. The avoided non-fatal cases were valued based on the willingness to pay

estimates for the avoidance of chronic bronchitis. The upper bound estimates have been adjusted upwards to reflect an 80% mortality rate, which is a plausible mortality rate for the area of Taiwan during the Chen study.

The "What if?" scenario for lung cancer benefits (described in section X.B.) was used to estimate potential benefits for avoided cases of lung cancer. This scenario is based on the statement in the NRC report "Arsenic in Drinking Water" that "some studies have shown that excess lung cancer deaths attributed to arsenic are 2-5 fold greater than the excess bladder cancer deaths (NRC, 1999, pg. 8)." It was shown in section X.D that the statement implies (if it were accurate for the U.S.), that, because of the relative U.S. mortality rates for bladder and lung cancer, the rate of contracting lung cancer could be essentially the same as

the rate of contracting bladder cancer. This would double the number of cancer cases avoided, for both low and high estimates. The potential monetized benefits for lung cancer would be several times higher than those for bladder cancer, due to the higher number of fatalities involved with lung cancer.

Another way of considering the addition of lung cancer effects would be to estimate the potential benefits from avoided cases of lung cancer using the 2-5 times range for fatalities (that is, taking the expected number of bladder cancer fatalities and multiplying them by 2 and then 5 to obtain a range of lung cancer fatalities, and then factoring in non-fatal cases).

Benefits (and costs) are assumed to accrue on the effective date of the rule. Table X-7 displays the results.

TABLE X-6.—MEAN BLADDER CANCER INCIDENCE RISKS <sup>1</sup> FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT <sup>2</sup> (COMPOSITE OF TABLES X-5A AND X-5B)

MCL (µg/L)	Mean exposed population risk
3 .....	2.1 - 4.5 × 10 <sup>-5</sup>
5 .....	3.6 - 7.5 × 10 <sup>-5</sup>
10 .....	5.5 - 11.4 × 10 <sup>-5</sup>
20 .....	6.9 - 13.9 × 10 <sup>-5</sup>

<sup>1</sup> See Sections III.C. and D. for a description of other health effects, and Section X.B. for "What-if?" estimates of magnitude for cancer risks.

<sup>2</sup> The bladder cancer risks presented in this table provide our "best" estimates at this time. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

TABLE X-7.—ESTIMATED COSTS AND BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER  
[Millions, 1999]

Arsenic level (µg/l)	Total national costs to CWSs <sup>1</sup>	Total national costs to CWSs and NTNCWSs <sup>2</sup>	Total bladder cancer health benefits <sup>3</sup>	"What if" scenario <sup>4</sup> and potential non-quantified benefits	
				"What If" lung cancer health benefits estimates	Potential non-quantifiable health benefits
3 .....	\$643.1-753	\$644.6-756.3	\$43.6-104.2 <sup>5</sup> (79)	\$47.2-448 <sup>6</sup> (213.4)	<ul style="list-style-type: none"> <li>• Skin Cancer.</li> <li>• Kidney Cancer.</li> <li>• Cancer of the Nasal Passages.</li> </ul>
5 .....	377.3-441.8	378.9-444.9	31.7-89.9 <sup>5</sup> (64.3)	35-384 <sup>6</sup> (173.4)	<ul style="list-style-type: none"> <li>• Liver Cancer.</li> <li>• Prostate Cancer.</li> </ul>
10 .....	163.3-191.8	164.9-194.8	17.9-52.1 <sup>5</sup> (37)	19.6-224 <sup>6</sup> (100)	<ul style="list-style-type: none"> <li>• Cardiovascular Effects.</li> <li>• Pulmonary Effects.</li> <li>• Immunological Effects.</li> <li>• Neurological Effects.</li> </ul>

TABLE X-7.—ESTIMATED COSTS AND BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER—Continued  
[Millions, 1999]

Arsenic level (µg/l)	Total national costs to CWSs <sup>1</sup>	Total national costs to CWSs and NTNCWSs <sup>2</sup>	Total bladder cancer health benefits <sup>3</sup>	“What if” scenario <sup>4</sup> and potential non-quantified benefits	
				“What If” lung cancer health benefits estimates	Potential non-quantifiable health benefits
20 .....	61.6–72.9	63.2–77.1	7.9–29.8 <sup>5</sup> (19.8)	8.8–128 <sup>6</sup> (53.4)	<ul style="list-style-type: none"> <li>• Endocrine Effects.</li> <li>• Reproductive and Developmental Effects.</li> </ul>

<sup>1</sup> Costs include treatment, monitoring, O&M, and administrative costs to CWSs and State costs for administration of water programs. The lower number shows costs annualized at a consumption rate of interest of 3%, EPA’s preferred approach. The higher number shows costs annualized at 7%, which represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations.

<sup>2</sup> Costs include treatment, monitoring, O&M, administrative costs to CWSs; monitoring and administrative costs to NTNCWSs; and State costs for administration of water programs.

<sup>3</sup> The upper bound estimate includes an adjustment to account for a possible mortality risk of 80%. It is possible that this risk could have been below 80%, which would lead to increased benefits. The actual risk depends on the survival rate for bladder cancer in the area of Taiwan studied by Chen, which is unknown.

<sup>4</sup> These estimates are based on the “what if” scenario for lung cancer, where the risks of a fatal lung cancer case associated with arsenic are assumed to be 2–5 times that of a fatal bladder cancer case.

<sup>5</sup> The number in parentheses indicates the bladder cancer health benefits assuming an 80% mortality rate for bladder cancer in the area of the Chen study, and starting from the midpoint of the benefits range when mortality and incidence are assumed equivalent.

<sup>6</sup> The number in parentheses is the midpoint of the range and corresponds to an assumption that the risk of fatal lung cancer is 3.5 times the risk of fatal bladder cancer.

*F. NDWAC Working Group (NDWAC, 1998) on Benefits*

The National Drinking Water Advisory Council (NDWAC) recommends that:

(1) EPA should focus its benefits analysis efforts primarily on assessing effects on human health, defining these effects as clearly as possible and using the best available data to value them. It is also recommended that EPA should also consider, where appropriate, taste and odor improvements, reduction of damage to water system materials, commercial water treatment cost reductions, benefits due to source water protection (e.g., ecological benefits and non-use benefits), and benefits derived from the provision of information on drinking water quality (e.g., a household’s improved ability to make informed decisions concerning the need to test or filter tap water);

(2) EPA should devote substantial efforts to better understanding the health effects of drinking water contaminants, including the types of effects, their severity, and affected sensitive subpopulations. Better information is also needed on exposures and the effects of different exposure levels, particularly for contaminants with threshold effects. These efforts should pay particular attention to obtaining improved information concerning impacts on children and other sensitive populations;

(3) EPA should clearly identify and describe the uncertainties in the benefits analysis, including descriptions of factors that may lead the analysis to significantly understate or overstate total benefits. Factors that may have significant but indeterminate effects on

the benefits estimates should also be described;

(4) EPA should consider both quantified and non-quantified benefits in regulatory decision-making. The information about quantified and non-quantified (qualitative) benefits should be presented together in a format, such as a table, to ensure that decision-makers consider both kinds of information;

(5) EPA should consider incremental benefits and costs, total benefits and costs, the distribution of benefits and costs, and cost-effectiveness in regulatory decision-making. This information should be presented together in a format, such as a table, to ensure its consideration by decision-makers;

(6) Whenever EPA considers regulation of a drinking water contaminant, it should evaluate and consider, along with water treatment requirements to remove a contaminant, source water protection options to prevent such a contaminant from occurring. The full range of benefits of those options should be considered.

**XI. Risk Management Decisions: MCL and NTNCWSs**

*A. What Is the Proposed MCL?*

EPA is proposing an arsenic MCL of 5 µg/L and soliciting comments on options of 3µg/L, 10 µg/L, and 20 µg/L. EPA is also asking that commenters provide their rationale and any supporting data or information for the option they prefer.

The SDWA generally requires that EPA set the MCL for each contaminant as close as feasible to the MCLG, based on available technology and taking costs

to large systems into account. The 1996 amendments to the SDWA added the requirement that the Administrator determine whether or not the quantifiable and nonquantifiable benefits of an MCL justify the quantifiable and nonquantifiable costs based on the Health Risk Reduction and Cost Analysis (HRRCA) required under section 1412(b)(3)(C). The 1996 SDWA amendments also provided new discretionary authority for the Administrator to set an MCL less stringent than the feasible level if the benefits of an MCL set at the feasible level would not justify the costs (section 1412(b)(6)). This proposal to establish an MCL for arsenic of 5 µg/L is the first time EPA has invoked this new authority.

In conducting this analysis, EPA considered all available scientific information concerning the health effects of arsenic, including various uncertainties in the interpretation of the results. As discussed in more detail below, an array of health endpoints of concern were considered in this analysis. For some of these, the risk can currently be quantified (i.e., expressed in numerical terms); and for some, it cannot. Similarly, there are a variety of health and other benefits attributable to reductions in levels of arsenic in drinking water, some of which can be monetized (i.e., expressed in monetary terms) and others that cannot yet be monetized. All were considered in this analysis. The array of factors taken into account in making risk management decisions for arsenic underscore the difficulty of recommending the most appropriate regulatory level. A detailed

discussion of each of the principal factors considered follows.

### 1. Feasible MCL

Because arsenic is a carcinogen with no established mode of action, EPA is proposing that the MCLG be set at zero. To establish the MCL, EPA must first determine the level which is as close to this level as feasible. EPA has determined that 3 µg/L is technologically feasible for large systems based on peer-reviewed treatment information and the practical quantitation level achievable with available analytical methods.

### 2. Principal Considerations in Analysis of MCL Options

In addition to the feasible MCL of 3 µg/L, the Agency evaluated MCL options of 5 µg/L, 10 µg/L, and 20 µg/L. EPA considered the health effects associated with arsenic, the risk levels to the population for these health effects that would remain after implementation, and the costs and benefits of the different options (both those that could be monetized and/or quantified now and those that could not). The Agency's assessment centered on the health risk posed by arsenic in drinking water as well as on the benefits and costs imposed by the options evaluated. These options were then analyzed, taking into consideration the uncertainties involved in each of these factors. EPA solicits public comment on all the factors it considered in making this decision.

Estimates of risk levels to the population remaining after the regulation is in place provide a perspective on the level of public health protection and benefits. The SDWA clearly places a particular focus on public health protection afforded by MCLs. For instance, where EPA decides to use its discretionary authority after a determination that the benefits of an MCL would not justify the costs, section 1412(b)(6)(A) requires EPA to set the MCL at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits."

The SDWA requires the Agency to consider both quantifiable and nonquantifiable health risk reduction benefits (quantifiable benefits can include both those that are monetizable and those that are not). Non-monetizable benefits range from those about which some quantitative information is known (such as skin cancer), and those which are more qualitative in nature (such as some of the non-cancer health effects associated with arsenic). If additional potential benefits that are presently not

monetized (see Table XI-1) could be estimated at some future point, the benefits might increase further. (Important assumptions inherent in EPA's benefits estimates, including the value of a statistical life and willingness to pay are discussed in section X.C.)

EPA considered the relationship of the monetized benefits to the monetized costs for each option. While equality of monetized benefits and costs is not a requirement under section 1412(b)(6)(A), this relationship is still a useful tool in comparing costs and benefits. However, EPA believes that reliance on a simple arithmetic analysis of whether monetized benefits outweigh monetized costs is inconsistent with the HRRCA's instruction to consider both quantifiable and non-quantifiable costs and benefits. The Agency therefore believes it is necessary to also examine the qualitative and non-monetized benefits and consider these benefits in establishing the MCL.

### 3. Findings of NRC and Consideration of Risk Levels

The Agency based its evaluation of the risk posed by arsenic at the MCL options of 3 µg/L, 5 µg/L, 10 µg/L and 20 µg/L on national and international research, the bladder cancer risk analysis provided by the National Research Council (NRC) report issued by the National Academy of Sciences (NRC 1999), and the NRC's qualitative statements of overall risk of combined cancers. The Agency is relying heavily on the findings of the NRC for a number of reasons. In carrying out its charge, the NRC assembled an independent body of preeminent scientists from several disciplines. This committee examined and carefully analyzed more information than has been available before, and NRC had the draft report peer reviewed by thirteen other individuals with "diverse perspectives and technical expertise (NRC 1999b)." EPA decided, in 1996, to charge the NRC with evaluating EPA's two risk assessments for arsenic and considering the most current national and international research on arsenic. The NRC determined that the current MCL of 50 µg/L is not adequately protective and should be revised downward as soon as possible. The NRC conducted a number of statistical analyses in making this determination. The report also recommended that EPA conduct separate analyses for "bladder, lung, and other internal cancers," as well as consider the combined impact of these various health effects.

Given the release date of the NRC report (March 1999) relative to the timing of the proposed rule and the

additional analyses needed to definitively quantify all endpoints of concern, EPA chose to use NRC's bladder cancer analysis to quantify and monetize the bladder cancer risk for the proposed rule. NRC provided quantitative risk factors for bladder cancer, that, when combined with key risk characterization scenarios by EPA and qualitative benefits, yield risks and benefits associated with various possible MCL options. The NRC report also noted that lung cancer deaths due to arsenic could be 2 to 5 times higher than bladder cancer deaths, considering the frequency and incidence of cancers projected from international studies. However, the report did not provide a numeric risk-based quantification analysis for this judgment similar to that provided for bladder cancer. As noted in section X.E., EPA approximated the potential benefits of avoiding arsenic-related lung cancer by assuming that the probability of incidence of lung cancer is approximately equal to that of bladder cancer. One can then use the death rate associated with lung cancer (88% for lung cancer as compared to 26% for bladder cancer) to derive benefits and to consider the implications of this health endpoint on risk. The risk factors associated with various MCL options increase under this "What If" analysis, with 10 µg/L being on the upper end or just outside of the Agency's  $1 \times 10^{-4}$  risk range and more stringent MCL options being more solidly under this risk ceiling.

EPA anticipates that a peer reviewed quantification of lung cancer risk from arsenic exposure may be available between the time of proposal and promulgation. If so, EPA will make this information available for public comment through a Notice of Data Availability (NODA) and consider the analysis and public comment for the final rulemaking.

Individual risk varies widely depending on susceptibility, amount of drinking water consumption, dietary levels of arsenic, years of exposure, and other factors. Consequently, any single MCL does not provide the same level of protection to all individuals. While not required by statute, the Agency has historically set protectiveness levels within a risk range of  $10^{-4}$  to  $10^{-6}$ . EPA has sought to ensure that drinking water standards were established at levels such that less than 10% of the exposed population faced a risk that exceeded the chosen risk level. This conclusion is based on a recognition of its responsibility to protect public health, together with its obligation to consider a range of risk management factors when establishing regulatory levels.

#### 4. Non-Monetized Health Effects

There are a number of important non-monetized benefits that EPA considered in its analysis. Chief among these are certain health impacts known to be caused by arsenic (such as skin cancer).

A number of epidemiologic studies conducted in several countries (*e.g.*, Taiwan, Japan, England, Hungary, Mexico, Chile, and Argentina) report an association between arsenic in drinking water and skin cancer in exposed populations. Studies conducted in the U.S. have not demonstrated an association between inorganic arsenic in drinking water and skin cancer. However, these studies may not have included enough people in their design to detect these types of effects.

There were also a large number of other health effects associated with arsenic, discussed in section III, and listed in Table XI.1, which are not monetized, due to lack of appropriate quantitative data. These health effects include other cancers such as prostate cancer and cardiovascular, pulmonary, neurological and other non-cancer endpoints.

Other benefits not monetized for this proposal include customer peace of mind from knowing drinking water has been treated for arsenic and reduced treatment costs for currently unregulated contaminants that may be co-treated with arsenic. To the extent that reverse osmosis is used for arsenic removal, these benefits could be substantial. Reverse osmosis is the primary point of use treatment, and it is expected that very small systems will use this treatment to a significant extent.

#### 5. Sources of Uncertainty

Among the non-quantifiable factors EPA considered in choosing the proposed MCL was Congress' intent that EPA "reduce \* \* \* [scientific] uncertainty" in promulgating the arsenic regulation, reflected in the 1412(b)(12) arsenic research plan provisions and the legislative history for the arsenic provision (S. Rep. 104-169, 104th Cong., 1st Sess. at 39-40).

All assessments of risk are characterized by an amount of uncertainty. Some of this can be reduced by collecting more data or data of a different sort; for other types of uncertainty, improved data or assessment methods can allow one to define the degree to which an estimate is likely to be above or below the "true" risk. For the arsenic risk assessment, there are some definable sources of uncertainty. These include (but aren't limited to) the following: choice of endpoint and population; uncertainty

about the exact exposure of individuals in the study population; issues on applying data from rural Taiwanese to the heterogenous population of the U.S.; the inability to know precisely how a chemical causes cancer in humans (the mode of action, which affects judgments as to the shape of the chemical's dose response curve at low doses); choice of mathematical modeling procedures. Congress established a dual path for arsenic in SDWA: on the one hand, EPA is to issue a proposed MCL in 4½ years; on a parallel track EPA is to develop a long-term research plan, complete the required consultations and peer reviews, complete the research, and fully consider the research results. While the plan has been developed and research is underway, not all research results will be available for the final rule. However, EPA did obtain through the NRC study the most authoritative review of existing scientific information available. This review examined the areas of uncertainty listed above.

EPA considered uncertainty about arsenic's mode of action and the shape of the dose response curve below the observable range of data. EPA is proposing an MCLG of zero. This decision is supported by the NRC's findings that the dose-response relationship at low doses is uncertain and that a conservative, default assumption of linearity is advisable. (An assumption of linearity in the dose-response relationship implies that there is no "safe" level that can be identified at which no health effects are expected to occur.) However, the Agency also notes the NRC's conclusion that "\* \* \* a sublinear dose-response curve in the low dose range is predicted, although linearity cannot be ruled out." (NRC, 1999, pg. 6). EPA believes the NRC study's articulation of uncertainty about the shape of the dose-response curve below the observed health effect range is an important qualitative consideration and, given Congress' concern about scientific "uncertainty" in setting the arsenic level, guides EPA to a default assumption of linearity.

The choice of one endpoint for risk assessment is a judgment call. While this choice is guided by the best available science, it introduces uncertainty. Basing the risk assessment on incidence of bladder tumors will underestimate the combined risk of all arsenic-induced health effects. Section XI.A.4. discusses how assessments of other tumor types and health endpoints would result in a higher estimate of arsenic risk.

Another source of uncertainty is in the application of data from one human population to another. EPA believes that

the differences in dietary contributions of arsenic that NRC identified in the Taiwan study population and the U.S. are important to consider and a source of uncertainty in interpreting the results. NRC estimated that daily inorganic arsenic intake from food in the U.S. ranges from 1.3 µg/day for infants, to 4.5 µg/day for males 14-16 years old and 5.2 µg/day for females 14-16 years old, to a maximum of 12.5 µg/day for 60-65 year-old males and 9.7 µg/day for 60-65 year old females. On the other hand, NRC cited a study (Schoof *et al.*, 1998) that estimated the Taiwanese obtain 31 µg/day of inorganic arsenic from yams and 19 µg/day from rice, "for a total of 50 µg/day within a range of estimates of 15-211 µg/day (NRC, 1999, pg. 51)." NRC noted (p. 24) that "Limited data on dietary arsenic intake in the blackfoot-disease region now available suggest that arsenic intake from food is higher in Taiwan than in the United States." NRC noted that EPA previously observed that arsenic intake from sources other than drinking water would overestimate the unit risk calculated from the Taiwan study (US EPA 1988, pg. 86). The report noted that improved quantification of arsenic in Taiwanese food might affect the risk assessment for arsenic in drinking water in the U.S. (NRC 1999, pg. 6).

