ACTION: Original

DATE: 04/26/2005 8:01 AM

Rule Summary and Fiscal Analysis (Part A)

Ohio Environmental Protection Agency
Agency Name

Division of Drinking and Ground Water (DDAGW)
Division

Kelly Butler
Contact

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3745-81-23
Rule Number

AMENDMENT
TYPE of rule filing

Rule Title/Tag Line **Inorganic chemical monitoring requirements..**

RULE SUMMARY

1. Is the rule being filed consistent with the requirements of the RC 119.032 review? **Yes**

2. Are you proposing this rule as a result of recent legislation? **No**

3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**

4. Statute(s) authorizing agency to adopt the rule: **RC Section 6109.04**

5. Statute(s) the rule, as filed, amplifies or implements: **RC Section 6109.04**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

> This rule is being proposed in order to adopt the new federal requirements of U.S. EPA's Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, Final Rule, published in the Federal Register on January 22, 2001. This rule is also being proposed to fulfill the five year rule review requirements of section 119.032 of the Revised Code.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE,

then summarize the content of the rule:

> This rule requires that all public water systems monitor their drinking water for nitrate and nitrite and all community and nontransient noncommunity public water systems monitor for certain other inorganic contaminants and details the specific monitoring requirements for each.
>
> For the purposes of consistency Ohio EPA is proposing to set the trigger level for increased monitoring for all inorganic contaminants at 80% of the contaminant's maximum contaminat level (MCL). The proposed amendments also clarify the scheduling of the initial monitoring for inorganic contaminants required of new public water systems and those with new sources of drinking water. Other amendments include new monitoring requirements for arsenic and for compliance with POU and POE devices. Also, requirements related to variances and exemptions have been removed, as the applicable variance and exemption rules have been rescinded.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

> This rule references Chapter 3745-89 and rules 3745-81-11, 3745-81-27, 3745-81-29, 3745-81-32, and 3745-81-75 of the Administrative Code. In accordance with section 121.76 of the Revised Code references to the Administrative Code are exempt from the requirements of sections 121.71 to 121.75.
>
> This rule also references EMSL94 methods 200.7, 200.8, and 200.9. These methods are generally accepted industry standards cited in an understandable manner and generally available to the persons affected by this rule, and have also been dated because they are subject to change. In accordance with section 121.75 of the Revised Code these references are therefore also exempt from the requirements of sections 121.71 to 121.74.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

> Not applicable.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so:

Not Applicable.

12. 119.032 Rule Review Date: **4/26/2005**

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

$0.00

The proposed amendments will not affect the Agency's budget.

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

Not applicable.

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

Please see the RSFA Part B for this rule.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **Yes**

You must complete Part B of the Rule Summary and Fiscal Analysis in order to comply with Am. Sub. S.B. 33 of the 120th General Assembly.

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? **Yes**

You must complete the Environmental rule Adoption/Amendment Form in order to comply with Am. Sub. 106 of the 121st General Assembly.

Rule Summary and Fiscal Analysis (Part B)

1. Does the Proposed rule have a fiscal effect on any of the following?

(a) School Districts	(b) Counties	(c) Townships	(d) Municipal Corporations
Yes	**Yes**	**Yes**	**Yes**

2. Please provide an estimate in dollars of the cost of compliance with the proposed rule for school districts, counties, townships, or municipal corporations. If you are unable to provide an estimate in dollars, please provide a written explanation of why it is not possible to provide such an estimate.

The cost for public water systems to comply with the proposed amendments to this rule will vary according to the type of water system and whether or not inorganic contaminants are detected at levels above 80 per cent of that contaminants maximum contaminant level (MCL). We estimate that the proposed amendments will impact public water systems in the following ways:

1, Arsenic: Pursuant to federal requirements, the MCL for arsenic in drinking water is being reduced to 0.10 µg/L in OAC rule 3745-81-11 as part of this rule package. Based on previous monitoring data, we anticipate approximately 40 community and nontrasient noncommunity systems will have sample results that are above 80 per cent of the new MCL and will therefore be required to go from monitoring tri-annually for arsenic to monitoring quarterly for arsenic. The cost to sample for arsenic is approximately $21 per sample site, so those 40 public water systems we anticipate will be affected will be spending appoximately $77 more per year per sample site to comply with this requirement until they qualify for reduced monitoring.