In addition, the NRC report discussed laboratory animal studies that indicated that selenium reduced the toxicity of arsenic. While there is no direct evidence for humans, NRC noted that "Selenium status there [in Taiwan] should be considered a moderator of arsenic toxicity and taken into account when the Taiwanese data are applied to populations with adequate selenium intakes (NRC, 1999, pg. 240)." The NRC report cited studies comparing urinary selenium concentrations and blood serum selenium concentrations; these were lower for the Taiwanese by comparison to other study populations including people in the U.S.

NRC noted that the "model choice can have a major impact on estimated low-dose risks when the analysis is based on epidemiological data (NRC 1999, pg. 294)." NRC noted that EPA's 1988 risk assessment used the multistage Weibull model to estimate a lifetime skin cancer risk of  $1 \times 10^{-3}$  for U.S. males exposed to arsenic at 50 µg/L. In their report NRC discussed the implications (both in a general sense and specifically for the Tseng data) of using data from an ecological study, and of using grouped data. They also reported the results of applying both a multistage Weibull and a Poisson model. When they re-assorted data into varying exposure groups, there

was a strong effect on the fitted Weibull model. NRC concluded: "Thus the fact that grouping does have a strong effect provides evidence of additional measurement error in the arsenic concentrations being assigned at the village level (NRC, 1999, pg. 284)." NRC used median village arsenic concentrations to represent exposure levels. The Expert Panel (US EPA, 1997d) noted that biases from using average doses for groups leads to overestimation of risk.

"\* \* \* [D]espite a distribution of doses in the population, those individuals exhibiting effects would tend also to be those who received the highest doses; because of this, deriving an average dose based on affected individuals would to some extent bias risk estimates upward. Similarly attribution of the total excess risk in the population to arsenic exposure alone could also be expected to inflate the estimate of risk if the population is also characterized by other risk factors such as smoking, excess exposure to sunlight,

nutritional status, and so on (US EPA, 1997d, pg. 31)."

The Poisson model with a quadratic term for age and a linear term for exposure fit as well as the multistage Weibull model, and had less variability in risks from regrouping the exposure intervals. Results from the NRC Poisson model estimations were used in the EPA analysis of bladder cancer risks.

NRC noted that "Ecological studies in Chile and Argentina have observed risks of lung and bladder cancer of the same magnitude as those reported in the studies in Taiwan at comparable levels of exposure." This observation increases confidence in the risk estimates based on the Tseng data. That these populations are different in terms of ethnic background, dietary patterns, and potential for other exposures also decreases the level of concern about generalized applicability of the Taiwanese data for risk assessment.

EPA considered these various uncertainties associated with interpretation of the health effects of arsenic in making risk management decisions and in selecting an appropriate regulatory level. The Agency requests

comment on whether we have properly weighed the uncertainties which overestimate and underestimate risk of the proposed MCL.

There is also a measure of uncertainty about the costs associated with various possible regulatory levels. EPA has provided its best estimates of the costs, but recognizes that a number of stakeholders have performed independent analyses suggesting that the costs may be higher than those estimated by EPA. EPA requests comment on its cost estimates and any additional information commenters may have on possible costs of the rule.

6. Comparison of Benefits and Costs

The monetized costs and monetized benefits of the proposed rule, and the methodologies used to calculate them, are discussed in detail in sections IX, X, and XIII of this preamble and in the HRRCA. Overall estimates of monetized costs and monetized benefits associated with various MCL options are provided in Table XI-1. There are also many health effects which have not been monetized, as is also shown in Table XI-1.

TABLE XI-1.—ESTIMATED COSTS AND BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER  
[In 1999 \$ millions]

Arsenic level (µg/L)	Total national costs to CWSs <sup>1</sup>	Total national costs to CWSs and NTNCWSs <sup>2</sup>	Total bladder cancer health benefits <sup>3</sup>	"What if" scenario <sup>4</sup> and potential non-quantified benefits	
				"What if" lung cancer health benefits estimates	Potential non-quantifiable health benefits
3 .....	643.1–753	644.6–756.3	43.6–104.2 <sup>5</sup> (79)	47.2–448 <sup>6</sup> (213.4)	<ul style="list-style-type: none"> <li>• Skin Cancer.</li> <li>• Kidney Cancer.</li> <li>• Cancer of the Nasal Passages.</li> </ul>
5 .....	377.3–441.8	378.9–444.9	31.7–89.9 <sup>5</sup> (64.3)	35–384 <sup>6</sup> (173.4)	<ul style="list-style-type: none"> <li>• Liver Cancer.</li> <li>• Prostate Cancer.</li> <li>• Cardiovascular Effects.</li> </ul>
10 .....	163.3–191.8	164.9–194.8	17.9–52.1 <sup>5</sup> (37)	19.6–224 <sup>6</sup> (100)	<ul style="list-style-type: none"> <li>• Pulmonary Effects.</li> <li>• Immunological Effects.</li> <li>• Neurological Effects.</li> </ul>
20 .....	61.6–72.9	63.2–77.1	7.9–29.8 <sup>5</sup> (19.8)	8.8–128 <sup>6</sup> (53.4)	<ul style="list-style-type: none"> <li>• Endocrine Effects.</li> <li>• Reproductive and Developmental Effects.</li> </ul>

<sup>1</sup> Costs include treatment, monitoring, O&M, and administrative costs to CWSs and State costs for administration of water programs. The lower number shows costs annualized at a consumption rate of interest of 3%, EPA's preferred approach. The higher number shows costs annualized at 7%, which represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations.

<sup>2</sup> Costs include treatment, monitoring, O&M, administrative costs to CWSs; monitoring and administrative costs to NTNCWSs; and State costs for administration of water programs.

<sup>3</sup> The upper bound estimate includes an adjustment to account for a possible mortality risk of 80%. It is possible that this risk could have been below 80%, which would lead to increased benefits. The actual risk depends on the survival rate for bladder cancer in the area of Taiwan studied by Chen, which is unknown.

<sup>4</sup> These estimates are based on the "what if" scenario for lung cancer, where the risks of a fatal lung cancer case associated with arsenic are assumed to be 2–5 times that of a fatal bladder cancer case.

<sup>5</sup> The number in parentheses indicates the bladder cancer health benefits assuming an 80% mortality rate for bladder cancer in the area of the Chen study, and starting from the midpoint of the benefits range when mortality and incidence are assumed equivalent.

<sup>6</sup> The number in parentheses is the midpoint of the range and corresponds to an assumption that the risk of fatal lung cancer is 3.5 times the risk of fatal bladder cancer.

7. Conclusion and Request for Comment

In summary, based on the NRC report, EPA agrees that the current MCL of 50 µg/L is too high and must be made more protective of human health. Because EPA is proposing an MCLG for arsenic of 0, the MCL must be set as close as feasible to the MCLG, unless EPA invokes its discretionary authority to set a different MCL at a level where the

costs are justified by the benefits. EPA believes that the feasible level for arsenic is 3 µg/L. Today, EPA is proposing that the arsenic MCL be set at 5 µg/L.

EPA believes that setting the MCL at 3 µg/L, the feasible level in this case, may not be justified at this time, given the uncertainty regarding the relationship between the monetized

benefits and the monetized costs at that level, the current uncertainty of the non-monetized benefits, and the degree of scientific uncertainty regarding the dose-response curve for an MCL at that level (affected by differences in nutrition and arsenic from food). Because there is a substantial possible imbalance between currently estimated monetized costs and benefits at the

feasible level of 3 µg/L, and a lack of certainty concerning the non-monetized costs and potential non-monetized benefits, EPA is proposing a standard other than the feasible level, using its discretionary authority in section 1412(b)(6). (See Senate Rep. 104–169, 104th Cong., 1st Sess. at 33). The statute requires that a level proposed or promulgated using this discretionary authority be one which maximizes health risk reduction at a level where the costs are justified by the benefits. EPA believes that the 5 µg/L MCL best meets this statutory test. EPA solicits comment on this finding, as described in more detail below.

As discussed earlier in section XI.A.4., EPA believes that there are a number of not yet quantified adverse health effects that pose a significant risk to public health. While the relationship of actual monetized benefits to monetized costs at 5 µg/L, \$31.7–\$89.9 million for bladder cancer benefits (plus possible lung cancer benefits of \$35–\$384 million based on the “What If” scenario) vs. \$378.9–444.9 million in costs, is uncertain. EPA believes the range of benefits supports that level, especially when there may potentially be substantial non-monetized benefits factored into the analysis. EPA believes that, given the guidance of the NRC report, these potential non-monetized benefits, including a number of non-cancer health effects (see Table XI–1), are substantial enough to strike a reasonable balance between benefits and costs. Strict parity of monetized costs and monetized benefits is not required to find that the benefits of a particular MCL option are justified under the statutory provisions of § 1412(b)(6). In addition, at 5 µg/L, the remaining risks (of bladder cancer) to the exposed population after the rule’s implementation are well within the  $10^{-4}$  range, which is protective of public health. As a result, EPA finds that the actual risk levels (including risks of potential non-monetized health effects) at 5 µg/L are high enough to justify this MCL, and it is therefore the level which maximizes health protection at a level where the costs are justified.

As discussed earlier, EPA has, as a matter of policy typically established MCLs for cancer-causing contaminants to ensure that the risks of excess cancer deaths represented by exposure to drinking water at the MCL over the course of a lifetime are within a range of one in 10,000 to one in 1,000,000. EPA believes that this range is reasonably protective of public health consistent with the goals of the Safe Drinking Water Act. In using its

statutory discretion under section 1412(b)(6)(A) to set a standard less stringent than the feasible level that maximizes health risk reduction at a cost that is justified by the benefits, EPA is proposing that it should choose a level that falls within the aforementioned target risk range. EPA is proposing to stay within this risk range even if the monetized benefits of a standard set at the upper end of the range are below the costs, as may be the case with this rule. EPA believes that important factors in this evaluation are the considerable non-quantifiable benefits that may be attributable to the proposed MCL. EPA also notes, as discussed earlier, that Congress did not direct EPA to ensure strict equality of monetizable costs and benefits in applying its discretionary authorities under section 1412(b)(6)(A). EPA requests comments on its proposed use of the new authority under section 1412(b)(6)(A) of the SDWA.

The risk assessment for bladder cancer indicates that a standard set at 10 µg/L would fall at the upper end of the target risk range, with 5 µg/L more solidly within that risk range. However, there are two important sets of considerations when using available health effects information and studies to help determine the appropriate level for a proposed new standard. On the one hand, multiple health endpoints are of concern in ensuring that the standard is adequately protective. As noted earlier, the NRC expresses concern about lung cancer and other health endpoints and indicated that excess lung cancer deaths from arsenic in drinking water could be 2–5 times the level of bladder cancer deaths. If these other risks were fully quantified, the total risk at 10 µg/L might be well above  $1 \times 10^{-4}$  (the upper end of the risk range), given that the quantified risk of bladder cancer alone appears to be at approximately this level.

On the other hand, there is uncertainty in the quantification of bladder cancer risk (as well as other health endpoints) and this risk estimate includes a number of conservative assumptions, as discussed previously. These include the assumptions of using a linear dose-response function; the fact that the dose-response data from the Taiwan epidemiologic study are based upon grouped occurrence information from wells used by the study population; and the possibility that the study population was more susceptible to arsenic in drinking water (as compared to the U.S. population) due to the relatively high dietary intake and dietary deficiencies in other elements (e.g., selenium) that might mitigate the results

of arsenic. Thus, the risk of bladder cancer alone might be well below current estimates which represent EPA’s best estimate at this time using currently available data and standard methodologies. The proposed MCL attempts to balance these countervailing considerations in establishing a level that is protective of public health.

Given these competing sources of uncertainty, EPA believes it is appropriate to propose a standard at 5 µg/L, because at this level it is more likely that the total risk would be within the target range than at a higher standard. However, between now and promulgation of the final rule, EPA will work to resolve as much of this uncertainty as possible, both in terms of quantifying risk of additional health endpoints (e.g., lung cancer) and in terms of reexamining conservative assumptions in the risk estimate. EPA requests comment on its proposed level of 5 µg/L and on its rationale for selecting this level. In selecting the final level of the standard, EPA will evaluate, in light of comments received and any new scientific information, its proposed way of using its discretionary authority under section 1412(b)(6)(A) and the total risk, costs, and benefits associated with each of the levels of the standard under consideration.

EPA requests comment on other potential MCLs and which of the MCLs and rationales presented here best fits the statutory framework. First, EPA is requesting comment on setting the MCL at 10 µg/L. The monetized costs of \$164.9–\$194.8 million, and monetized benefits of \$17.9–\$52.1 million for bladder cancer (plus possible lung cancer benefits of \$19.6–\$224 based on the “What If” scenario) are closer at 10 µg/L. The risk levels (of bladder cancer) to the exposed population are within the  $10^{-4}$  risk range, and the uncertainties already discussed in Section XI.A.6. may be a basis for inferring lower expected possible non-monetized benefits than assumed for the MCL option of 5 µg/L.

EPA is also requesting comment on an MCL option of 20 µg/L. Some stakeholders favor an MCL in this range and cite, as justification for such a level, their belief that if all uncertainties are taken into consideration, risk estimates would be within the Agency’s risk range of range of  $1 \times 10^{-6}$  to  $1 \times 10^{-4}$ . As can be seen from Table XI–1, costs are considerably reduced at this level, since far fewer CWSs would be impacted (i.e., occurrence of arsenic, without treatment, is already below this level for many systems). Approximately 1,200 CWSs would be projected to incur costs of approximately \$63–\$77 million to

comply with an MCL of 20 µg/L. Benefits would also be considerably lower than for other options, at \$7.9–\$29.8 million for bladder cancer (plus possibly \$8.8–\$128 million for lung cancer, based on the “What If” scenario). EPA’s principal concern with an MCL option in this range is that it may not be sufficiently protective after consideration of all health endpoints of concern. In other words, when the effects of bladder cancer, lung cancer, and skin cancer are considered, together with the various non-quantifiable endpoints such as circulatory system impacts, an MCL option of 20 µg/L could result in an unacceptably high risk, well outside of the risk range of  $1 \times 10^{-6}$  to  $1 \times 10^{-4}$ . As noted above, in using its statutory discretion to set a standard above the feasible level, EPA is proposing not to set a standard that exceeds this target risk range. However, EPA solicits comment on an MCL option of 20 µg/L along with any supporting rationale that commenters wish to offer.

EPA is also requesting comment on setting the MCL at 3 µg/L. As explained in section XI.A.1., this is the level as close to the MCLG as is feasible. It is also the level at which the risks are most solidly within the  $10^{-4}$  risk range of the three MCLs considered. If EPA were to set the MCL at this level, EPA would not use its discretionary authority to set the MCL at a less stringent level based on costs and benefits. The Agency estimates that the likelihood that actual monetized benefits of \$43.6–\$104.2 million for bladder cancer (plus possible lung cancer benefits of \$47.2–\$448 million based on the “What If” scenario), are close to monetized costs of \$644.6–\$756.3 million is less certain than at 5 µg/L. (See Table XI-1.) While EPA believes that benefits may be substantially less than monetized costs for the feasible level, the feasible level would be the most protective of the options presented here and would conservatively account for the uncertainties about the severity of various health effects endpoints and their potential additive impacts.

Finally, Congress indicated interest in assuring that EPA considered impacts of an MCL decision on people served by large systems who could afford protective MCLs and an MCL of 3 would respond to this interest. Section 1412(b)(6)(B), however, provides that the interests of people served by large systems are to be considered along with benefits and costs to systems not expected to get small system variances. Because this proposal does not include small system variance technologies (*i.e.*, affordable technologies for small

systems at the proposed MCL have been identified), the interests of persons served by large and small systems are being considered together and the provisions of section 1412(b)(6)(B) do not apply in this case.

#### *B. Why Is EPA Proposing a Total Arsenic MCL?*

The previous drinking water standard for arsenic of 0.05 mg/L was based on total arsenic. Total arsenic includes the dissolved and undissolved arsenic species present in drinking water and makes no distinction between inorganic or organic species. Consistent with the previous standard for arsenic, today’s proposed regulation of 0.005 mg/L will be based on total arsenic. From an occurrence and analytical methods standpoint, the Agency believes it is inappropriate to make a regulatory distinction between inorganic and organic arsenic forms in drinking water.

According to Irgolic (1994) and as mentioned in section II.B, the inorganic arsenic species (As III and As V) are present in drinking water, and organic arsenic compounds are rarely found in water supplies. Furthermore, inorganic As V (arsenate) is more prevalent in drinking water supplies than inorganic As III (arsenite), which tends to occur in anaerobic waters. If organic species are present in drinking water, methylarsonic acid (MMA) and dimethylarsonic acid (DMA) are the predominant organic forms. These organic species, when present, can result from the leaching of arsenic-containing herbicides or from the conversion of the inorganic forms to the organic forms in the presence of microbial activity. In arsenic-rich ground water wells from Taiwan, methylated compounds were not present above concentrations of 1 µg/L. No DMA or MMA was detected in the ground water samples from six districts in West Bengal, India (Chatterjee et al., 1995). Regarding surface water, Anderson and Bruland (1991) reported that organic species (DMA and MMA) accounted for 1 to 59% of the total arsenic concentration from fourteen lake and river samples taken in California. As Irgolic pointed out in his review of the Anderson and Bruland study, the level of the organic arsenic found in these surface water samples were in the low nanomolar (nM or nm/L) range. After converting the reported units from nm/L to µg/L, analysis of the Anderson and Bruland data indicate that only two of the fourteen water samples exceeded a concentration of 1 µg/L of organic arsenic (DMA and MMA combined).

There is currently no EPA approved method for arsenic analysis in drinking

water that distinguishes inorganic arsenic species from organic arsenic forms. The method would need to meet the criteria listed in section VI.B. and would require interlaboratory studies for validation. The estimated costs of such an analytical method could range from \$150 to \$250 per analysis. In addition, laboratory capacity for this type of method would most likely be limited at this time.

Few toxicity studies exist for organic arsenicals. The NRC report noted that methylated arsenic has less developmental toxicity than inorganic arsenic. Concentrations of DMA administered that decreased fetal weight produced over 50% maternal mortality in studies with rats and mice (Rogers et al., 1981 as reported in NRC, 1999); hamsters had no developmental toxicity from exposure to MMA nor DMA (Willhite, 1981, as reported in NRC, 1999). NRC noted that EPA has two unpublished studies of rats fed MMA which had some increase in thyroid tumors, but no effect on mice. In addition, MMA and DMA produced mutations in cells at concentrations over one thousand times higher than the concentrations of inorganic arsenite and arsenate (Moore et al., 1997 as reported in NRC, 1999). It takes roughly ten times more DMA than arsenite to cause chromosome changes in a human cell line (Oya-Ohata et al., 1996, as reported in NRC, 1999).

Because of the limited occurrence of organic arsenic species in water and the lack of a suitable and widely available analytical method for inorganic arsenic, the Agency believes compliance with the proposed arsenic standard of 0.005 mg/L should be based on total arsenic. EPA requests comments on setting the MCL based on total arsenic and any data or established analytical methods that would support setting an MCL based on inorganic arsenic.

#### *C. Why Is EPA Proposing To Require Only Monitoring and Notification for NTNCWSs?*

In this rulemaking, the Agency is soliciting comment on an approach which would not extend coverage of the rule to Non-Transient Non-Community (NTNC) water systems, but would instead create an intermediate level of control for these systems (monitoring and notification requirements). The suggested approach would recognize the lower level of risk generally posed to individuals by these systems. Simultaneously, it would provide a mechanism for the public to be adequately informed in those situations where unusual concentrations of NTNC systems, customer overlap, and high

local arsenic water concentrations caused risk levels to more closely approach community water system levels.

There are approximately 20,000 NTNCs water systems regulated under the Safe Drinking Water Act. By definition, these systems do not serve over 25 people as year round residents, as would be the case for a community water system. However, they must serve at least 25 of the same people for over six months out of the year, or they would be classified as Transient Non-Community (TNC) water systems. It is generally an important distinction since the Agency has not applied regulations for contaminants with chronic health effects to TNC water systems, while it often has regulated NTNC systems similar to community water systems when addressing the risks posed by chronic contaminants.

In the case of arsenic, the existing regulation does not apply to NTNC systems. While it is feasible to control arsenic in NTNC water systems, extending regulation to these systems needs to be considered in light of the new SDWA requirement to determine whether the benefits extending coverage to this category would justify the costs and whether such regulation would provide a reasonable opportunity for health risk reduction. As discussed elsewhere in the preamble, this analysis requires a balancing of both quantitative and non-quantitative factors. Based on the modeling to be discussed, the ninetieth percentile lifetime risk of contracting bladder cancer posed to an individual consuming water from a NTNC water system, even in their present untreated state, does not exceed one in 100,000.<sup>3</sup> As a consequence, costs per each bladder cancer case avoided at the proposed MCL would approach the fifty million dollar mark if coverage of the rule were extended to NTNCs. This level is well above the range of historical environmental risk management decisions.

These much lower risk levels result because most individuals served by NTNC systems are expected to receive only a small portion of their lifetime drinking water exposure from such systems. For example, even with twelve years of perfect attendance at schools served by NTNC water systems, the water consumed by an individual student is estimated to represent less than five percent of lifetime consumption.

<sup>3</sup> Throughout this discussion, exposures and risks were only considered for populations potentially addressable by regulation, *i.e.*, systems with present arsenic levels in excess of 3 µg/L.

On the other hand, there are some segments of the NTNC water system population where exposure is a more significant portion of the total lifetime exposure. Manufacturing and other workers, although they represent only five percent of the population served by NTNC systems, could receive twenty to forty percent of their lifetime exposure at work. Nevertheless, as manufacturing workers represent a small portion of the NTNC population, overall risks among the NTNC population are small.

Another factor of potential concern is the extent to which users of the different NTNC water systems overlap. It is conceivable that some areas in the country exist where individuals are subjected to arsenic 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 arsenic levels. For some individuals, the exposure could approach levels observed in corresponding community water systems. This concern is alleviated by the fact that NTNC systems generally serve only a very small portion of the total population. For example, over ninety-five percent of all school children are served by community water systems. Only a small percentage are served by NTNC water systems and, of that group, only about twelve percent (or less than one half of one percent of the overall student population) would be expected to have arsenic in their water above the proposed regulatory level). 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. The groups have been treated independently for this analysis. Comment and data are solicited to support any alternative treatments of the exposure data.

Finally, although the Agency does not believe there is sufficient evidence to support unusual sensitivity on the part of children, they generally do consume more water on a weight adjusted basis. For this reason, NTNC systems which were likely to pose the greatest exposure risk to children were separately examined and their higher relative doses considered in the modeling effort. All of these factors contributed to the Agency's evaluation of whether or not to extend regulation to NTNC water systems for arsenic and are discussed further in the results section.

## 1. Methodology for Analyzing NTNCWS Risks

*Determination of system and individual exposure factors*—In the past, the Agency has directly used SDWIS population estimates for assessing the risks posed to users of NTNC water systems. In other words, it was assumed that the same person received the exposure on a year round basis. Under this approach it was generally assumed that all NTNC users were exposed for 270 days out of the year and obtained fifty percent of their daily consumption from these systems. TNC users were assumed to use the system for only ten days per year.

With the recent completion of "Geometries and Characteristics of Public Water Systems (US EPA, 1999e)," however, the Agency has developed a more comprehensive understanding of NTNC water systems. These systems provide water in due course as part of operating another line of business. Many systems are classified as NTNC, rather than TNC, water systems solely because they employ sufficient workers to trigger the "25 persons served for over six months out of the year" requirement. Client utilization of these systems is actually much less and more similar to exposure in TNC water systems. For instance, it is fairly implausible that highway rest areas along interstate highways serve the same population on a consistent basis (with the exception of long distance truckers). Nevertheless, there are highway rest areas in both NTNC and TNC system inventories. The "Geometries" report suggests that population figures reported in SDWIS which have been used for past risk assessments generally appear to reflect the number of workers in the establishment coupled with peak day customer utilization.

Under these conditions use of the SDWIS figures for population greatly overestimates the actual individual exposure risk for most of the exposed population and also significantly underestimates the number of people exposed to NTNC water.<sup>4</sup> Adequately characterizing individual and

<sup>4</sup> For example, airports constitute only about a hundred of the NTNC water systems. Washington's Reagan National and Dulles, Dallas/Fort Worth, Seattle/Tacoma, and Pittsburgh airports are the five largest of the airports. SDWIS reports that these five airports serve about 300,000 people. In actuality, Bureau of Transportation Statistics suggest that they serve about eleven million passengers per year. Examination of this information and other BTS statistics suggests that these airports serve closer to seven million unique individuals over the course of a year and that exposure occurs on an average of ten times per year per individual customer, not 270 times.

population risks necessitates some adjustments to the SDWIS population figures. For chronic contaminants, such as arsenic, health data reflect the consequences of a lifetime of exposure. Consequently, risk assessment requires the estimation of the portion of total lifetime drinking water consumption that any one individual would receive from a particular type of water system. In turn, one needs to estimate the appropriate portions for daily, days per year, and years per lifetime consumption. These estimates need to be prepared for both the workers at the facility and the "customers" of the facility.

This adjustment was accomplished through a comprehensive review of government and trade association statistics on entity utilization by the U.S. Department of Commerce's Standard Industrial Classification (SIC) code. These figures, coupled with SDWIS information relating to the portion of a particular industry served by non-community water systems, made possible the development of two

estimates needed for the risk assessment: customer cycles per year and worker per population served per day. These numbers are required to distinguish the more frequent and longer duration exposure of workers from that of system customers.<sup>5</sup> A more detailed characterization of the derivation of these numbers is contained in the docket. Table XI-2 provides the factors used in the NTNC risk assessment to account for the intermittent nature of exposure. Comment is solicited on the appropriateness of the various factors.

Once the population adjustment factors were derived, it was possible to determine the actual population served by NTNC water systems. Table XI-3 provides a breakout of these figures by type of establishment. Although not included in Table XI-3, there are other equally important characteristics to note about these systems. With notable exceptions (such as the airports in Washington, DC and Seattle), the systems generally serve a fairly small population on any given day. In fact, 99

percent of the systems serve less than 3300 users on a daily basis. This means that water production costs will be relatively high on a per gallon basis.

*Risk calculation*—Calculations of individual risk were prepared for each industrial sector. Even within a given sector, however, risk varies as a function of an individual's relative water consumption, body weight, vulnerability to arsenic exposure, and the water's arsenic concentration. Computationally, risks were estimated by performing Monte Carlo modeling, as was done in the community water system risk estimation, with two exceptions. First, each realization in a given sector was multiplied by the portion of lifetime exposure factor presented in Table XI-2 to reflect the decreased consumption associated with the NTNC system. Secondly, relative exposure factors were limited to age specific ratings where appropriate.<sup>6</sup> For example, in the case of school children, water consumption rates and weights for six to eighteen year olds were used.

TABLE XI-2.—EXPOSURE FACTORS USED IN THE NTNC RISK ASSESSMENT

NTNCWS	Number of cycles per yr	Worker/pop/day	Worker fraction daily	Worker days/yr	Worker exposure years	Customer fraction daily	Days of use/yr	Customer exposure years
Water wholesalers .....	1.00	0.000				0.25	270	70
Nursing homes .....	1.00	0.230	0.50	250	40	1.00	365	10
Churches .....	1.00	0.010	0.50	250	40	0.50	52	70
Golf/country clubs .....	4.50	0.110	0.50	250	40	0.50	52	70
Food retailers .....	2.00	0.070	0.50	250	40	0.25	185	70
Non-food retailers .....	4.50	0.090	0.50	250	40	0.25	52	70
Restaurants .....	2.00	0.070	0.50	250	40	0.25	185	70
Hotels/motels .....	86.00	0.270	0.50	250	40	1.00	3.4	40
Prisons/jails .....	1.33	0.100	0.50	250	40	1.00	270	3
Service stations .....	7.00	0.060	0.50	250	40	0.25	52	54
Agricultural products/ services .....	7.00	0.125	0.50	250	40	0.25	52	50
Daycare centers .....	1.00	0.145	0.50	250	10	0.50	250	5
Schools .....	1.00	0.073	0.50	200	40	0.50	200	12
State parks .....	26.00	0.016	0.50	250	40	0.50	14	70
Medical facilities .....	16.40	0.022	0.50	250	40	1.00	6.7	10.3
Campgrounds/RV .....	22.50	0.041	0.50	180	40	1.00	5	50
Federal parks .....	26.00	0.016	0.50	250	40	0.50	14	70
Highway rest areas .....	50.70	0.010	0.50	250	40	0.50	7.2	70
Misc. recreation service	26.00	0.016	0.50	250	40	1.00	14	70
Forest Service .....	26.00	0.016	1.00	250	40	1.00	14	50
Interstate carriers .....	93.00	0.304	0.50	250	40	0.50	2	70
Amusement parks .....	90.00	0.180	0.50	250	10	0.50	1	70
Summer camps .....	8.50	0.100	1.00	180	10	1.00	7	10
Airports .....	36.50	0.308	0.50	250	40	0.25	10	70
Military bases .....		1.000	0.50	250	40			
Non-water utilities .....		1.000	0.50	250	40			
Office parks .....		1.000	0.50	250	40			
Manufacturing: Food ....		1.000	0.50	250	40			
Manufacturing: Non- food .....		1.000	0.50	250	40			
Landfills .....		1.000	1.00	250	40			
Fire departments .....		1.000	1.00	250	40			

<sup>5</sup> For example, travel industry statistics provide information on total numbers of hotel stays, vacancy rates, traveller age ranges, and average duration of stay. These figures can be combined with the SDWIS peak day population estimates to

allocate daily population among workers, customers and vacancies. The combination of these factors provides an estimate of the number of independent customer cycles experienced in a year.

<sup>6</sup> For example, school kid water consumption was weighted to reflect consumption between ages 6 and 18, while factory worker consumption was weighted over ages 20 to 64.

TABLE XI-2.—EXPOSURE FACTORS USED IN THE NTNC RISK ASSESSMENT—Continued

NTNCWS	Number of cycles per yr	Worker/pop/day	Worker fraction daily	Worker days/yr	Worker exposure years	Customer fraction daily	Days of use/yr	Customer exposure years
Construction .....		1.000	1.00	250	40			
Mining .....		1.000	1.00	250	40			
Migrant labor camps ....		1.000	1.00	250	40			

TABLE XI-3.—COMPOSITION OF NON-TRANSIENT, NON-COMMUNITY WATER SYSTEMS  
[Percentage of total NTNC population served by sector]

Schools .....	9.7	Medical Facilities .....	8	Interstate Carriers .....	7.1	Campgrounds .....	1.3
Manufacturing .....	2.7	Restaurants .....	0.9	State Parks .....	8.6	Misc Recreation .....	1.8
Airports .....	26.1	Non-food Retail .....	1.6	Amusement Parks .....	17.7	Other .....	3.5
Office Parks .....	0.6	Hotels/Motels .....	9.2	H'way Rest Area .....	1.0		

To illustrate the process, it was conservatively assumed that a child would attend only NTNC served schools for all twelve years. Further, it was assumed that a child would get half of their daily water consumption at school (for an average first grader this would correspond to roughly nine ounces of water per school day). Finally, it was assumed that the child would have perfect attendance and attend school for 200 days per year. Table XI-4 provides a sample output for the upper bound individual risk distribution to school children resulting from exposure to the range of untreated arsenic observed in community ground water systems<sup>7</sup> as well as an estimate based on more moderate assumptions of four ounces per day and 150 days attendance for four years. Upper and lower bound risk distributions were prepared for both workers and “customers” at all types of NTNC water systems and are contained in the docket.

TABLE XI-4.—UPPER BOUND SCHOOL CHILDREN RISK ASSOCIATED WITH CURRENT ARSENIC EXPOSURE IN NTNC WATER SYSTEMS

[Risks are per 10,000 students. i.e.,  $\times 10^{-4}$ ]

	Moderate exposure scenario	Upper bound scenario
Mean Lifetime Risk .....	0.0087	0.079
90th Percentile Lifetime Risk .....	0.019	0.17
Lifetime Bladder Cancers in Student Population .....	0.5	4.5

**Note:** This table does not include potential non-quantified lung or skin cancers.

The distribution of population risks overall was determined as part of the same simulation by developing sector weightings to reflect the total portion of the NTNC population served by each sector. Population weighted proportional sampling of the individual sectors provided an overall distribution of risk among those exposed at NTNC systems.

2. Results

It is important to note that the results presented in the discussion of NTNC benefits are based on the currently quantified health endpoint for arsenic related bladder cancer. As noted elsewhere in Section X of today’s proposal, there are a number of health end points that have not yet been quantified and which could provide a rationale for extending coverage to NTNCs—in the event that a substantial portion of the consumers of water from such systems fall outside the 1 in 10,000

risk range frequently used by the Agency as a benchmark for such decisions. (Any additional data quantifying such endpoints would made available for public comment in a Notice of Data Availability.)

Table XI-5 presents a summary of the Benefit Cost Analysis for all NTNC systems. As can be seen from a review of the Table, regulation of arsenic in NTNC water systems provides only very limited opportunity for national risk reduction. Table XI-6 presents risk figures for three particular sets of individuals: children in daycare centers and schools, and construction workers. Construction and other strenuous activity workers comprise an extremely small portion of the population served by NTNC systems (less than 0.1%), but face the highest relative risks of all NTNC users (90th percentile risks of  $0.7$  to  $1.6 \times 10^{-4}$  lifetime risk). Nevertheless, there is considerable uncertainty about these exposure

numbers. It is quite likely that they overestimate consumption and may be revised downward by subsequent analysis (Any additional data quantifying such endpoints would made available for public comment in a Notice of Data Availability.). The risks for children are much lower with an upper bound, 90th percentile estimate of  $1.7 \times 10^{-5}$  lifetime risk.

What is not possible to determine from the analysis of NTNC systems is the extent to which there is overlap of individual exposure between the various sectors. As mentioned earlier, NTNC establishments generally constitute a small portion of their SIC sectors. This fact and the observation that NTNC populations would only serve about one percent of the total population if all of the sectors with significant exposure (greater than five percent of lifetime) if they were

<sup>7</sup> Community ground water occurrence information was used since NTNC systems are almost exclusively supplied by ground water

sources. Further, as there was no depth dependence of arsenic levels observed in the community

information, it is believed that the data are an adequate approximation.

mutually exclusive,<sup>8</sup> provide some support for treating the SIC groups independently. However, it is equally plausible that there are communities where one individual might go from an NTNC day care center to a series of NTNC schools and then work in an NTNC factory.

The Agency is concerned about the potential for local issues to arise with respect to combined arsenic exposures. In the rare community where all ground water is contaminated with the highest levels of arsenic, risks could be outside of the Agency's traditionally allowable realm. Further, different levels of protection being provided by schools served by community water systems versus those served by NTNC systems could be seen as posing equity considerations for rural communities. For all of these reasons, the Agency does not believe it is appropriate to

completely exempt NTNC systems from arsenic regulation. On the other hand, it does not believe an adequate basis exists to prescribe a standard.

The Agency is proposing to take a somewhat different approach with respect to NTNC water systems than previously practiced. We are proposing that NTNC water systems be subject to arsenic monitoring requirements applicable to community water systems. When an individual NTNC system has arsenic present in excess of the MCL for community systems, it would be required to post a notice to customers as described in Section VIII.I. of this rule. The Agency believes that this approach will provide localities with high arsenic concentrations the opportunity to limit their consumption of water from these systems. Because the NTNC is not the sole source of water available to these consumers as would be the case with a

community water system, they would have the ability to use bottled water, or in the case of schools for instance, to install voluntary treatment to reduce their exposure.

The Agency requests comment on this approach for addressing NTNC water systems as well as on two other possible approaches: exempting NTNC systems entirely from coverage under this rule or extending coverage to NTNC systems in the same manner as CWSs. EPA requests an accompanying rationale and any data commenters wish to submit as part of their comments on this topic. The Agency may decide, as part of the final rule, to incorporate any of these three approaches without further opportunity for comment (except where a NODA may be issued to provide the public with additional new information not taken into consideration for today's rulemaking).

TABLE XI-5.—NON-TRANSIENT NON-COMMUNITY BENEFIT COST ANALYSIS

[All risk values are per 10,000-i.e., 10<sup>-4</sup>]

MCL option	Untreated		10		5		3	
	Lower bound	Upper bound						
Mean Individual Risk .....	0.019	0.042	0.012	0.026	0.0077	0.017	0.0046	0.01
90th Percentile Individual .....	0.037	0.08	0.027	0.058	0.017	0.037	0.01	0.025
Annual Bladder Cancers .....	0.427	0.95	0.265	0.583	0.16	0.36	0.101	0.215
Cancer Cases Avoided .....	0	0	0.162	0.367	0.267	0.59	0.326	0.735
Benefit Million Dollars .....	0	0	0.31	0.70	0.51	1.1	0.62	1.4
Cost Million Dollars .....	.....	0	.....	6.121	.....	14.69	.....	25.21

Note: This table does not include potential non-quantified lung cancer benefits.

TABLE XI-6.—SENSITIVE GROUP EVALUATION LIFETIME RISKS

Group	Mean risk	90th percentile risk
Forest Service, Construction and Mining Workers .....	3.2-7×10 <sup>-5</sup>	7.2-16×10 <sup>-5</sup>
School Children .....	3.8-7.9×10 <sup>-6</sup>	0.84-1.7×10 <sup>-5</sup>
Day Care Children .....	3.4-6.8×10 <sup>-6</sup>	0.74-1.5×10 <sup>-5</sup>

**XII. State Programs**

*A. How Does Arsenic Affect a State's Primacy Program?*

States must revise their programs to adopt any part of today's rule which is more stringent than the approved State program. Primacy revisions must be completed in accordance with 40 CFR 142.12, and 142.16. States must submit their revised primacy application to the Administrator for approval. State requests for final approval must be submitted to the Administrator no later than 2 years after promulgation of a new standard unless the State requests and is granted an additional 2-year extension.