2, All other Inorganic Contaminants: Previous monitoring data indicates that less than 1% of the public water systems in the state have exceeded 80 per cent of the MCL for all other inorganic contaminants in the last ten years. We therefore estimate that very few systems will be required to take quarterly samples for the other inorganic contaminants. Those that do will go from spending between $3-$67 per sample site each year (depending on the contaminant) to $48-$800 per sample site per year until they qualify for reduced monitoring.

3. If the proposed rule is the result of a federal requirement, does the proposed rule exceed the scope and intent of the federal requirement? **No**

4. If the proposed rule exceeds the minimum necessary federal requirement,

please provide an estimate of, and justification for, the excess costs that exceed the cost of the federal requirement. In particular, please provide an estimate of the excess costs that exceed the cost of the federal requirement for (a) school districts, (b) counties, (c) townships, and (d) municipal corporations.

Not Applicable.

5. Please provide a comprehensive cost estimate for the proposed rule that includes the procedure and method used for calculating the cost of compliance. This comprehensive cost estimate should identify all of the major cost categories including, but not limited to, (a) personnel costs, (b) new equipment or other capital costs, (c) operating costs, and (d) any indirect central service costs.

The estimates above are based on average laboratory prices in Ohio and could include personnel and other costs.

(a) Personnel Costs

See above

(b) New Equipment or Other Capital Costs

Not applicable

(c) Operating Costs

Not applicable

(d) Any Indirect Central Service Costs

Not applicable

(e) Other Costs

See above

6. Please provide a written explanation of the agency's and the local government's ability to pay for the new requirements imposed by the proposed rule.

As this is an existing rule and the amendments proposed are not anticipated to cause a significant increase in the cost of compliance, the agency's and local government's ability to pay are established.

7. Please provide a statement on the proposed rule's impact on economic development.

The proposed amendments are not expected to have any impact on economic development.

Environmental Rule Adoption/Amendment Form

Pursuant to Am. Sub. H.B. 106 of the 121st General Assembly, prior to adopting a rule or an amendment to a rule dealing with environmental protection, or containing a component dealing with environmental protection, a state agency shall:

(1) Consult with organizations that represent political subdivisions, environmental interests, business interests, and other persons affected by the proposed rule or amendment.

(2) Consider documentation relevant to the need for, the environmental benefits or consequences of, other benefits of, and the technological feasibility of the proposed rule or rule amendment.

(3) Specifically identify whether the proposed rule or rule amendment is being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal environmental law or to participate in a federal environmental program, whether the proposed rule or rule amendment is more stringent than its federal counterpart, and, if the proposed rule or rule amendment is more stringent, the rationale for not incorporating its federal counterpart.

(4) Include with the proposed rule or rule amendment and rule summary and fiscal analysis required to be filed with the Joint Committee on Agency Rule Review information relevant to the previously listed requirements.

(A) Were organizations that represent political subdivisions, environmental interests, business interests, and other persons affected by the proposed rule or amendment consulted ? **Yes**

Please list each contact.

The interested parties listed in Attachment A were contacted and provided an opportunity to comment.

(B) Was documentation that is relevant to the need for, the environmental benefits or consequences of, other benefits of, and the technological feasibility of the proposed rule or amendment considered ? **Yes**

Please list the information provided and attach a copy of each piece of documentation to this form. (A SUMMARY OR INDEX MAY BE ATTACHED IN LIEU OF THE ACTUAL DOCUMENTATION.)

Please see Attachment B: National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule, published in the Federal Register on January 22, 2001.