For revisions of State programs, § 142.12 requires States to submit, among other things, "[a]ny additional materials that are listed in § 142.16 of this part for a specific EPA regulation, as appropriate (§ 142.12(c)(1)(ii))." Based on comments from stakeholders at the arsenic in drinking water regulatory development meetings held prior to proposal, EPA believes that the information required in § 142.16(e) is not required for States revising the MCL for arsenic. Although that section refers to applications that adopt requirements of §§ 141.11, 141.23, 141.32, and 141.62, EPA believes that existing State programs which contain the

standardized monitoring framework for inorganic contaminants (40 CFR 141.23) can ensure all CWSs monitor for arsenic. Therefore, EPA is proposing to clarify that § 141.16(e) applies only to new contaminants, not revisions of existing contaminants regulations. The Agency requests comment on whether this is an appropriate change.

EPA believes that the requirements in § 142.12(c) will provide sufficient information for EPA review of the State revision. The side-by-side comparison of requirements required in § 142.12(c)(1)(i) will only consist of sections revised to adopt the changes required for the arsenic regulation and

<sup>8</sup> This is considerably less than the estimated rural population in the U.S. which is the smallest

group among which users of these systems would conceivably be distributed.

any other revisions requested by the State. In addition, the Attorney General's statement required in § 142.12(c)(1)(iii) will certify that the revised regulations will be effective and enforceable. The Agency requests comment on whether any other documentation is necessary to approve revisions to State programs enforcing the new arsenic regulation.

The Agency is proposing to add § 142.16(j) to clarify primacy requirements relating to monitoring plans and waiver procedures for revisions of existing monitoring requirements such as arsenic. Section 142.16(j) clarifies that the State simply needs to inform the Agency in their application of any changes to the monitoring plans and waiver procedures. Alternatively, a State may indicate in the primacy application that they will use the existing monitoring plans and waiver criteria approved for primacy under the National Primary Drinking Water Standards for other contaminants (for example, *i.e.* the Phase II/V rules). This information may be provided in the primacy application crosswalk which identifies revisions to the State primacy program.

#### *B. When Does a State Have To Apply?*

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

#### *C. How Are Tribes Affected?*

Currently, no federally recognized Indian tribes have primacy to enforce any of the drinking water regulations. EPA Regions implement the rules for all Tribes under section 1451(a)(1) of SDWA. Tribes must submit a primacy

application to have oversight for the inorganic contaminants (*i.e.*, the Phase II/V rule) to obtain the authority for the revised arsenic MCL. Tribes with primacy for drinking water programs are eligible for grants and contract assistance (section 1451(a)(3)). Tribes are also eligible for grants under the Drinking Water State Revolving Fund Tribal set aside grant program authorized by section 1452(i) for public water system expenditures.

### **XIII. HRRCA**

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

Section 1412(b)(3)(C) of the 1996 Amendments requires EPA to prepare a Health Risk Reduction and Cost Analysis (HRRCA) in support of any NPDWR that includes an MCL. According to these requirements, EPA must analyze each of the following when proposing a NPDWR that includes an MCL: (1) Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level; (2) quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations; (3) quantifiable and non-quantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the MCL, including monitoring, treatment, and other costs, and excluding costs resulting from compliance with other proposed or promulgated regulations; (4) the incremental costs and benefits associated with each alternative MCL considered; (5) the effects of the contaminant on the general population and on groups within the general population, such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population; (6) any increased health risk that may occur as

the result of compliance, including risks associated with co-occurring contaminants; and (7) other relevant factors, including the quality and extent of the information, the uncertainties in the analysis, and factors with respect to the degree and nature of the risk.

This analysis summarizes EPA's estimates of the costs and benefits associated with various arsenic levels. Summary tables are presented that characterize aggregate costs and benefits, impacts on affected entities, and tradeoffs between risk reduction and compliance costs. This analysis also summarizes the effects of arsenic on the general population as well as any sensitive subpopulations and provides a discussion on the uncertainties in the analysis and any other relevant factors.

#### *B. What Are the Quantifiable and Non-Quantifiable Health Risk Reduction Benefits?*

Arsenic ingestion has been linked to a multitude of health effects, both cancerous and non-cancerous. These health effects include cancer of the bladder, lungs, skin, kidney, nasal passages, liver, and prostate. Arsenic ingestion has also been attributed to cardiovascular, pulmonary, immunological, neurological, endocrine, and reproductive and developmental effects. A complete list of the arsenic-related health effects reported in humans is shown in Table X-1. Current research on arsenic exposure has only been able to define scientifically defensible risks for bladder cancer. Because there is currently a lack of strong evidence on the risks of other arsenic-related health effects noted above, the Agency has based its assessment of the quantifiable health risk reduction benefits solely on the risks of arsenic induced bladder cancers. It is important to note that if the Agency were able to quantify additional arsenic-related health effects, the quantified benefits estimates may be significantly higher than the estimates presented in this analysis.

The quantifiable health benefits of reducing arsenic exposures in drinking water are attributable to the reduced number of fatal and non-fatal cancers, primarily of the bladder. Table XIII-1 shows the health risk reductions (number of total bladder cancers avoided and the proportions of fatal and non-fatal bladder cancers avoided) at various arsenic levels.

TABLE XIII-1.—RISK REDUCTION FROM REDUCING ARSENIC IN DRINKING WATER <sup>1</sup>

Arsenic level <sup>2</sup> (µg/L)	Risk reduction (total bladder cancers avoided per year)	Risk reduction (fatal bladder cancers avoided per year)	Risk reduction (non-fatal bladder cancers avoided per year)
3 .....	22–42	5.7–10.9	16.3–31.1
5 .....	16–36	4.2–9.4	11.8–26.6
10 .....	9–21	2.3–5.5	296
20 .....	4–12	1–3	6.7–15.5 3–9

<sup>1</sup> The number of bladder cancer cases avoided provide our “best” estimates at this time. The actual number of cases could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

The above ranges of total, fatal, and non-fatal bladder cancer cases are based on a range of mean bladder cancer risks for exposed populations at or above arsenic levels of 3, 5, 10, and 20 µg/L as shown in Table XIII-2. For example, if we multiply the risk range at 3 µg/L ( $2.1 \times 10^{-5}$  to  $4.5 \times 10^{-5}$ ) by the

population exposed at 3 µg/L (26.6 million), we find that the total cancers avoided at this arsenic level range from 22 to 42 bladder cancers per year, when subtracted from the number of bladder cancers per year at the baseline (50 µg/L). Fatal bladder cancer cases are determined through the relationship

(EPA, 1999a) that approximately 26 percent of the total bladder cancer cases avoided at each level result in fatalities. Non-fatal bladder cancer cases are calculated by subtracting the total number of cancers from the number of fatal cancer cases.

TABLE XIII-2.—MEAN BLADDER CANCER RISKS AND EXPOSED POPULATION<sup>1</sup>

Arsenic level (µg/L)	Mean exposed population risk <sup>2</sup>	Total bladder cancer cases avoided per year <sup>3</sup>
Baseline (50 µg/L):		
3 .....	$2.1 - 4.5 \times 10^{-5}$	22–42
5 .....	$3.6 - 7.5 \times 10^{-5}$	16–36
10 .....	$5.5 - 11.4 \times 10^{-5}$	9–21
20 .....	$6.9 - 13.9 \times 10^{-5}$	4–12

<sup>1</sup> The population exposed at 3 µg/L or greater is approximately 26.6 million.

<sup>2</sup> The bladder cancer risks presented in this table provide our “best” estimates at this time. Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume a 100% mortality rate. An 80% mortality rate is used in the computation of upper bound benefits.

<sup>3</sup> Total bladder cancer cases avoided could be higher, depending on the survival rate for bladder cancer in the study area of Taiwan for the duration of the study.

The Agency has developed monetized estimates of the health benefits associated with the risk reductions from arsenic exposures. The SDWA, as amended, requires that a cost-benefit analysis be conducted for each NPDWR, and places a high priority on better analysis to support rulemaking. The Agency is interested in refining its approach to both the cost and benefit analysis, and in particular recognizes that there are different approaches to monetizing health benefits.

The approach used in this analysis for the measurement of health risk reduction benefits is the monetary value of a statistical life (VSL) applied to each fatal cancer avoided. Estimating the VSL involves inferring individuals’ implicit tradeoffs between small changes in mortality risk and monetary compensation. In this analysis, a central

tendency estimate of \$5.8 million (1997\$) is used in the monetary benefits calculations. This figure is determined for the VSL estimates in 26 studies reviewed in EPA’s recent draft guidance on benefits assessment (US EPA, 1997f). It is important to recognize the limitations of existing VSL estimates and to consider whether factors such as differences in the demographic characteristics of the populations and differences in the nature of the risks being valued have a significant impact on the value of mortality risk reduction benefits. Also, medical care or lost-time costs are not separately included in the benefits estimates for fatal cancers, since it is assumed that these costs are captured in the VSL for fatal cancers.

For non-fatal cancers, willingness to pay (WTP) data to avoid chronic bronchitis is used as a surrogate to

estimate the WTP to avoid non-fatal bladder cancers. The use of such WTP estimates is supported in the SDWA, as amended, at section 1412(b)(3)(C)(iii): “The Administrator may identify valid approaches for the measurement and valuation of benefits under this subparagraph, including approaches to identify consumer willingness to pay for reductions in health risks from drinking water contaminants.”

A WTP central tendency estimate of \$536,000 (in 1997 \$) is used to monetize the benefits of avoiding non-fatal cancers (Viscusi *et al.*, 1991). The fatal, non-fatal, and non-quantifiable health benefits are summarized in Table XIII-3. As expected, the quantified bladder cancer benefits increase as arsenic levels decrease.

TABLE XIII-3.—ESTIMATED COSTS AND BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER  
[In 1999 \$ millions]

Arsenic level (µg/L)	Total national costs to CWSs <sup>1</sup>	Total national costs to CWSs and NTNCWSs <sup>2</sup>	Total bladder cancer health benefits <sup>3</sup>	“What if” scenario <sup>4</sup> and potential non-quantified benefits	
				“What if” lung cancer health benefits estimates	Potential non-quantifiable health benefits
3 .....	643.1–753	644.6–756.3	43.6–104.2 <sup>5</sup> (79)	47.2–448 <sup>6</sup> (213.4)	<ul style="list-style-type: none"> <li>• Skin Cancer.</li> <li>• Kidney Cancer.</li> <li>• Cancer of the Nasal Passages.</li> <li>• Liver Cancer.</li> <li>• Prostate Cancer.</li> <li>• Cardiovascular Effects.</li> <li>• Pulmonary Effects.</li> <li>• Immunological Effects.</li> <li>• Neurological Effects.</li> <li>• Endocrine Effects.</li> <li>• Reproductive and Developmental Effects.</li> </ul>
5 .....	377.3–441.8	378.9–444.9	31.7–89.9 <sup>5</sup> (64.3)	35–384 <sup>6</sup> (173.4)	
10 .....	163.3–191.8	164.9–194.8	17.9–52.1 <sup>5</sup> (37)	19.6–224 <sup>6</sup> (100)	
20 .....	61.6–72.9	63.2–77.1	7.9–29.8 <sup>5</sup> (19.8)	8.8–128 <sup>6</sup> (53.4)	

<sup>1</sup> Costs include treatment, monitoring, O&M, and administrative costs to CWSs and State costs for administration of water programs. The lower number shows costs annualized at a consumption rate of interest of 3%, EPA’s preferred approach. The higher number shows costs annualized at 7%, which represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations.

<sup>2</sup> Costs include treatment, monitoring, O&M, administrative costs to CWSs; monitoring and administrative costs to NTNCWSs; and State costs for administration of water programs.

<sup>3</sup> The upper bound estimate includes an adjustment to account for a possible mortality risk of 80%. It is possible that this risk could have been below 80%, which would lead to increased benefits. The actual risk depends on the survival rate for bladder cancer in the area of Taiwan studied by Chen, which is unknown.

<sup>4</sup> These estimates are based on the “what if” scenario for lung cancer, where the risks of a fatal lung cancer case associated with arsenic are assumed to be 2–5 times that of a fatal bladder cancer case.

<sup>5</sup> The number in parentheses indicates the bladder cancer health benefits assuming an 80% mortality rate for bladder cancer in the area of the Chen study, and starting from the midpoint of the benefits range when mortality and incidence are assumed equivalent.

<sup>6</sup> The number in parentheses is the midpoint of the range and corresponds to an assumption that the risk of fatal lung cancer is 3.5 times the risk of fatal bladder cancer.

Reductions in arsenic exposures may also be associated with non-quantifiable benefits. EPA has identified several potential non-quantifiable benefits associated with regulating arsenic in drinking water. In addition to the non-quantifiable benefits noted in Table XIII-3, these benefits may include any customer peace of mind from knowing that their drinking water has been

treated for arsenic. Also, using reverse osmosis to remove arsenic from drinking water may also reduce other contaminants such as sulfate, nitrate, and iron due to the high removal efficiency of this treatment technology.

*C. What Are the Quantifiable and Non-Quantifiable Costs?*

The costs of reducing arsenic to various levels are summarized in Table XIII-4, which shows that, as expected, aggregate arsenic mitigation costs increase with decreasing arsenic levels. Total national costs range from \$646 million per year at 3 µg/L to \$65 million per year at 20 µg/L.

TABLE XIII-4.—ESTIMATED ANNUALIZED NATIONAL COSTS OF REDUCING ARSENIC EXPOSURES  
[In 1999 \$ millions]

Arsenic level (µg/L)	Costs to CWSs <sup>1</sup>	Total national costs to CWSs <sup>2</sup>	Total national costs to CWSs and NTNCWSs <sup>3</sup>	Total cost per fatal bladder cancer case avoided <sup>4</sup>
3 .....	639–746.4	643.1–753	644.6–756.3	59–113 (69.4–132.7)
5 .....	374–436	377.3–441.8	378.9–444.9	40–91 (47–106)
10 .....	160–187	163.3–191.8	164.9–194.8	30.2–70.5 (35.4–84.7)
20 .....	59–68	61.6–72.9	63.2–77.1	20.3–60.7 (26–77.1)

<sup>1</sup> Costs include treatment and O&M costs only. The lower number shows costs annualized at 3 percent; the higher number shows costs annualized at 7%. The 7% rate represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations.

<sup>2</sup> Costs include treatment, monitoring, O&M, and administrative costs to CWSs and State costs for administration of water programs. Costs annualized at 3 and 7 percent.

<sup>3</sup> Costs include treatment, monitoring, O&M, administrative costs to CWSs; monitoring and administrative costs to NTNCWSs; and State costs for administration of water programs. Costs annualized at 3 and 7 percent.

<sup>4</sup> Range based on range of fatal bladder cancer cases avoided per year shown in Table XIII.1. The range of costs per fatal bladder cancer avoided could be one-half of the value presented, depending on the mortality rate for bladder cancer in the study area of Taiwan for the duration of the study. A plausible estimate for that mortality rate is 80%.

The cost impact of reducing arsenic in drinking water at the household level was also assessed. Table XIII-5

examines the cost per household for each system size category. As shown in the table, costs per household decrease

as system size increases. Costs per household also do not vary significantly across arsenic levels. This is because

costs do not vary significantly with removal efficiency; once a system installs a treatment technology to meet an MCL, costs based upon the removal

efficiency that the treatment technology will be operated under remain relatively flat. Per household costs are, however, somewhat lower at less stringent arsenic

levels. This is due to the assumption that some systems would blend water at these levels and treat only a portion of the flow.

TABLE XIII-5.—ESTIMATED ANNUAL COSTS PER HOUSEHOLD <sup>1</sup> (IN 1999 \$) AND (NUMBER OF HOUSEHOLDS AFFECTED)

System size	3 µg/L	5 µg/L	10 µg/L	20 µg/L
25-100 .....	\$368 (93,900)	\$364 (58,600)	\$357 (27,000)	\$349 (10,000)
101-500 .....	\$259 (366,900)	\$254 (229,000)	\$246 (103,000)	\$238 (41,000)
501-1,000 .....	\$106 (356,000)	\$104 (223,000)	\$98 (102,000)	\$93 (41,000)
1,001-3,300 .....	\$64 <sup>2</sup> (1)	\$60 (626,000)	\$57 (290,000)	\$52 (118,000)
3,301-10,000 .....	\$44 <sup>2</sup> (1.6)	\$41 <sup>2</sup> (1)	\$37 (478,000)	\$33 (196,000)
10,001-50,000 .....	\$36 <sup>2</sup> (3.25)	\$33 <sup>2</sup> (2.1)	\$29 (998,000)	\$25 (406,000)
50,001-100,000 .....	\$30 <sup>2</sup> (1.4)	\$27 <sup>2</sup> (0.9)	\$23 (465,000)	\$19 (189,000)
100,001-1 million .....	\$23 <sup>2</sup> (3.1)	\$21 <sup>2</sup> (1.8)	\$18 (937,000)	\$15 (365,000)

<sup>1</sup> Costs include treatment and O&M costs to CWSs only.

<sup>2</sup> Million.

Costs per household are higher for households served by smaller systems than larger systems for two reasons. First, smaller systems serve far fewer households than larger systems and, consequently, each household must bear a greater percentage share of the capital and O&M costs. Second, smaller systems tend to have higher influent arsenic concentrations that, on a per-capita or per-household basis, require

more expensive treatment methods (e.g., a higher percentage removal efficiency) to comply with an MCL.

Table XIII-6 summarizes the estimates of total national costs of compliance with the proposed MCL options of 3, 5, and 10, and 20 µg/L. This table is divided into two major groupings; the first grouping displays the estimated costs to Community Water Systems (CWSs) and the second

grouping displays the estimated costs to Non-Transient Non-Community Water Systems (NTNCWSs). The State costs presented in Table XIII-6 were developed as part of the analyses to comply with the Unfunded Mandates Reform Act (UMRA) and also the Paperwork Reduction Act (PRA). Additional information on State costs is provided in Section XIV of this preamble.

TABLE XIII-6.—SUMMARY OF THE TOTAL ANNUAL NATIONAL COSTS OF COMPLIANCE WITH THE PROPOSED ARSENIC RULE ACROSS MCL OPTIONS

[In 1997 \$ millions] <sup>1</sup>

Costs	CWS		NTNCWS	
	3 percent	7 percent	3 percent	7 percent
<b>3 µg/L</b>				
Treatment .....	639.2	746.4	*(25.2)	*(30.5)
Monitoring, Reporting & Recordkeeping .....	2.2	2.9	0.95	1.1
State & EPA Administrative Costs .....	2.2	3.7	1.1	2.2
Total Costs .....	643.6	753.0	* 1.2 (27.3)	* 3.3 (33.8)
<b>5 µg/L</b>				
Treatment .....	373.9	436.0	*(14.7)	*(17.8)
Monitoring, Reporting & Recordkeeping .....	1.9	2.7	0.92	1.1
State & EPA Administrative Costs .....	1.8	3.1	1.0	2.0
Total Costs .....	377.8	441.8	* 1.2 (16.6)	* 3.1 (20.9)
<b>10 µg/L</b>				
Treatment .....	160.4	186.7	*(6.1)	*(7.4)
Monitoring, Reporting & Recordkeeping .....	1.8	2.5	0.90	1.1
State & EPA Administrative Costs .....	1.5	2.6	0.93	1.9
Total Costs .....	163.7	191.8	* 1.8 (7.9)	* 3.0 (10.3)

TABLE XIII-6.—SUMMARY OF THE TOTAL ANNUAL NATIONAL COSTS OF COMPLIANCE WITH THE PROPOSED ARSENIC RULE ACROSS MCL OPTIONS—Continued  
[In 1997 \$ millions]<sup>1</sup>

Costs	CWS		NTNCWS	
	3 percent	7 percent	3 percent	7 percent
Cost of capital				
<b>20 µg/L</b>				
Treatment .....	58.9	68.3	*(2.1)	*(2.6)
Monitoring, Reporting & Recordkeeping .....	1.7	2.4	2.0	2.3
State & EPA Administrative Costs .....	1.3	2.3	0.91	1.9
<b>Total Costs .....</b>	<b>61.9</b>	<b>72.9</b>	<b>*2.9 (5.1)</b>	<b>*4.2 (6.7)</b>

<sup>1</sup> Totals may not add due to rounding.