(C) Is the proposed rule or rule amendment being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal environmental law or to participate in a federal environmental program ? **Yes**

Is the proposed rule or rule amendment more stringent than its federal counterpart ? **No**

(D) If this is a rule amendment that is being adopted under a state statute that establishes standards with which the amendment is to comply, is the proposed rule amendment more stringent than the rule that it is proposing to amend? **No**

Not Applicable

Rule Summary Fiscal Analysis
Attachment A: List of Interested Parties

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Rule Summary Fiscal Analysis
Attachment B

National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Monitoring; Final Rule

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

Federal Register

Monday,
January 22, 2001

Part VIII

Environmental Protection Agency

40 CFR Parts 9, 141, and 142

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

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141 and 142

[WH–FRL–6934–9]

RIN 2040–AB75

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today EPA is establishing a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (10 µg/L). This regulation will apply to non-transient non-community water systems, which are not presently subject to standards on arsenic in drinking water, and to community water systems.

In addition, EPA is publishing clarifications for monitoring and demonstration of compliance for new systems or sources of drinking water. The Agency is also clarifying compliance for State-determined monitoring after exceedances for inorganic, volatile organic, and synthetic organic contaminants. Finally, EPA is recognizing the State-specified time period and sampling frequency for new public water systems and systems using a new source of water to demonstrate compliance with drinking water regulations. The requirement for new systems and new source monitoring will be effective for inorganic, volatile organic, and synthetic organic contaminants.

DATES: This rule is effective March 23, 2001, except for the amendments to §§ 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) which are effective January 22, 2004.

The compliance date for requirements related to the clarification for monitoring and compliance under §§ 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) is January 22, 2004. The compliance date for requirements related to the revised arsenic standard under §§ 141.23(i)(4), 141.23(k)(3), 141.23(k)(3)(ii), 141.51(b), 141.62(b), 141.62(b)(16), 141.62(c), 141.62(d), and 142.62(b) is January 23, 2006. For purposes of judicial review, this rule is promulgated as of January 22, 2001.

ADDRESSES: Copies of the public comments received, EPA responses, and all other supporting documents are available for review at the U.S. EPA Water Docket (4101), East Tower B–57, 401 M Street, SW, Washington DC 20460. For an appointment to review the docket, call 202–260–3027 between 9 a.m. and 3:30 p.m. and refer to Docket W–99–16.

FOR FURTHER INFORMATION CONTACT: The Safe Drinking Water Hotline, phone: (800) 426–4791, or (703) 285–1093, e-mail: hotline.sdwa@epa.gov for general information about, and copies of, this document and the proposed rule. For technical inquiries, contact: Jeff Kempic, (202) 260–9567, e-mail: kempic.jeffrey@epa.gov for treatment and costs, and Dr. John B. Bennett, (202) 260–0446, e-mail: bennett.johnb@epa.gov for benefits.

SUPPLEMENTARY INFORMATION:

Regulated Entities

A public water system (PWS), 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 regulated entities
Industry	Privately owned/operated community water supply systems using ground water, surface 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, surface water, or mixed ground and surface water.
Federal Government	Federally owned/operated community water supply systems using ground water, surface 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 the general information contact listed in the section listing contacts for further information.

Abbreviations used in this rule

<—less than

≤—less than or equal to

>—greater than

≥—greater than or equal to

±—plus or minus

§—section

σ—σ, Greek letter, in statistics represents standard deviation

µg—Microgram, one-millionth of a gram (3.5×10^{-8} of an ounce)