\* Costs in parentheses include treatment costs if NTNCWS had to comply with the MCL.

*D. What Are the Incremental Benefits and Costs?*

Table XIII-7 summarizes the incremental benefits and costs associated with arsenic exposure reduction.

TABLE XIII-7.—ESTIMATES OF THE ANNUAL INCREMENTAL RISK REDUCTION, BENEFITS, AND COSTS OF REDUCING ARSENIC IN DRINKING WATER  
[\$millions, 1999]

Arsenic level	20 µg/L	10 µg/L	5 µg/L	3 µg/L
Incremental Risk Reduction, Fatal Bladder Cancers Avoided Per Year .....	1-3	1.3-2.5	1.9-3.9	1.5-1.5
Incremental Risk Reduction, Non-Fatal Bladder Cancers Avoided Per Year .....	3-9	3.7-6.5	5.1-11.1	4.5-4.5
Annual Incremental Monetized Benefits <sup>1</sup> .....	7.9-29.8	10-22.3	13.8-37.8	11.9-14.3
Annual Incremental Costs <sup>2</sup> .....	63.2	101.7	214	265.7

<sup>1</sup> The incremental upper bound benefits estimates presented in this table have been adjusted upwards to reflect an 80% mortality rate, which is a plausible mortality rate for the area of Taiwan during the Chen study.

<sup>2</sup> Costs include treatment, monitoring, O&M, and administrative costs to CWSs; monitoring and administrative costs to NTNCWSs and State costs.

*E. What Are the Risks of Arsenic Exposure to the General Population and Sensitive Subpopulations?*

The SDWA, as amended, includes specific provisions in section 1412(b)(3)(C)(i)(V) to assess the effects of the contaminant on the general population and on groups within the general population such as children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population. The NRC Report concluded that there is insufficient scientific information to permit separate cancer risk estimates for potential subpopulations such as pregnant women, lactating women, and children and that factors that influence sensitivity to or expression of arsenic-associated cancer and noncancer effects need to be better characterized. Despite the inconclusive nature of the effects on subpopulations, EPA is planning to issue a health advisory for arsenic in early 2000. See section IV.C of this preamble for further information on the health advisory.

*F. What Are the Risks Associated With Co-Occurring Contaminants?*

The SDWA, as amended, requires EPA to take into account the activities under preceding rules that may have impacts on future rules. To address this requirement, EPA analyzed the co-occurrence of arsenic with other drinking water contaminants (EPA, 1999f). The results of this analysis help determine the level of overlap in regulatory requirements (cost of technology that can remove more than one contaminant) and also indicate where specific levels of one contaminant may interfere with the treatment technology for another. This analysis indicates that there is some co-occurrence of arsenic with sulfate, iron, and radon. Co-occurrence can also indicate the likelihood for increased, or in this case, decreased risks due to arsenic and selenium.

As discussed in section XI.A.5. of the preamble, animal studies suggest that selenium reduces the toxicity of arsenic, and people in Taiwan have much lower levels of selenium in their blood and urine than people in China, the U.S., and Canada. Deficient selenium intake is linked to heart problems, and excessive intake can lead to thick brittle

nails and changes in the nervous system. The U.S. recommends a daily dietary intake of 55 µg/day for females and 70 µg/day for males. The WHO lower limit of safe ranges are 30 (for females) and 40 (for males) µg/day (NRC, 1990). EPA's study of co-occurrence of arsenic (at 2, 5, 10, 20, and > 20 µg/L) and selenium above 50 µg/L levels found no significant correlations between arsenic and selenium. EPA believes that, in general, the U.S. population does not experience selenium toxicity which would be reduced by the presence of arsenic and that there is sufficient selenium in the American diet to reduce the toxicity of arsenic. The Agency requests data and comments on whether selenium decreases arsenic toxicity on a regional basis. Section V of this preamble summarizes the results of EPA's arsenic co-occurrence analysis.

*G. What Are the Uncertainties in the Analysis?*

The models used to estimate arsenic-related cancer risks, risk reduction, and monetary benefits take many inputs which are both uncertain and highly variable. The benefits estimates that have been discussed in this preamble were derived using point estimates of

the monetary surrogates for fatal and non-fatal bladder cancers. The value of statistical life (VSL) has been approximated by a single-value estimate of \$5.8 million, and willingness-to-pay (WTP) to avoid non-fatal bladder cancer has been modeled as a constant with a value of \$536,000. These are the central tendency values derived by EPA, based on studies from the economic literature and previous regulatory analyses (US EPA 1997f, Viscusi *et al.*, 1991). Because the VSL is much larger than the WTP value, the VSL value dominates the total monetary benefits calculation.

The studies that have been reviewed by EPA (US EPA 1997f) have developed a wide range of VSL values, from \$700,000 to \$16.3 million. This implies that the monetized benefits of reduced bladder cancer risks could take a wide range of values, depending upon the VSL that is chosen.

Additional sources of uncertainty in this analysis are also found in the NRC Report. Such uncertainties include the shape of the dose-response curve, the contribution of arsenic exposure from food, and the choice of model when conducting arsenic risk assessment. These sources of uncertainties are discussed in further detail in section XI. of today's document.

#### XIV. Administrative Requirements

##### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

##### B. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*

###### 1. Overview

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

###### 2. Use of Alternative Small Entity Definition

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

EPA is proposing the Arsenic Rule which contains provisions which apply to small PWSs serving fewer than 10,000 persons. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. Because this definition does not correspond to the definitions of "small" for small businesses, governments, and non-profit organizations, EPA requested comment on an alternative definition of "small entity" in the preamble to the proposed Consumer Confidence Report (CCR) regulation (63 FR 7605 at 7620, February 13, 1998, US EPA 1998j). Comments showed that stakeholders supported the proposed alternative definition. EPA also consulted with the SBA Office of Advocacy on the definition as it relates to small business analysis. In the preamble to the final CCR regulation (63 FR 44511, August

19, 1998, US EPA, 1998e), EPA stated its intent to establish this alternative definition for regulatory flexibility assessments under the RFA for all drinking water regulations and has thus used it in this proposed rulemaking.

###### 3. Initial Regulatory Flexibility Analysis

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could reduce that impact. The IRFA is available for review in the docket and is summarized below.

The RFA requires EPA to address the following when completing an IRFA:

- (1) Describe the reasons why action by the Agency is being considered;
- (2) State succinctly the objectives of, and legal basis for, the proposed rule;
- (3) Describe, and where feasible, estimate the types and number of small entities to which the proposed rule will apply;
- (4) Describe the projected reporting, record keeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of reports or records;
- (5) Identify, to the extent practicable, all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule; and
- (6) Describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes while minimizing any significant economic impact of the proposed rule on small entities.

EPA has considered and addressed all of the previously described requirements. The following is a summary of the IRFA. The first and second requirements are discussed in section I.A. of this Preamble. The third and fourth requirements are summarized as follows. The fifth requirement is discussed under section VIII.F. of this Preamble in a subsection addressing potential interactions between the arsenic rule and upcoming and existing rules affecting community water systems. The sixth requirement, regulatory alternatives, is detailed in section XIII.

*a. Number of Small Entities Affected.* The number of small entities subject to today's rule is shown in Table XIV-1 below.

TABLE XIV-1.—PROFILE OF THE UNIVERSE OF SMALL WATER SYSTEMS REGULATED UNDER THE ARSENIC RULE

Water system type	System size category				
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000
Publicly-Owned:					
CWS .....	1,729	5,795	3,785	6,179	3,649
NCWS .....	1,783	3,171	1,182	361	29
Privately-Owned:					
CWS .....	13,640	11,266	2,124	1,955	654
NCWS .....	8,178	4,162	902	411	56
Total Systems:					
CWS .....	15,369	17,061	5,909	8,134	4,303
NCWS .....	9,961	7,333	2,084	772	85
Total .....	25,330	24,394	7,993	8,906	4,388

Source: Safe Drinking Water Information System (SDWIS), December 1998 freeze.

b. *Reporting, Recordkeeping and Other Requirements for Small Systems.* The proposed arsenic rule continues to require small systems to maintain records and to report arsenic concentration levels at the point-of-entry to the water system's distribution system. Small systems are also required to provide arsenic information in the Consumer Confidence Report or other public notification if the system exceeds the MCL. Arsenic monitoring and reporting will be required annually for surface water (and mixed surface and ground water systems) or once every three years for ground water systems, unless the small system obtains a monitoring waiver from the State, demonstrating compliance with the proposed MCL. Other existing information and reporting requirements, such as Consumer Confidence Reports and public notification requirements, will be revised to include the lower arsenic MCL (see sections VII. H. and I.). As is the case for other contaminants, required information on system arsenic levels must be provided by affected systems and is not considered to be confidential. The professional skills necessary for preparing the reports are the same skill level required by small systems for current reporting and monitoring requirements for other drinking water standards.

The classes of small entities that are subject to the proposed arsenic rule include public water systems serving less than 10,000 people.

#### 4. Small Business Advocacy Review (SBAR) Panel Recommendations

As required by section 609(b) of the RFA, as amended by SBREFA, EPA also conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the small entities that potentially

would be subject to the rule's requirements.

EPA identified 22 representatives of small entities that were most likely to be subject to the proposal. In December, 1998, EPA prepared and distributed to the small entity representatives (SERs) an outreach document on the arsenic rule titled "Information for Small Entity Representatives Regarding the Arsenic in Drinking Water Rule" (US EPA, 1998g).

On December 18, 1998, EPA held a small entity conference call from Washington D.C. to provide a forum for small entity input on key issues related to the planned proposal of the arsenic in drinking water rule. These issues included, but were not limited to issues related to the rule development, such as arsenic health risks, treatment technologies, analytical methods, and monitoring. Fifteen SERs from small water systems participated on the call from the following States: Alabama, Arizona, California, Georgia, Massachusetts, Montana, Nebraska, New Hampshire, New Jersey, Utah, Virginia, Washington, and Wisconsin.

Efforts to identify and incorporate small entity concerns into this rulemaking culminated with the convening of a SBAR Panel on March 30, 1999, pursuant to section 609 of RFA/SBREFA. The four-person Panel was headed by EPA's Small Business Advocacy Chairperson and included the Director of the Standards and Risk Management Division within EPA's Office of Ground Water and Drinking Water, the Administrator of the Office of Information and Regulatory Affairs with the Office of Management and Budget, and the Chief Counsel for Advocacy of the SBA. For a 60-day period starting on the convening date, the Panel reviewed technical background information related to this rulemaking, reviewed comments provided by the SERs, and met on several occasions. The Panel also

conducted its own outreach to the SERs and held a conference call on April 21, 1999 with the SERs to identify issues and explore alternative approaches for accomplishing environmental protection goals while minimizing impacts to small entities. Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small-entity comments on issues related to the elements of the IRFA. A copy of the June 4, 1999 Panel report is included in the docket for this proposed rule (US EPA, 1999c).

Today's notice incorporates all of the recommendations on which the Panel reached consensus, except for a number of recommendations on information to include in small system guidance. The small system guidance materials will be provided before or soon after the final rule is published in the **Federal Register**. EPA is committed to addressing the following Panel recommendations regarding guidance for small systems: highlight the various waste disposal options and the necessary technical and procedural steps for small CWSs to follow in exploring these alternatives; provide specific recommendations and technical information relative to the use of POU devices; provide guidance to State and local authorities on waste disposal issues relative to the use of these devices; and provide information to assist in making treatment decisions to address multiple contaminants in the most cost-effective manner. The Panel also recommended that EPA provide guidance identifying cost-effective treatment trains for ground water systems that need to treat for both arsenic and radon in the proposed rule. However, treatment trains cannot be accurately identified until after the radon and arsenic standards are finalized because these standards would affect which treatment technologies are appropriate. Since the co-occurrence of

arsenic and radon seems to be statistically significant in only two EPA regions, the impact from this co-occurring pair is not significant on a national level. However, for the regions which are impacted, there is the potential that aeration treatment technology that may be used to mitigate radon may also help to mitigate arsenic. Aeration technology can oxidize the soluble form of arsenic to the insoluble form. This would reduce the cost of arsenic mitigation by making it easier to remove arsenic. EPA will address this recommendation further in the small system guidance materials.

The following is a summary of the rest of the Panel recommendations and EPA's response to these recommendations, by subject area:

*Treatment Technologies, Waste Disposal, and Cost Estimates:* The Panel recommended the following: further develop the preliminary treatment and waste disposal cost estimates; fully consider these costs when identifying affordable compliance technologies for all system size categories; and provide information to small water systems on possible options for complying with the MCL, in addition to installing any listed compliance technologies.

In response to these recommendations, the treatment section of the preamble (see section VIII.A.) and the Treatment and Cost document (US EPA, 1999i) describe the development of final cost estimates for treatment and waste disposal, including the request for comment on its projected household costs; how EPA identified the affordable compliance technologies, including the consideration of cost (section VIII.B.); and information has been added to the treatment section about options for complying with the MCL other than installing compliance technologies, such as selecting to regionalize (see section VIII.B.).

Regarding POU devices, the Panel recommended the following: continue to promote the use of POU devices as alternative treatment options for very small systems where appropriate; account for all costs, including costs that may not routinely be explicitly calculated; and consider liability issues from POU/POE devices when evaluating their appropriateness as compliance technologies; and investigate waste disposal issues with POE devices.

In response to these recommendations, the treatment section of the preamble: includes an expanded description regarding available POU compliance treatment technologies and conditions under which POU treatment may be appropriate for very small systems (see section VIII.D.); describes

the components which contribute to the POU cost estimates (see section VIII.D.); and clarifies that water systems will be responsible for POU operation and maintenance to prevent liability issues from customers maintaining equipment themselves (see section VIII.D.). In addition, EPA does not recommend reverse osmosis as a POE treatment technology due to the evaluation of corrosion control issues (see section VIII.D.).

*Relevance of Other Drinking Water Regulations:* The Panel recommended the following: include discussion of the co-occurrence of arsenic and radon in the proposed rule for arsenic; take possible interactions among treatments for different contaminants into account in costing compliance technologies and determining whether they are nationally affordable for small systems; and encourage systems to be forward-looking and test for the multiple contaminants to determine if and how they would be affected by the upcoming rules.

In response, the co-occurrence section of the preamble includes a discussion on the co-occurrence analysis of radon and arsenic (see section V.H.), and the treatment section of the preamble has been expanded to describe the relationship of treatment for arsenic with other drinking water rules and how this issue was taken into account in cost estimates (see section VIII.F.). The preamble encourages systems to consider other upcoming rules when making future plans on monitoring or treatment (see section VIII.E.).

*Small Systems Variance Technologies and National Affordability Criteria:* The Panel recommended the following: include a discussion of the issues surrounding appropriate adjustment of its national affordability criteria to account for new regulatory requirements; consider revising its approach to national affordability criteria to address the concern that the current cumulative approach for adjusting the baseline household water bills is based on chronological order rather than risk, to the extent allowed by statutory and regulatory requirements; and examine the data in the 1995 Community Water Supply Survey to determine if in-place treatment baselines can be linked with the current annual water bill baseline in each of the size categories for the proposed rule.

In response to these recommendation, the treatment section of the preamble (VIII.C.) includes an expanded discussion about the national affordability criteria and adjusting it to account for new regulations; information and rationale have been

added to explain the national affordability approach (see section VIII.C.). The 1995 Community Water System Survey (US EPA, 1997g) does not provide sufficient data to link in-place treatment baselines with annual water bill baselines.

*Monitoring and Arsenic Species:* The Panel recommended that EPA consider allowing States to use recent compliance monitoring data to satisfy initial sampling requirements or to obtain a waiver and that EPA continue to explore whether or not to make a regulatory distinction between organic and inorganic arsenic based on compliance costs and other considerations. In response, the monitoring section of the preamble and the proposed regulatory language describe the allowance of monitoring data that meet analytical requirements and have reporting limits sufficiently below the revised MCL and collected after 1990. The MCL section of the preamble contains information and rationale to support EPA's decision to base the MCL on total arsenic (see section XI).

*Considerations in setting the MCL:* The Panel recommended the following: in performing its obligations under SDWA, take cognizance of the scientific findings, the large scientific uncertainties, the large potential costs (including treatment and waste disposal costs), and the fact that this standard is scheduled for review in the future; give full consideration to the provisions of the Executive Order 12866 and to the option of exercising the new statutory authority under SDWA sections 1412(b)(4)(C) and 1412(b)(6)(A) in the development of the arsenic rule; and fully consider all of the "risk management" components of its rulemaking effort to ensure that the financial and other impacts on small entities are factored into its decision-making processes. The Panel also recommended that EPA take into account both quantifiable and non-quantifiable costs and benefits of the standard and the needs of sensitive sub-populations, and give due consideration to the impact of the rule upon small systems.

In response to all these recommendations, EPA describes in detail the factors that were considered in setting in the MCL and provides the rationale for this selection (see section XI).

*Applicability of proposal:* The Panel recommended that EPA carefully consider the appropriateness of extending the scope of the rule to Non-Transient, Non-Community Water Systems (NTNCWSs). In response, the

proposed MCL for arsenic does not apply to NTNCWSs and the MCL section of the preamble describes the basis for this decision, including the incremental costs and benefits attributable to coverage of these water systems (see section XI.C.).

*Other Issues:* The Panel recommended that EPA encourage small systems to discuss their infrastructure needs for complying with the arsenic rule with their primacy agency to determine their eligibility for DWSRF loans, and if eligible, to ask for assistance in applying for the loans. In response, the UMRA section XIV.C. has been expanded to discuss funding options for small systems, and guidance will be written to encourage systems to be proactive in communicating with their primacy agency.

Regarding health effects, the Panel recommended the following: Further evaluate the Utah study and its relationship to the studies on which the NRC report was based and give it appropriate weight in the risk assessment for the proposed arsenic standard; and examine the NRC recommendations in the light of the uncertainties associated with the report's recommendations, and any new data that may not have been considered in the NRC report. In response to these recommendations, the benefits and MCL sections (sections X and XI) describe the quantitative and non-quantitative benefits evaluation and use of research data.

We invite comments on all aspects of the proposal and its impacts on small entities.

### C. Unfunded Mandates Reform Act (UMRA)

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

apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation on why that alternative was not adopted.

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

#### 1. Summary of UMRA Requirements

EPA has determined that this rule contains a Federal mandate that may result in expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, and the private sector in any one year. Accordingly, EPA has prepared, under section 202 of the UMRA, a written statement addressing the following areas:

- (1) Authorizing legislation;
- (2) cost-benefit analysis including an analysis of the extent to which the costs to State, local, and tribal governments will be paid for by the Federal government;
- (3) estimates of future compliance costs and disproportionate budgetary effects;
- (4) macro-economic effects; and
- (5) a summary of EPA's consultation with State, local, and tribal governments, a summary of their concerns, and a summary of EPA's evaluation of their concerns.

A summary of this analysis follows and a more detailed description is presented in EPA's Regulatory Impact Analysis (RIA) of the Arsenic Rule (US EPA, 2000e) which is included in the docket for this proposed rulemaking.

*a. Authorizing legislation.* Today's proposed rule is proposed pursuant to section 1412(b)(13) of the 1996 amendments to the SDWA which requires EPA to propose and promulgate a national primary drinking water regulation for arsenic, establishes a statutory deadline of January 1, 2000, to propose this rule, and establishes a statutory deadline of January 1, 2001, to promulgate this rule.

*b. Cost-benefit analysis.* Section XIII. of this Preamble, describing the Regulatory Impact Analysis (RIA) and Health Risk Reduction and Cost Analysis (HRRCA) for arsenic, contains a detailed cost-benefit analysis in support of the arsenic rule. Today's proposed rule is expected to have a total annualized cost of approximately \$379 to 445 million.<sup>9</sup> This total annualized cost includes the total annual administrative costs of State, local, and tribal governments, in aggregate, less than 1% of the cost, and total annual treatment (CWS only, as proposed), monitoring, reporting, and record keeping impacts on public water systems, in aggregate, of approximately \$376.7 to 439.8 million.<sup>10</sup> Treatment costs estimates are presented in Sections IX.D. and E. of this Preamble, and administrative costs are discussed in section 9 of the RIA (US EPA, 2000e).

The RIA includes both qualitative and monetized benefits for improvements in health and safety. EPA estimates the proposed arsenic rule will have annual monetized benefits for bladder cancer of approximately \$43.6 to 104.2 million if the MCL were to be set at 3 µg/L, \$31.7 to 89.9 million if set at 5 µg/L, \$17.9 to 52 million if set at 10 µg/L, and \$7.9 to 29.8 million if set at 20 µg/L (EPA also estimates possible lung cancer benefits based on the "What If" scenario of \$47-448 million at 3 µg/L, \$35-384 million at 5 µg/L, \$19.6-224 million at 10 µg/L, and \$8.8-128 million at 20 µg/L).<sup>11</sup> The monetized health benefits of reducing arsenic exposures in drinking water are attributable to the reduced incidence of fatal and non-fatal bladder cancers. Under baseline assumptions (no control of arsenic exposure <50 µg/L), 10-17 fatal bladder cancers and 29-48 non-fatal bladder cancers per year are associated with arsenic exposures through CWSs. At a arsenic level of 3 µg/L, an estimated 5.7 to 10.9 fatal bladder cancers and 22 to 42 non-fatal bladder cancers per year are prevented. At a level of 5 µg/L, an estimated 4 to 9 fatal bladder cancers and 16 to 36 non-fatal bladder cancers per year are prevented. At a level 10 µg/L, 2 to 6 fatal and 9 to 21 non-fatal bladder cancers per year are prevented. At a level 20 µg/L, 1 to 3 fatal and 3 to 9 non-fatal bladder cancers per year are prevented.

<sup>9</sup> Costed as proposed, using the 3 percent and 7 percent discount rate cost-of-capital values in Table X-8, in 1999 \$ with NTNCWS monitoring and reporting, but not required to comply with the MCL. If NTNCWS were to comply with the MCL, their treatment costs would bring the annualized cost to \$394.4 million.

<sup>10</sup> Source: table XII-6, in 1997 \$.

<sup>11</sup> Source: Table X-7.

In addition to quantifiable benefits, EPA has identified several potential non-quantifiable benefits associated with reducing arsenic exposures in drinking water. These potential benefits are difficult to quantify because of the uncertainty surrounding their estimation. Non-quantifiable benefits may include any peace-of-mind benefits specific to reduction of arsenic risks that may not be adequately captured in the Value of Statistical Life (VSL) estimate.

State, local and Tribal governments will incur a range of administrative costs with the MCL options in complying with the arsenic rule. Administrative costs associated with water mitigation can include costs associated with program management, inspections, and enforcement activities. EPA estimates the total annual costs of administrative activities for compliance with the MCL to be approximately \$2.8 million.

*c. Financial Assistance.* Various Federal programs exist to provide financial assistance to State, local, and tribal governments to administer and comply with this and other drinking water rules. The Federal government provides funding to States that have a primary enforcement responsibility for their drinking water programs through the Public Water Systems Supervision (PWSS) Grants program. Additional funding is available from other programs administered either by EPA or other Federal agencies. These include the Drinking Water State Revolving Fund (DWSRF) and Housing and Urban Development's Community Development Block Grant Program. For example, the SDWA authorizes the Administrator of the EPA to award capitalization grants to States, which in turn can provide low cost loans and other types of assistance to eligible public water systems. The DWSRF

assists public water systems with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Each State will have considerable flexibility to determine the design of its program and to direct funding toward its most pressing compliance and public health protection needs. States may also, on a matching basis, use up to ten percent of their DWSRF allotments for each fiscal year to assist in running the State drinking water program.

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

*d. Estimates of future compliance costs and disproportionate budgetary effects.* To meet the requirement in section 202 of the UMRA, EPA analyzed future compliance costs and possible disproportionate budgetary effects of the MCL options. The Agency believes that the cost estimates, indicated previously and discussed in more detail in Section XIII.B of today's Preamble accurately characterize future compliance costs of the proposed rule.

With regard to the disproportionate impacts, EPA considered available data sources in analyzing the

disproportionate impacts upon geographic or social segments of the nation or industry. No rationale for disproportionate impacts by geography were identified. EPA will prepare a small entity compliance guide, a monitoring/analytical manual, and a small systems technology manual that will assist the public and private sector. To fully consider the potential disproportionate impacts of this proposed rule, this analysis also developed three other measures:

- (1) Reviewing the impacts on small versus large systems;
- (2) reviewing the costs to public versus private water systems; and
- (3) reviewing the household costs for the proposed rule.

The first measure, the national impacts on small versus large systems, is shown in Section IX, Table IX-12, Total Annual Costs per Household. Small systems are defined as those systems serving 10,000 people or less and large systems are those systems that serve more than 10,000 people. The higher compliance costs to small systems is primarily due to the greater number of small systems as opposed to large systems (*i.e.*, there are 39,420 small systems versus 1,443 large systems).

The second measure of disproportionate impacts evaluated is the relative total costs to public versus private water systems, by size. Table XIV-2 presents the total annualized costs for public and private systems by system size category for the 3 µg/L, 5 µg/L, 10 µg/L, and 20 µg/L arsenic levels. The costs are comparable for public and private systems across system sizes for all options. This pattern may be due in large part to the limited number of treatment options assumed to be available to either public or private systems to remove arsenic.

TABLE XIV-2.—AVERAGE ANNUAL COST PER CWS BY OWNERSHIP

System size	Treatment and monitoring costs		Total cost
	Public	Private	All systems
MCL = 3 µg/L			
<100 .....	\$9,475	\$7,354	\$7,559
101-500 .....	25,228	18,570	20,588
501-1,000 .....	34,688	31,645	33,474
1,001-3,300 .....	60,929	51,097	58,189
3,301-10,000 .....	135,573	111,396	131,197
10,001-1,000,000 .....	578,591	547,969	573,423
>1,000,000 .....	3,885,713	.....	3,885,713
MCL = 5 µg/L			
<100 .....	9,720	7,212	7,450
101-500 .....	24,560	18,223	20,198

TABLE XIV-2.—AVERAGE ANNUAL COST PER CWS BY OWNERSHIP—Continued

System size	Treatment and monitoring costs		Total cost
	Public	Private	All systems
501–1,000 .....	34,124	30,697	32,778
1,001–3,300 .....	57,277	48,198	54,666
3,301–10,000 .....	124,552	102,005	120,399
10,001–1,000,000 .....	518,647	459,930	508,640
>1,000,000 .....	2,669,474	.....	2,669,474
MCL = 10 µg/L			
<100 .....	9,453	7,135	7,350
101–500 .....	23,584	17,675	19,551
501–1,000 .....	32,271	29,160	31,048
1,001–3,300 .....	53,357	44,785	50,921
3,301–10,000 .....	113,338	91,244	109,278
10,001–1,000,000 .....	458,340	415,520	450,835
>1,000,000 .....	1,395,498	.....	1,395,498
MCL = 20 µg/L			
<100 .....	9,121	6,950	7,157
101–500 .....	22,778	16,954	18,738
501–1,000 .....	30,493	27,668	29,376
1,001–3,300 .....	48,399	41,625	46,501
3,301–10,000 .....	99,872	79,128	95,983
10,001–1,000,000 .....	394,742	334,737	384,868
>1,000,000 .....	921,121	.....	921,121

\*Costs were calculated at a commercial interest rate and include system treatment, monitoring, and administrative costs; note that systems serving over 1 million people are public surface water systems.

The third measure, household costs, can also be used to gauge the impact of a regulation and to determine whether there are disproportionately high impacts in particular segments of the population. A detailed analysis of household cost impacts by system size is presented in the RIA (US EPA 2000e). The costs for households served by public and private water systems are presented in Table XIV-3. As expected, cost per household increases as system size decreases. Cost per household is

higher for households served by smaller systems than larger systems for two reasons. First, smaller systems serve far fewer households than larger systems and, consequently, each household must bear a greater percentage share of the system's costs. Second, smaller systems tend to have higher influent arsenic concentrations that, on a per-capita or per-household basis, require more expensive treatment methods to achieve the target arsenic level.

There is a moderate difference in annual cost per household for the 3 µg/L, 5 µg/L, 10 µg/L, and 20 µg/L levels for each size category. However, the costs per household are higher for private systems than for public systems. For public systems, the cost per household ranges from \$24.73 to \$341.78 per year at 5 µg/L and from \$22.03 to \$329.17 per year at 10 µg/L. For private systems, the ranges are \$21.91 to \$369.21 per year, and \$19.06 to \$363.08 per year, respectively.

TABLE XIV-3.—AVERAGE COMPLIANCE COSTS PER HOUSEHOLD FOR CWSS EXCEEDING MCLS

System size	Groundwater		Surface water	
	Public	Private	Public	Private
MCL = 3 µg/L				
<100 .....	\$338.44	\$374.86	328.94	\$385.61
101–500 .....	218.59	285.61	135.98	183.96
501–1,000 .....	108.63	112.60	45.44	46.72
1,001–3,300 .....	62.17	83.24	21.13	27.91
3,301–10,000 .....	44.67	62.96	18.34	22.94
10,001–1,000,000 .....	31.29	31.29	26.49	22.81
>1,000,000 .....	.....	.....	2.70	.....
MCL = 5 µg/L				
<100 .....	341.78	369.21	323.48	330.05
101–500 .....	213.11	280.76	135.22	182.65
501–1,000 .....	106.00	108.40	44.86	46.35
1,001–3,300 .....	58.31	77.54	20.07	26.57
3,301–10,000 .....	40.60	57.25	16.89	21.54
10,001–1,000,000 .....	28.12	28.63	24.73	21.91

TABLE XIV-3.—AVERAGE COMPLIANCE COSTS PER HOUSEHOLD FOR CWSs EXCEEDING MCLs—Continued

System size	Groundwater		Surface water	
	Public	Private	Public	Private
>1,000,000 .....	.....	.....	1.73	.....
MCL = 10 µg/L				
<100 .....	329.17	363.09	317.80	325.64
101-500 .....	203.40	273.04	132.74	180.88
501-1,000 .....	99.45	102.19	42.98	44.48
1,001-3,300 .....	53.70	71.97	18.62	25.49
3,301-10,000 .....	36.30	50.41	14.68	18.55
10,001-1,000,000 .....	24.09	24.47	22.03	19.06
>1,000,000 .....	.....	.....	0.89	.....
MCL = 20 µg/L				
<100 .....	320.13	352.42	310.11	324.84
101-500 .....	195.99	262.01	132.68	179.93
501-1,000 .....	93.27	96.63	42.26	44.04
1,001-3,300 .....	48.03	66.12	18.20	24.87
3,301-10,000 .....	31.38	44.14	13.35	17.53
10,001-1,000,000 .....	20.27	20.39	19.96	.....
>1,000,000 .....	.....	.....	0.55	.....

\*Costs to households were calculated at a commercial interest rate and include system treatment, monitoring, and administrative costs; note that systems serving over 1 million people are public surface water systems.

TABLE XIV-4.—AVERAGE COMPLIANCE COSTS PER HOUSEHOLD FOR CWSs EXCEEDING MCLs AS A PERCENT OF MEDIAN HOUSEHOLD INCOME

System size	Groundwater		Surface water	
	Public	Private	Public	Private
MCL = 3 µg/L				
<100 .....	0.85	0.95	0.83	0.85
101-500 .....	0.55	0.72	0.34	0.46
501-1,000 .....	0.27	0.28	0.11	0.12
1,001-3,300 .....	0.16	0.21	0.05	0.07
3,301-10,000 .....	0.11	0.16	0.05	0.06
10,001-1,000,000 .....	0.08	0.08	0.07	0.06
>1,000,000 .....	.....	.....	0.01	.....
MCL = 5 µg/L				
<100 .....	0.86	0.93	0.82	0.83
101-500 .....	0.54	0.71	0.34	0.46
501-1,000 .....	0.27	0.27	0.11	0.12
1,001-3,300 .....	0.15	0.20	0.05	0.07
3,301-10,000 .....	0.10	0.14	0.04	0.05
10,001-1,000,000 .....	0.07	0.07	0.06	0.06
>1,000,000 .....	.....	.....	0.00	.....
MCL = 10 µg/L				
<100 .....	0.83	0.92	0.80	0.82
101-500 .....	0.51	0.69	0.33	0.46
501-1,000 .....	0.25	0.26	0.11	0.11
1,001-3,300 .....	0.14	0.18	0.05	0.06
3,301-10,000 .....	0.09	0.13	0.04	0.05
10,001-1,000,000 .....	0.06	0.06	0.06	0.05
>1,000,000 .....	.....	.....	0.00	.....
MCL = 20 µg/L				
<100 .....	0.81	0.89	0.78	0.82
101-500 .....	0.49	0.66	0.33	0.45
501-1,000 .....	0.24	0.24	0.11	0.11
1,001-3,300 .....	0.12	0.17	0.05	0.06
3,301-10,000 .....	0.08	0.11	0.03	0.04
10,001-1,000,000 .....	0.05	0.05	0.05	0.00

TABLE XIV-4.—AVERAGE COMPLIANCE COSTS PER HOUSEHOLD FOR CWSS EXCEEDING MCLs AS A PERCENT OF MEDIAN HOUSEHOLD INCOME—Continued

System size	Groundwater		Surface water	
	Public	Private	Public	Private
>1,000,000 .....	.....	.....	0.00	.....

\* Costs to household were calculated at a commercial interest rate and include system treatment, monitoring, and administrative costs; median household income in May 1999 was \$39,648 from the 1998 annual median household income from the Census.

To further evaluate the impacts of these household costs, the costs per household were compared to median household income data for each system-size category. The result of this calculation, presented in Table XIV-4 for public and private systems, indicate a household's likely share of incremental costs in terms of its household income. For all system sizes, household costs as a percentage of median household income are less than one percent for households served by either public or private systems. Similar to the cost per household results on which they are based, household impacts exhibit little variability across arsenic levels.

*e. Macroeconomic effects.* As required under UMRA § 202, EPA is required to estimate the potential macro-economic effects of the regulation. These types of effects include those on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness. Macroeconomic effects tend to be measurable in nationwide econometric models only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of Gross Domestic Product (GDP). In 1998, real GDP was \$7,552 billion so a rule would have to cost at least \$18 billion annually to have a measurable effect. A regulation with a smaller aggregate effect is unlikely to have any measurable impact unless it is highly focused on a particular geographic region or economic sector. The macro-economic effects on the national economy from the arsenic rule should be negligible based on the fact that, assuming 100 percent compliance with an MCL, the total annual costs are approximately \$756 million at the 3 µg/L level, \$445 million at the 5 µg/L level, about \$195 million at the 10 µg/L level, and at the 20 µg/L level, about \$77 million (at a 7 percent discount rate), and the costs are not expected to be highly focused on a particular geographic region or industry sector.

*f. Summary of EPA's consultation with State, local, and tribal governments and their concerns.* Under UMRA section 204, EPA is to provide a summary of its consultation with

elected representatives (or their designated authorized employees) of affected State, local, and Tribal governments in this rulemaking. EPA initiated consultations with governmental entities and the private sector affected by this rulemaking through various means. This included five stakeholder meetings announced in the **Federal Register** and open to any one interested in attending in person or by phone, and presentations at meetings of the American Water Works Association (AWWA), the Association of State Drinking Water Administrators (ASDWA), the Association of California Water Agencies (ACWA), and the Association of Metropolitan Water Agencies (AMWA). Participants in EPA's stakeholder meetings also included representatives from the National Rural Water Association, AMWA, ASDWA, AWWA, ACWA, Rural Community Assistance Program, State departments of environmental protection, State health departments, State drinking water programs, and a Tribe. EPA also made presentations at Tribal meetings in Nevada, Alaska, and California. To address the proposed rule's impact on small entities, the Agency consulted with representatives of small water systems and convened a Small Business Advocacy Review Panel in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). Two of the small entity representatives were elected officials from local governments. EPA also invited State drinking water program representatives to participate in a number of workgroup meetings. In addition to these consultations, EPA participated in and gave presentations at AWWA's Technical Workgroup for Arsenic. State public health department and drinking water program representatives, drinking water districts, and ASDWA participated in the Technical Workgroup meetings. Finally EPA presented the benefits analysis to State and Tribal health and environmental agencies.

The public docket for this proposed rulemaking contains meeting summaries for EPA's five stakeholder meetings on

arsenic in drinking water, written comments received by the Agency, and provides details about the nature of State, local, and Tribal government's concerns. A summary of State, local, and Tribal government concerns on this proposed rulemaking is in the next section.

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

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

The major meeting objectives were to:

- (1) identify key issues of concern to Tribal representatives;
- (2) solicit input on issues concerning current OGWDW regulatory efforts;
- (3) solicit input and information that should be included in support of future drinking water regulations; and

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

EPA staff also provided an overview on the forthcoming arsenic rule at the meeting. The presentation included the health concerns associated with arsenic, EPA's current position on arsenic in drinking water, the definition of an MCL, an explanation of the difference between point-of-use and point-of-entry treatment devices, and specific issues for Tribes. The following questions were posed to the Tribal representatives to begin discussion on arsenic in drinking water:

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

(2) What are Tribal water systems affordability issues in regard to arsenic?

(3) Does your Tribe use well water, river water or lake water?

(4) Purchase water from another drinking water utility?

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

EPA also conducted a series of workshops at the Annual Conference of the National Tribal Environmental Council which was held on May 18–20, 1999 in Eureka, California.

Representatives from over 50 Tribes attended all, or part, of these sessions. The objectives of the workshops were to provide an overview of forthcoming EPA regulations affecting water systems; discuss changes to operator certification requirements; discuss funding for Tribal water systems; and to discuss innovative approaches to regulatory cost reduction. Meeting summaries for EPA's Tribal consultations are available in the public docket for this proposed rulemaking.