µg/L—micrograms per liter

AA—Activated alumina

AIC—Akaike Information Criterion

ACWA—Association of California Water Agencies

AMWA—Association of Metropolitan Water Agencies

APHA—American Public Health Association

ARARs—Applicable or relevant and appropriate requirements
As (III)—Trivalent arsenic. Common inorganic form in water is arsenite
As (V)—Pentavalent arsenic. Common inorganic form in water is arsenate
ASDWA— Association of State Drinking Water Administrators
AsH$_3$—Arsine
ASTM—American Society for Testing and Materials
ATSDR—Agency for Toxic Substances and Disease Registry, U.S. Department of Health & Human Services
AWWA—American Water Works Association
AWWARF—American Water Works Association Research Foundation
BAT—Best available technology
BV—Bed volume
CCR—Consumer Confidence Report
CERCLA—Comprehensive Environmental Response, Compensation, and Liability Act administered by EPA for hazardous substances
C/F—Modified coagulation/filtration
CFR—Code of Federal Regulations
CSFII—Continuing Survey of Food Intakes by Individuals
CWA—Clean Water Act administered by EPA for surface waters of the U.S.
CWS—Community water system
CWSS—Community Water System Survey
DMA—Dimethyl arsinic acid, cacodylic acid, $(CH_3)_2HAsO_2$
DNA—Deoxyribonucleic acid
DWSRF—Drinking Water State Revolving Fund
EA—Economic analysis
EDR—Electrodialysis reversal
EEAC—Environmental Economics Advisory Committee
e.g.—*exempli gratia,* Latin for ‘‘for example’’
EPA—U.S. Environmental Protection Agency
et al.—*et alia,* Latin for ‘‘and others’’
FACA—Federal Advisory Committee Act
FR—Federal Register
FRFA—Final Regulatory Flexibility Analysis
FSIS—Federalism Summary Impact Statement
GDP—Gross Domestic Product
GFAA—Graphite furnace atomic absorption
GHAA—Gaseous hydride atomic absorption
GI—Gastrointestinal
GW—Ground water
GWR—Ground Water Rule
HRRCA—Health Risk Reduction and Cost Analysis
ICP–AES—Inductively coupled plasma-atomic emission spectroscopy
ICP–MS—Inductively coupled plasma mass spectroscopy
ICR—Information collection request
i.e.—*id est,* Latin for ‘‘that is’’
IOCs—Inorganic contaminants
ISCV—Intra-system coefficient of variation
IX—Ion exchange
L—Liter, also referred to as lower case ‘‘l’’ in older citations
LD$_{50}$—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
LS—Modified lime softening
LT1/FBR—Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Recycling Rule
MCL—Maximum contaminant level
MCLG—Maximum contaminant level goal
MDL—Method detection limit
mg—Milligrams, one-thousandth of a gram, 1 milligram=1,000 micrograms
mg/kg—Milligrams arsenic per kilogram body weight or soil weight
mg/L—Milligrams per liter
MHI—Mean household income
MMA—Monomethyl arsenic, arsonic acid, $CH_3H_2ASO_3$
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 for EPA
NIRS—National Inorganic and Radionuclide Survey done by EPA
NODA—Notice of Data Availability
NOMS—National Organic Monitoring Survey done by EPA
NPDES—National Pollutant Discharge Elimination System for CWA
NPDWR—National primary drinking water regulation
NR—Not reported
NRC—National Research Council, the operating arm of NAS
NTNCWS—Non-transient non-community water system
NTTAA—National Technology Transfer and Advancement Act
NWIS—National Water Information System of USGS
OGWDW—Office of Ground Water and Drinking Water in EPA
OMB—Office of Management and Budget
PE—Performance evaluation, studies to certify laboratories for EPA drinking water testing
pH—Negative log of hydrogen ion concentration
PNR—Public Notification Rule
POE—Point-of-entry treatment devices
POTWs—Publicly owned treatment works, treat wastewater
POU—Point-of-use treatment devices
ppb—Parts per billion
ppm—Parts per million
PQL—Practical quantitation level
PRA—Paperwork Reduction Act
psi—Pounds per square inch
PT—Performance testing
PUC—Public utilities commission
PWS—Public water systems
QALYs—Quality adjusted life years
RCRA—Resource Conservation and Recovery Act
REF—Relative exposure factors
RFA—Regulatory Flexibility Act
RIA—Regulatory Impact Analysis
RO—Reverse osmosis
RUS—Rural Utilities Service
RWS—Rural Water Survey
SAB—Science Advisory Board
SBAR—Small Business Advocacy Review
SBREFA—Small Business Regulatory Enforcement Fairness Act
SD—Standard deviation
SDWA—Safe Drinking Water Act
SDWIS—Safe Drinking Water Information System
SEER—Surveillance, Epidemiology, and End Results
SM—Standard Method for Examination of Water and Wastewater
SMF—Standardized monitoring framework
SMRs—Standardized mortality ratios
SO4—Sulfate
SOCs—Synthetic organic contaminants
STP–GFAA—Stabilized temperature platform graphite furnace atomic absorption
SW—Surface water
TBLLs—Technically based local limits
TC—Toxicity Characteristic, RCRA hazardous waste
TCLP—Toxicity Characteristic Leaching Procedure, tests for hazardous waste
TDS—Total dissolved solids
TMF—Technical, managerial, financial capacity
TOC—Total organic carbon
UMRA—Unfunded Mandates Reform Act
URTH—Unreasonable risk to health
U.S.—United States
USDA—US Department of Agriculture
USGS—US Geological Survey
UV—Ultraviolet
VOCs—Volatile organic contaminants
VSL—Value of statistical life
VSLY—Value of statistical life year
WHO—World Health Organization
WS—Water supply
WTP—Willingness-to-pay

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I. Background and Summary of the Final Rule

A. What Did EPA Propose?

On June 22, 2000, the **Federal Register** published EPA's proposed arsenic regulation for community water systems and non-transient non-community water systems (65 FR 38888; EPA, 2000i). EPA proposed a health-based, non-enforceable goal, or Maximum Contaminant Level Goal (MCLG), of zero micrograms per liter (µg/L) and a Maximum Contaminant Level (MCL) of 5 µg/L. The Agency also requested comment on alternate MCL levels of 3 µg/L, 10 µg/L, and 20 µg/L. (In the proposed rule EPA expressed arsenic concentration in milligrams per liter (mg/L) or parts per million, which matches the units of the former and current standard for arsenic. Except as noted, the Agency will refer to arsenic concentration in micrograms per liter (µg/L) in this preamble.)

EPA based the June 2000 proposal on extensive analysis including a careful consideration of the following issues: a nonzero MCLG; occurrence of arsenic in public water systems; our approach for estimating national occurrence and co-occurrence; acceptance limits used to establish the practical quantitation level (PQL); rounding of measured values for compliance purposes; extending compliance by two years for systems serving under 10,000 people in order to add capital improvements; dates for reporting changes in the consumer confidence reports and public notification; appropriateness of the national affordability criteria; affordable technologies for small systems; implementation issues for point-of-use (POU) and point-of-entry (POE) treatments; appropriateness of non-hazardous residual costing; our overall analysis of costs; adjusting benefits estimates (*e.g.*, for factors such as latency); our approach for considering uncertainties that affected risk; use of the authority to set an MCL at a level other than the feasible MCL; expression of the MCL as total arsenic; approaches to regulation of NTNCWSs; State program revisions; selenium levels as an attenuation factor in arsenic toxicity; impacts on small entities; use of consensus analytical methods; methods to address environmental justice concerns; and comments on use of plain language. We asked commenters to submit data and comments on these issues, as well as any other issues raised in the proposal.

The proposal reflected several types of technical evaluations, including analytical methods performance and laboratory capacity; the likelihood of different size water systems choosing treatment technologies based on source water characteristics; and the national occurrence of arsenic in drinking water supplies. Furthermore, the Agency assessed the quantifiable and nonquantifiable costs and health risk reduction benefits likely to occur at the treatment levels considered, and the effects of arsenic on sensitive subpopulations.