*g. Nature of State, local, and Tribal government concerns and how EPA addressed these concerns.* State and local governments raised several concerns, including the high costs of the rule to small systems; the burden of revising the State primacy program; the high degree of uncertainty associated with the benefits; the high costs of including Non-Transient Non-Community Water Systems (NTNCWSs). EPA modified regulations governing the revision of State primacy in order to decrease the burden of the new arsenic regulation in response to State concerns that EPA minimize paperwork and documentation of existing programs that would manage the arsenic regulation. Section XI. asks for comment on alternate MCL options, based partly on the high costs of the rule for small systems and uncertainty associated with the risks.

Tribal representatives were generally supportive of regulations which would ensure a high level of water quality, but raised concerns over funding for regulations. With regard to the forthcoming proposed arsenic rule, many Tribal representatives saw the health benefits as highly desirable, but felt that unless additional funds were made available, implementing the regulation would be difficult for many Tribes.

EPA understands the State, local, and tribal government concerns with the above issues. The Agency believes the options for small systems, proposed for public comment in this rulemaking, will address stakeholder concerns pertaining to small systems and will help to reduce the financial burden to these systems. Small systems compliance technologies and associated costs were listed in section VIII.E. Regionalization, the process by which a small system can connect with another system and purchase water, is a non-treatment option that could be considered for small systems. The costs for regionalization by system size are presented as Treatment Train #1 in Table VIII–3 of section VIII.B. Sections XII.C address tribal SRF and grant funding.

Non-Transient Non-Community Water Systems (NTNCWSs) are only required to monitor and report exceedances of the MCL. A detailed discussion of the exposure to arsenic in NTNCWSs is shown in section V.F. of this Preamble. EPA has conducted a preliminary analysis on exposure and risks to NTNCWSs and is soliciting public comment on this preliminary analysis. An analysis of the potential benefits and costs of arsenic in drinking water for NTNCWSs is summarized in the preamble and included in the docket for this proposed rulemaking (US EPA 2000e).

The Agency is basing this regulation on the risks to the general population and is not excluding any particular segments of the population. For a more complete discussion on the risks of arsenic in drinking water and air, see section II.C. of this Preamble.

*h. Regulatory Alternatives Considered.* As required under section 205 of the UMRA, EPA considered several regulatory alternatives in developing an MCL for arsenic in drinking water. In preparation for this consideration, the Regulatory Impact Analysis and Health Risk Reduction and Cost Analysis (HRRCA) for Arsenic evaluated arsenic levels of 3 µg/L, 5 µg/L, 10 µg/L, and 20 µg/L.

The Regulatory Impact Analysis and HRRCA also evaluated national costs

and benefits of States choosing to reduce arsenic exposure in drinking water. For further discussion on the regulatory alternatives considered in this proposed rulemaking, see section XIII. of this Preamble. EPA examined a range of regulatory alternatives that could be employed to achieve the objectives of this rule and chose what it believes is the least burdensome such alternative. The regulatory approach embodied in this rule includes a proposed MCL that relies on the use of the Administrator's discretionary authority under section 1412(b)(6) of the SDWA to set a less stringent level than the feasible level. The exercise of these authorities in this manner is expected to reduce overall burden on regulated entities (as compared to the burden of a more stringent level) but still maximize health risk reduction. (See section XI.A for a more complete discussion of the rationale for the exercise of these authorities.) In terms of coverage of the rule, we are proposing that only CWSs be fully covered by the rule, driven, in part by consideration of the burden associated with not covering NTNCWSs in view of the minimal health risk reduction that would be achieved. The proposed approach is also based upon an analysis and listing of least cost treatment alternatives (including use of point of use treatment devices) that are collectively expected to reduce regulatory burden. Finally, today's proposal includes an approach to monitoring and reporting that involves a framework that provides for reduced regulatory burden where arsenic levels are low. Also, see EPA's Regulatory Impact Analysis for Arsenic (US EPA 2000e).

## 2. Impacts on Small Governments

In developing this rule, EPA consulted with small governments pursuant to section 203 of the UMRA to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. In preparation for the proposed arsenic rule, EPA conducted analysis on small government impacts and included small government officials or their designated representatives in the rule making process. EPA conducted stakeholder meetings on the development of the arsenic rule which gave a variety of stakeholders, including small governments, the opportunity for timely and meaningful participation in the regulatory development process. Groups such as the National Association of Towns and Townships, the National League of Cities, and the National Association of Counties participated in the proposed rulemaking process.

Through such participation and exchange, EPA notified potentially affected small governments of requirements under consideration and provided officials of affected small governments with an opportunity to have meaningful and timely input into the development of the regulatory proposal. See section XIV.B.6.a. for a summary of the Small Business Review Panel consultations.

In addition, EPA will educate, inform, and advise small systems, including those run by small governments, about the arsenic rule requirements. One of the most important components of this process is the Small Entity Compliance Guide, required by the Small Business Regulatory Enforcement Fairness Act of 1996 shortly after the rule is promulgated. This plain-English guide will explain what actions a small entity must take to comply with the rule. Also, the Agency is developing fact sheets that concisely describe various aspects and requirements of the arsenic rule.

#### *D. Paperwork Reduction Act (PRA)*

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR, No. 1948.01) and a copy may be obtained from Sandy Farmer by mail at Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at [farmer.sandy@epamail.epa.gov](mailto:farmer.sandy@epamail.epa.gov), or by calling (202) 260-2740. A copy may also be downloaded off the Internet at <http://www.epa.gov/icr>.

Two types of information will be collected under the proposed arsenic rule. First, information on CWSs and NTNCWSs and their arsenic levels reported under 50 µg/L will enable the States and EPA to evaluate compliance with the lower MCL. This information, most of which consists of monitoring results, corresponds to arsenic information already collected from water systems. Arsenic monitoring and reporting will continue annually for surface water systems or once every three years for ground water systems, unless the MCL is exceeded or a State grants a waiver (see section VII). Other existing information and reporting requirements, such as Consumer Confidence Reports (US EPA, 1998j) and the public notification requirements (US EPA, 2000c), will be amended to reflect the lower MCL for arsenic. As proposed, NTNCWSs will not be required to

comply with the MCL because of the low exposure levels as explained in section XI.C. However, EPA is requiring NTNCWSs to report to the State and public when it exceeds the MCL through public notification requirements. As is the case for other contaminants, required information on system arsenic levels must be provided by affected systems and is not considered to be confidential. EPA believes the information needs discussed previously, on compliance with the MCL programs, are essential to achieving the arsenic-related health risk reductions anticipated by EPA under the proposed rule.

EPA has estimated the burden associated with the specific record keeping and reporting requirements of the proposed rule in an accompanying Information Collection Request (ICR), which is available in the public docket for this proposed rulemaking. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing procedures to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR for the proposed rule covers the information collection, reporting and record-keeping requirements for the three-year period following promulgation of the Arsenic Rule. There are several activities that PWSs must perform in preparation for compliance with the revised Arsenic Rule in the first three years. Start-up activities include reading the final rule to become familiar with the requirements and training staff to perform the required activities. The number of hours required to perform each activity varies by system size. The total start-up burden per system for systems serving less than 10,000 people is estimated to be 24 hours; the total start-up burden per system for systems serving more than 10,000 people is estimated to be 40 hours. The total hour burden for the 74,607 PWSs (including NTNCWS) covered by this rule is estimated to be 1,847,784 hours, or an annual average of 615,928 hours. There are no monitoring,

record-keeping, reporting or equipment costs for PWSs during the first three-year period. EPA expects States to incur only nominal information collection, reporting or record-keeping costs during the first three years. (For estimates of the cost of information collection, reporting and record-keeping over a 20-year period, see ICR No. 1948.01)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW, Washington, DC 20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after June 22, 2000, a comment to OMB is best assured of having its full effect if OMB receives it by July 24, 2000. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

#### *E. National Technology Transfer and Advancement Act (NTTAA)*

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

EPA's process for selecting analytical methods is consistent with section 12(d) of the NTTAA. EPA performed a

literature search to identify analytical methods from industry, academia, voluntary consensus standard bodies and other parties that could be used to reliably measure total arsenic in drinking water at the proposed MCL of 0.005 mg/L. Today's proposed rulemaking allows the use of analytical methods which are described in the "Annual Book of ASTM Standards" (American Society for Testing and Materials, 1994 and 1996) and in "Standards for the Examination of Water and Wastewater" (APHA, 1992 and 1995). The four methods published by these consensus organizations include SM 3113B, SM 3114B, ASTM 2972-93B and ASTM 2972-93C. These methods were all approved for arsenic analysis in previous methods-related rulemakings for the MCL of 0.050 mg/L. Along with the review of other analytical methods, EPA also re-evaluated these consensus methods for the new arsenic standard. The Agency believes these methods will still be reliable for compliance monitoring at the proposed MCL of 0.005 mg/L. Additional information on these methods are shown in section VI. C. and F. of today's preamble. One consensus method, SM 3120B, will be withdrawn in today's rulemaking. As discussed in section VI.D., SM 3120B will be withdrawn because the detection limit for this method is inadequate to reliably determine the presence of arsenic at the proposed MCL of 0.005 mg/L.

Although no other methods were identified from the literature search, EPA welcomes comments on this aspect of today's proposed rulemaking and specifically invites the public to identify potentially-applicable voluntary consensus standards, explain why such standard should be considered for inclusion with this regulation, and to provide the necessary information from inter-laboratory studies on detection limits, accuracy, recovery and precision.

*F. Executive Order 12898: Environmental Justice*

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

with minority and low-income stakeholders by convening a stakeholder meeting via video conference specifically to address environmental justice issues.

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

- (1) Solicit ideas from Environmental Justice (EJ) stakeholders on known issues concerning current drinking water regulatory efforts;
- (2) Identify key issues of concern to EJ stakeholders; and
- (3) Receive suggestions from EJ stakeholders concerning ways to increase representation of EJ communities in OGWDW regulatory efforts.

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

During the presentation of separate cities' discussions, several arsenic issues came up. In Region 6 one stakeholder thought that test results for arsenic (discussed in ppb and µg/L) were hard to understand, and the health effects appear to be complicated. Region 6 participants had concerns about the toxic effects on mothers, individuals with different metabolisms, and individuals with poor nutrition. One of the stakeholders expressed a concern that the government was not protecting poorer communities against pollution. In Region 7, one stakeholder lives in an area that purchases water which has to be monitored. The area has a shrinking population that is increasing in age and immune conditions. Although there are pesticides in the water and air, it would

not be economically practical to consolidate to a regional drinking water system. One member of an Indian tribe said Tribes tend to have more diabetes than the rest of the country, and diabetes seemed to be linked to arsenic exposure. In Region 8 a stakeholder wanted affordable or equally protective treatment options. A Region 8 participant asked for disclosure of environmental contamination. Region 9 reported some individual monitoring difficulties. Stakeholders wanted better access to funding sources. Stakeholders in Region 9 had concerns about the immuno-compromised, young children, and pregnant women. Some stakeholders wanted standard setting to address regional needs, include local governments in the standard setting, more technical assistance and training, and more stakeholder involvement. Tribes and large cities with low income families may be burdened with more of the risk.

The Agency considered equity-related issues concerning the potential impacts of this action. There is no factual basis to indicate that minority and low income communities are more (or less) exposed to arsenic in drinking water. The occurrence information suggests there is no difference between the percent of systems likely to be impacted in small communities versus larger ones. Further, arsenic in drinking water is primarily natural in origin (rather than related to contamination events) and a systematic bias based on socioeconomic factors would not be expected to occur. A key issue of concern is the potential for an uneven distribution of risk reduction benefits across water systems and society.

The public is invited to comment on EPA's analysis of environmental justice and, specifically, to recommend additional methods to address environmental justice concerns with the approach for treating arsenic in drinking water.

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

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," (62 FR 19885 April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and

explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is not subject to the Executive Order because the Agency does not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. Nonetheless, we have evaluated the environmental health or safety effects of arsenic in drinking water on children. The results of this evaluation are contained in section III.F.5. of this Preamble. Copies of the documents used to evaluate the environmental health or safety effects of arsenic in drinking water on children have been placed in the public docket for this proposed rulemaking.

The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life exposure to arsenic via ingestion.

#### *H. Executive Order 13132: Federalism*

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

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the Office of Management and Budget (OMB), in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include

a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

EPA has concluded that this proposed rule will have federalism implications. This rule will impose substantial direct compliance costs on State and local governments, and the Federal government will not provide the funds necessary to pay those costs. Accordingly, EPA provides the following FSIS as required by section 6(b) of Executive Order 13132.

EPA consulted with State and local officials early in the process of developing the proposed regulation to permit them to have meaningful and timely input into its development. Summaries of the meetings have been included in public record for this proposed rulemaking. EPA consulted extensively with State, local, and tribal governments. For example, we held four public stakeholder meetings in Washington, D.C. (two meetings); San Antonio, Texas; and Monterey, California. Invitations to stakeholder meetings were extended to the National Association of Counties, The National Governors' Association, the National Association of Towns and Townships, the National League of Cities, and the National Conference of State Legislators. In addition, several elected officials were part of the Small Business Advocacy Review Panel convened by EPA (as required by section 609(b) of the Regulatory Flexibility Act). Consultation has not ended, however, but will be an on-going transactional process. EPA officials presented a summary of the rule to the National Governor's Association in a meeting on May 24, 2000. In addition, we scheduled a one-day stakeholders' meeting for the trade associations that represent elected officials on May 30, 2000 to discuss and solicit comment on this and other upcoming contaminant rules. EPA will continue to seek input from its State and local government partners.

Several key issues were raised by stakeholders regarding the arsenic rule provision, many of which were related to reducing burden and maintaining

flexibility. The Office of Water was able to reduce burden and increase flexibility in a number of areas in response to these comments. More specifically, elected officials expressed overall concerns about: (1) Factors considered in setting of the MCL and (2) the treatment technologies, their associated costs and waste disposal costs. Specific issues regarding the setting of the MCL included:

- The treatment costs associated with a lower drinking water standard;
- Concerns about affordability for lower income areas;
- Asking the Agency to delay setting a standard below 25 µg/L until the development of affordable technologies; and
- A lack of evidence for health effects data below 50 µg/L.

Specific concerns regarding the treatment technologies, their associated costs and waste disposal costs included:

- The difficulty of using oxidation/filtration for arsenic removal when concentrations are <25 µg/L (even after the addition of iron salts and pH adjustment);
- The waste disposal costs created from the use of ion exchange;
- The more intensive need for operator oversight and the amount of sludge generated using coagulation filtration and lime softening at a high pH;
- The difficulty in finding and the expense associated with activated alumina;
- The expense associated with reverse osmosis, nano-filtration and pre-oxidation.

The Agency responded to these concerns in several ways. We are very sensitive to the potential costs of treatment for a lower drinking water standard and have examined an array of treatment options (especially those that are most appropriate for small systems) in order to identify the least cost, affordable options that systems may use to comply with a new standard. We therefore do not believe that it is necessary to delay promulgating a rule with an MCL below 25 µg/L pending identification of such technologies, as one of the comments suggests. We have also included higher MCL options than the proposed MCL in the preamble for comment, due in large part to concerns expressed by elected officials and other stakeholders about the treatment costs associated with a low MCL. These issues are discussed in more detail in the sections VIII. (treatment) and XI. (regarding choice of the MCL). We also share the concerns of elected officials in connection with the affordability of a new rule for lower income areas and

have identified special programs and avenues that may be pursued to provide relief for such areas (see section VIII.C.).

In response to the comment that there is a lack of evidence for health effects below 50 µg/L, we note that the National Academy of Sciences' National Research Council has categorically determined, based on their review of the most recent data and information concerning the health effects of arsenic, that the current standard of 50 µg/L is not protective and should be revised downward as soon as possible (NRC, 1999). This topic is discussed in more detail in section III.

In response to concerns about specific treatment technologies, their associated costs and waste disposal costs, EPA identifies several treatment technologies in section VIII. Section VIII. A. identifies the BATs for arsenic removal and section VIII.B. identifies technologies which are considered affordable. The Agency agrees with the statement that oxidation/filtration is not an appropriate technology to treat arsenic to low levels. For this reason, it is not considered a BAT. The Agency also agrees that wastes are created using ion exchange. Section VIII. addresses the use of brine recycling in reducing wastes and waste disposal costs. In addition, regionalization or finding a new water source (section VIII.) are alternative non-treatment options to consider to avoid treatment and the costs and disposal issues associated with treatment. The Agency agrees with the concern that coagulation/filtration is more operator intensive but this technology and pH modifications are only considered if this treatment process is already in place. In regards to the amount of sludge produced, the additional amount of sludge generated due to the removal of arsenic is minor. The Agency disagrees that activated alumina is expensive and difficult to find. As shown in Table VIII-3, activated alumina is one of the cheaper treatment technologies. The Agency agrees that reverse osmosis, nano-filtration and the need for pre-oxidation are expensive treatment options. In these cases, a PWS should consider one of the more affordable treatment options shown in section VIII.B.

#### *I. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments*

Under Executive Order 13084, "Consultation and Coordination with Indian Tribal Governments," 63 FR 27655 (May 19, 1998) EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal

governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian Tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

EPA has concluded that this rule may significantly affect communities of Indian Tribal governments. It will also impose substantial direct compliance costs on such communities, and the Federal government will not provide the funds necessary to pay the direct costs incurred by the Tribal governments in complying with the rule. In developing this rule, EPA consulted with representatives of Tribal governments pursuant to Executive Order 13084. Summaries of the meetings have been included in the public docket for this proposed rulemaking. EPA's consultation, the nature of the governments' concerns, and EPA's position supporting the need for this rule are discussed in sections XIV.C.1.f. and g. of this Preamble.

#### *J. Request for Comments on Use of Plain Language*

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. We invite your comments on how to make this proposed rule easier to understand. For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?

- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

#### **XV. References**

The following references are referred to in this notice and are included in the public docket together with other correspondence and information. The public docket is available as described at the beginning of this notice. All public comments received on the proposal are included in the public docket.

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### List of Subjects

#### 40 CFR Part 141

Environmental protection, Chemicals, Indians—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

#### 40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indians—lands, Reporting and recordkeeping requirements, Water supply.

Dated: May 24, 2000.

**Carol M. Browner,**  
*Administrator.*

For reasons set out in the preamble, the Environmental Protection Agency proposes to amend 40 CFR parts 141 and 142 as follows:

### PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

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

#### Subpart A—General

##### § 141.2 [Amended]

2. Section 141.2 is amended by revising the definition heading for “Point-of-entry treatment device” to read “Point-of-entry treatment device (POE)” and revising the definition heading for “Point-of-use treatment device” to read “Point-of-use treatment device (POU)”.

3. Section 141.6 is amended by:
- In paragraph (a) by revising the reference “(a) through (i)” to read “(a) through (k)”.
  - Revising paragraph (c).
  - Adding paragraphs (j) and (k).
- The revisions and additions read as follows:

##### § 141.6 Effective dates.

\* \* \* \* \*

(c) The regulations set forth in §§ 141.11(d); 141.21(a), (c) and (i); 141.22(a) and (e); 141.23(a)(3) and (a)(4); 141.23(f); 141.24(e) and (f); 141.25(e); 141.27(a); 141.28(a) and (b); 141.31(a), (d) and (e); 141.32(b)(3); and 141.32(d) shall take effect immediately upon promulgation.

\* \* \* \* \*

(j) The arsenic MCL listed in § 141.62 is effective [THREE YEARS AFTER PUBLICATION DATE OF THE FINAL RULE]. Compliance with the arsenic MCL listed in § 141.62 is required for community water systems serving 10,000 people or less on [DATE 5 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE], and for all other community water systems on [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for §§ 141.23(a)(4), (a)(4)(i), (a)(5), (c), (f)(1), (g), (i), (k)(1), (k)(2), and (k)(3)(ii); 141.62(b)(16) and (c); 141.203, and revisions to arsenic in Appendices A and B of Subpart Q of this part for the public notification rule. However, the reporting date for the arsenic MCL listed in Appendix A of Subpart O of this part of the consumer confidence rule requirements and the arsenic reporting requirements in § 141.154(b) are [THIRTY DAYS AFTER PUBLICATION DATE OF THE FINAL RULE]. Non-transient non-community water systems will be subject to the sampling, monitoring, and reporting requirements of §§ 141.23(a), 141.23(c)(1)–(6), 141.23(f), 141.23(g), 141.23(k), 141.203, and 141.209 for arsenic exceeding the MCL listed in § 141.62 [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE].

(k) Compliance with §§ 141.23(c)(9), 141.24(f)(15)(ii), 141.24(f)(22) and 141.24(h)(20) regulations for inorganics and organics other than total trihalomethanes and sampling frequencies for new systems and new sources of water is required on [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE].

#### Subpart B—[Amended]

4. Section 141.11 is amended by revising the second sentence of paragraph (a) and revising paragraph (b) to read as follows:

#### § 141.11 Maximum contaminant levels for inorganic chemicals.

(a) \* \* \* The analyses and determination of compliance with the 0.05 milligrams per liter maximum contaminant level for arsenic use the requirements of § 141.23(l).

(b) The maximum contaminant level for arsenic is 0.05 milligrams per liter for community water systems serving 10,000 people or less until [DATE 5 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE], and for all other community water systems until [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE]. Non-transient non-community water systems will be subject to sampling, monitoring and reporting requirements for arsenic as of [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE]; however, they will not be subject to §§ 141.23(c)(7) and (8) and 141.62(b)(16).

\* \* \* \* \*

#### Subpart C—[Amended]

5. Section 141.23 is amended by:
- Adding a new entry for “Arsenic” in alphabetical order to the table in paragraph (a)(4)(i) and footnotes 6 and 7.
  - Adding “arsenic,” before “barium,” in paragraph (a)(5).
  - Adding “arsenic,” before “barium,” in paragraph (c) introductory text.
  - Adding paragraph (c)(9).
  - Revising the words “asbestos, antimony,” to read “antimony, arsenic, asbestos,” in paragraph (f)(1).
  - Adding “arsenic,” before “asbestos,” in paragraph (i)(1).
  - Adding one sentence at the end of paragraph (i)(1).
  - Revising paragraph (i)(2).
  - Adding paragraph (i)(5).
  - Revising “arsenic” entry in the table in paragraph (k)(1).
  - Adding “arsenic,” before “asbestos,” in paragraph (k)(2) introductory text.
  - In the table to paragraph (k)(2) by adding in alphabetical order a new entry for “Arsenic”.
  - Adding “arsenic,” before “asbestos,” in paragraph (k)(3) introductory text.
  - Adding in alphabetical order a new entry for “Arsenic” to the table in paragraph (k)(3)(ii).
- The revisions and additions read as follows:

#### § 141.23 Inorganic chemical sampling and analytical requirements.

- (a) \* \* \*  
(4) \* \* \*  
(i) \* \* \*

DETECTION LIMITS FOR INORGANIC CONTAMINANTS

Contaminant	MCL (mg/l)	Methodology	Detection Limit (mg/l)
Arsenic	0.005	Atomic Absorption; Furnace	0.001
		Atomic Absorption; Platform—Stabilized Temperature	<sup>6</sup> 0.0005
		Atomic Absorption; Gaseous Hydride	0.001
		ICP-Mass Spectrometry	<sup>7</sup> 0.0014

<sup>6</sup>The MDL reported for EPA Method 200.9 (Atomic Absorption; Platform—Stabilized Temperature) was determined using a 2x concentration step during sample digestion. The MDL determined for samples analyzed using direct analysis (i.e., no sample digestion) will be higher. Using multiple depositions, EPA 200.9 is capable of obtaining a MDL of 0.0001 mg/L.

<sup>7</sup>Using selective ion monitoring, EPA Method 200.8 (ICP-MS) is capable of obtaining a MDL of 0.0001 mg/L.

\* \* \* \* \*

(c) \* \* \*  
 (9) All new systems or systems that use a new source of water that begin operation after [EFFECTIVE DATE OF THE FINAL RULE] must demonstrate compliance with the MCL within a period of time specified by the State. The system must also comply with the initial sampling frequencies specified by the State to ensure a system can demonstrate compliance with the MCL. Routine and increased monitoring frequencies shall be conducted in

accordance with the requirements in this section.  
 \* \* \* \* \*  
 (i) \* \* \*  
 (1) \* \* \* If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.  
 (2) For systems which are monitoring annually, or less frequently, the system is out of compliance with the maximum contaminant levels for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium if the level of a contaminant is greater

than the MCL. If confirmation samples are required by the State, the determination of compliance will be based on the annual average of the initial MCL exceedance and any State-required confirmation samples. If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(5) Arsenic sampling results will be reported to the nearest 0.001 mg/L.

(k) \* \* \*  
 (1) \* \* \*

Contaminant and methodology <sup>13</sup>	EPA	ASTM <sup>3</sup>	SM <sup>4</sup>	Other
Arsenic <sup>14</sup> :				
ICP—Mass Spectrometry	<sup>2</sup> 200.8			
Atomic Absorption; Platform	<sup>2</sup> 200.9			
Atomic Absorption; Furnace		D-2972-93C	3113B.	
Hydride Atomic Absorption		D-2972-93B	3114B.	

<sup>2</sup>"Methods for the Determination of Metals in Environmental Samples—Supplement I", EPA/600/R-94/111, May 1994. Available at NTIS, PB95-125472.

<sup>3</sup>Annual Book of ASTM Standards, 1994 and 1996, Vols. 11.01 and 11.02, American Society for Testing and Materials. The previous versions of D1688-95A, D1688-95C (copper), D3559-95D (lead), D1293-95 (pH), D1125-91A (conductivity) and D859-94 (silica) are also approved. These previous versions D1688-90A, C; D3559-90D, D1293-84, D1125-91A and D859-88, respectively are located in the Annual Book of ASTM Standards, 1994, Vols. 11.01. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

<sup>4</sup>18th and 19th editions of Standard Methods for the Examination of Water and Wastewater, 1992 and 1995, respectively, American Public Health Association; either edition may be used. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street NW, Washington, DC 20005.

<sup>13</sup>Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2X preconcentration step during sample digestion, MDLs determined when samples are analyzed by direct analysis (i.e., no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559-90D unless multiple in-furnace depositions are made.

<sup>14</sup>If ultrasonic nebulization is used in the determination of arsenic by Methods 200.7, 200.8, or SM 3120 B, the arsenic must be in the pentavalent state to provide uniform signal response. For methods 200.7 and 3120 B, both samples and standards must be diluted in the same mixed acid matrix concentration of nitric and hydrochloric acid with the addition of 100 µL of 30% hydrogen peroxide per 100ml of solution. For direct analysis of arsenic with method 200.8 using ultrasonic nebulization, samples and standards must contain one mg/L of sodium hypochlorite.

(2) \* \* \*

Contaminant	Preservative <sup>1</sup>	Container <sup>2</sup>	Time <sup>3</sup>
Arsenic .....	Conc HNO <sub>3</sub> to pH <2 .....	P or G .....	6 months.

<sup>1</sup> When indicated, samples must be acidified at the time of collection to pH <2 with concentrated acid or adjusted with sodium hydroxide to pH > 12. When chilling is indicated the sample must be shipped and stored at 4°C or less.

<sup>2</sup> P = plastic, hard or soft; G=glass, hard or soft.

<sup>3</sup> In all cases samples should be analyzed as soon after collection as possible. Follow additional (if any) information on preservation, containers or holding times that is specified in method.

- (3) \* \* \*
- (ii) \* \* \*

Contaminant	Acceptance limit
Arsenic .....	±30 at ≥0.005 mg/l

\* \* \* \* \*

6. Section 141.24 is amended by:

a. Adding one sentence to the end of paragraph (f)(15)(i).

b. Removing the last sentence of paragraph (f)(15)(ii) and adding in its place two new sentences.

c. Adding paragraph (f)(22).

d. Adding a sentence to the end of paragraph (h)(11)(i).

e. Removing the last sentence of paragraph (h)(11)(ii) and adding in its place two new sentences.

f. Adding paragraph (h)(20).

The revisions and additions read as follows:

**§ 141.24 Organic chemicals other than total trihalomethanes, sampling and analytical methods.**

\* \* \* \* \*

(f) \* \* \*

(15) \* \* \*

(i) \* \* \* If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(ii) \* \* \* If confirmation samples are required by the State, the determination of compliance will be based on the annual average of the initial MCL exceedance and any State-required confirmation samples. If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(22) All new systems or systems that use a new source of water that begin operation after [DATE THREE YEARS AFTER PUBLICATION DATE OF FINAL RULE] must demonstrate compliance with the MCL within a

period of time specified by the State. The system must also comply with the initial sampling frequencies specified by the State to ensure a system can demonstrate compliance with the MCL. Routine and increased monitoring frequencies shall be conducted in accordance with the requirements in this section.

\* \* \* \* \*

(h) \* \* \*

(11) \* \* \*

(i) \* \* \* If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(ii) \* \* \* If confirmation samples are required by the State, the determination of compliance will be based on the annual average of the initial MCL exceedance and any State-required confirmation samples. If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(20) All new systems or systems that use a new source of water that begin operation after [DATE THREE YEARS AFTER PUBLICATION OF THE FINAL RULE] must demonstrate compliance with the MCL within a period of time specified by the State. The system must also comply with the initial sampling frequencies specified by the State to ensure a system can demonstrate compliance with the MCL. Routine and increased monitoring frequencies shall be conducted in accordance with the requirements in this section.

**Subpart F—[Amended]**

7. In § 141.51(b), the table is amended by adding in alphabetical order an entry for Arsenic to read as follows:

**§ 141.51 Maximum contaminant level goals for inorganic contaminants.**

Contaminant	MCLG (mg/l)
Arsenic .....	zero

**Subpart G—[Amended]**

8. Section 141.60 is amended by adding paragraph (b)(4) to read as follows:

**§ 141.60 Effective dates.**

(b) \* \* \*

(4) The compliance date for § 141.62(b)(16) is [DATE 5 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for community water systems serving 10,000 people or less, and [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for all other community water systems.

9. Section 141.62 is amended by:

a. Revising the second sentence of paragraph (b).

b. Adding entry “(16)” to the table in paragraph (b).

c. Adding an entry and footnote for “Arsenic” in alphabetical order to the

table in paragraph (c) and revising the table heading.

d. Adding paragraph (d).

The revisions and additions read as follows:

(c) \* \* \*

**§ 141.62 Maximum contaminant levels for inorganic contaminants.**

\* \* \* \* \*

(b) \* \* \* The maximum contaminant level specified in paragraphs (b)(1) and (b)(16) of this section only apply to community water systems. \* \* \*

Contaminant	MCL (mg/l)
(16) Arsenic .....	0.005

**BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(B)**

Chemical name	BAT(s)
Arsenic <sup>4</sup> .....	1, 2, 5, 6, 7, 9

\* \* \* \* \*

<sup>4</sup>BATs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

(d) The Administrator, pursuant to section 1412 of the Act, hereby identifies in the following table the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant level for arsenic:

**SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTs) <sup>1</sup> FOR ARSENIC <sup>2</sup>**

Small System Compliance Technology	Affordable for listed small system categories <sup>3</sup>
Activated Alumina (centralized) .....	All size categories
Activated Alumina (Point-of-Entry) <sup>4</sup> .....	All size categories
Activated Alumina (Point-of-Use) <sup>4</sup> .....	All size categories
Coagulation/Filtration .....	501–3,300, 3,301–10,000
Coagulation-assisted Microfiltration .....	501–3,300, 3,301–10,000
Ion Exchange .....	All size categories
Lime Softening .....	501–3,300, 3,301–10,000
Oxidation/Filtration <sup>5</sup> .....	All size categories
Reverse Osmosis (centralized) .....	501–3,300, 3,301–10,000
Reverse Osmosis (Point-of-Use) <sup>4</sup> .....	All size categories

<sup>1</sup> Section 1412(b)(4)(E)(ii) of the SDWA specifies that SSCTs must be affordable and technically feasible for small systems.

<sup>2</sup> SSCTs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

<sup>3</sup> The Act (*ibid.*) specifies three categories of small systems: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.

<sup>4</sup> When POU or POE devices are used for compliance, programs to ensure proper long-term operation, maintenance, and monitoring must be provided by the water system to ensure adequate performance.

<sup>5</sup> For use only when the removal efficiency needed to reach an MCL is less than 50%.

**Subpart O—[Amended]**

10. Section 141.154 is amended by revising paragraph (b) to read as follows:

**§ 141.154 Required additional health information.**

\* \* \* \* \*

(b) Beginning [30 DAYS AFTER PUBLICATION DATE OF THE FINAL

RULE], community water systems that detect arsenic above 0.005 mg/L must make a good faith effort, as described in § 141.155(b) to provide to its customers an annual report that contains the information specified in § 141.153 for arsenic.

\* \* \* \* \*

11. The table in Appendix A, published at 65 FR 26024 on May 4, 2000 and effective June 5, 2000, is amended by revising the entry for arsenic to read as follows:

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

\* \* \* \* \*

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
Inorganic contaminants:	*	*	*	*	*	*
Arsenic (ppb) .....	0.005	1000	5	0	Erosion of natural deposits; Runoff from orchards; Runoff from glass and electronics production wastes.	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.
Key:	*	*	*	*	*	*
ppb = parts per billion, or micrograms per liter (µg/l)	*	*	*	*	*	*

**Subpart Q—[Amended]**

12. Section 141.203(a), published at 65 FR 26036 on May 4, 2000, and

effective June 5, 2000, is amended by adding entry (4) in numerical order to Table 1 to read as follows:

**§ 141.203 Tier 2 Public Notice—Form, manner, and frequency of notice.**

(a) \* \* \*

TABLE 1 TO § 141.203.—VIOLATION CATEGORIES AND OTHER SITUATIONS REQUIRING A TIER 2 PUBLIC NOTICE

(4) Non-transient non-community water systems exceeding the arsenic MCL.

13. Appendix A to Subpart Q, published at 65 FR 26040 on May 4, 2000, effective June 5, 2000, is amended

in the table by revising the entry for “2. Arsenic” under B. Inorganic Chemicals (IOCs), revising endnote 1 and adding endnotes 18 and 19 to read as follows:

**Appendix A to Subpart Q of Part 141.—NPDWR Violations and Other Situations Requiring Public Notice<sup>1</sup>**

Contaminant	MCL/MRDL/TT violations <sup>2</sup>		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
B. Inorganic Chemicals (IOCs)	*	*	*	*
2. Arsenic .....		2 18 141.62(b)	3	19 141.23(a), (c)

**Appendix A—Endnotes**

1. Violations and other situations not listed in this table (e.g., reporting violations and failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a).

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

18. The arsenic MCL citations apply [DATE 5 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for community water systems serving 10,000 people or less and [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for all other community water systems and non-transient non-community water systems. Until then, the citations are § 141.11(b) and § 141.23(n).

19. The arsenic Tier 3 violation MCL citations apply [DATE 5 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for community water systems serving 10,000

people or less and [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for all other community water systems. Until then, the citations are § 141.23(a,l).

14. Appendix B to Subpart Q published at 65 FR 26043 on May 4, 2000, effective June 5, 2000, is amended in the table by revising entry “9. Arsenic” and adding footnote 23 to read as follows:

**Appendix B to Subpart Q of Part 141.—Standard Health Effects Language for Public Notification**

Contaminant	MCLG <sup>1</sup> mg/L	MCL <sup>2</sup> mg/L	Standard health effects language for public notification
9. Arsenic <sup>23</sup> .....	0	0.005	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.

**Appendix B—Endnotes**

- 1. MCLG—Maximum contaminant level goal.
- 2. MCL—Maximum contaminant level.
- 23. These arsenic values apply [DATE 5 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for community water systems serving 10,000 people or less and [DATE 3 YEARS AFTER PUBLICATION DATE OF THE FINAL RULE] for all other community water systems and non-transient non-community water systems. Until then, the MCL is 0.050 mg/L and there is no MCLG.

**PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION**

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

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

**Subpart B—Primary Enforcement Responsibility**

2. In § 142.16, revise paragraph (e) introductory text and add paragraphs (j) and (k) to read as follows:

**§ 142.16 Special primacy requirements.**

(e) An application for approval of a State program revision which adopts the requirements specified in §§ 141.11, 141.23, 141.24, 141.40, 141.61 and 141.62 for a newly regulated contaminant must contain the following

(in addition to the general primacy requirements enumerated elsewhere in this part, including the requirement that State regulations be at least as stringent as the federal requirements):

(j) An application for approval of a State program revision which adopts the requirements specified in §§ 141.11, 141.23, 141.24, 141.32, 141.40, 141.61 and 141.62 for an existing regulated contaminant must contain the following (in addition to the general primacy requirements enumerated elsewhere in this part, including the requirement that State regulations be at least as stringent as the federal requirements):

(1) If a State chooses to issue waivers from the monitoring requirements in §§ 141.23, 141.24, and 141.40, the State shall describe the procedures and criteria which it will use to review waiver applications and issue wavier determinations. The State shall provide the same information required in paragraphs (e)(1)(i) and (ii) of this section. States may update their existing waiver criteria or use the requirements submitted under the National Primary Drinking Water Regulations for the inorganic and organic contaminants (*i.e.*, Phase II/V rule) in paragraph (e) of this section. States may simply note in their application any revisions to existing waiver criteria or note that the same procedures to issue waivers will be used.

(2) A monitoring plan by which the State will assure all systems complete

the required monitoring with the regulatory deadlines. States may update their existing monitoring plan or use the same monitoring plan submitted under the National Primary Drinking Water Regulations for the inorganic and organic contaminants (*i.e.* Phase II/V rule) in paragraph (e) of this section. States may simply note in their application any revisions to an existing monitoring plan or note that the same monitoring plan will be used. The State must demonstrate that the monitoring plan is enforceable under State law.

(k) States establish the initial monitoring requirements for new systems and new sources. States must explain their initial monitoring schedules and how these monitoring schedules ensure that public water systems and sources that begin operation after [DATE THIRTY DAYS AFTER PUBLICATION OF THE FINAL RULE] comply with MCL's and monitoring requirements. States must also specify the time frame in which new systems will demonstrate compliance with the MCLs.

4. In § 142.62(b), the table is amended by revising the table heading and adding arsenic in alphabetical order to the list of contaminants to read as follows:

**§ 142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals**

(b) \* \* \*

**BAT FOR INORGANIC COMPOUNDS LISTED IN § 141.62(B)<sup>1</sup>**

Chemical name	BAT(s)
Arsenic .....	1, 2, 5, 6, 7, 9

\* \* \* \* \*

**Key to BATs in Table**

- 1 = Activated Alumina
- 2 = Coagulation/Filtration (not BAT for systems < 500 service connections)

\* \* \* \* \*

- 5 = Ion Exchange
- 6 = Lime Softening (not BAT for systems < 500 service connections)
- 7 = Reverse Osmosis

\* \* \* \* \*

- 9 = Electrodialysis

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