The proposed MCL was consistent with the Agency's use of the new benefit/cost provisions of the Safe Drinking Water Act (SDWA), as amended in 1996 (see section II. of this preamble for additional information about this provision). EPA proposed 3 μg/L as the feasible MCL, after considering treatment costs and efficiency under field conditions as well as considering the appropriate analytical methods. Because EPA determined that the benefits of regulating arsenic at the feasible level would not justify the costs, the Agency proposed an MCL of 5 μg/L, while requesting comment on MCL options of 3 μg/L (the feasible level), 10 μg/L, and 20 μg/L.

We based our estimates of large system compliance costs primarily on costs for coagulation/filtration and lime softening, although we consider several other technologies to be appropriate as best available technology (BAT) technologies. (See Table I.F–1.) For small-system (systems serving 10,000 people and less) compliance costs, we considered the costs for ion exchange, activated alumina, reverse osmosis, and nanofiltration. EPA proposed extending the effective date to five years after the final rule issuance for small community water systems and maintaining the effective date at three years after promulgation for all other community water systems. EPA proposed 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. EPA proposed that NTNCWSs monitor for arsenic and report exceedances of the MCL.

The Agency also clarified the procedure used for determining compliance after exceedances for inorganic, volatile organic, and synthetic organic contaminants in §§ 141.23(i)(2), 141.24(f)(15)(ii), and 141.24(h)(11)(ii), respectively. Finally, EPA proposed that new systems and systems using a new source of water be required to demonstrate compliance with the MCLs using State-specified time frames. The clarified new source and new system compliance regulations require that States establish initial sampling frequencies and compliance periods for inorganic, volatile organic, and synthetic organic contaminants in §§ 141.23(c)(9), 141.24(f)(22), and 141.24(h)(20), respectively.

B. Overview of the Notice of Data Availability (NODA)

In the proposed rule, EPA quantified the risk reduction and benefits of avoiding bladder cancer and noted that a peer-reviewed quantification of lung cancer risk from arsenic exposure would probably be available in time to consider for the final rule (65 FR 38888 at 38899; EPA, 2000i). Relying upon a discussion in the National Research Council (NRC) report (NRC, 1999, pg. 8) about the qualitative risks of lung cancer (65 FR 38888 at 38944; 2000i), EPA provided a ''What-If'' estimate of lung cancer benefits (65 FR 38888 at 38946, 2000i) in the proposed rule. On October 20, 2000, the **Federal Register** published EPA's Notice of Data Availability (NODA) containing a revised risk analysis for bladder cancer and new risk information concerning lung cancer (65 FR 63027; EPA, 2000m), and identified a correction to Table 4 on October 27, 2000 (65 FR 64479; EPA, 2000n). The NODA also provided information concerning the availability of cost curves used to develop the costs published in the proposal.

EPA used new risk information for lung and bladder cancer from a peer-reviewed article written by Morales *et al.* (2000). In the NODA, EPA explained that the authors used several alternative statistical models to estimate cancer risk. EPA explained its reasons for selecting ''Model 1'' with no comparison population for further analysis. We used daily water consumption (EPA, 2000c) reported by gender, region, age, economic status, race, and separately for pregnant women, lactating women, and women in childbearing years combined with weight data to derive exposure factors for the U.S. We used these exposure factors, our occurrence estimate (EPA 2000g) of populations exposed to arsenic at different concentrations, and the risk distributions from the Morales *et al.* (2000) paper in Monte Carlo simulations to estimate the upper bound of risks faced by the U.S. population. The NODA compared the bladder cancer risks derived for the proposal against the bladder cancer risks derived from the Morales *et al.* (2000) study. EPA also derived lung cancer risks using the same approach and the risk model contained in the Morales *et al.* (2000) study.

EPA also used the newly calculated risks to estimate a lower bound risk in the U.S. This calculation took into account the amount of additional arsenic people in Taiwan were likely to have ingested from water used in food preparation. EPA showed the effects on risks for the U.S. population at both the mean and 90th percentile levels for various arsenic levels in drinking water. Based on the revised risk assessment, we updated our assessment of the relative risk of lung cancer as compared to bladder cancer. The NODA indicated that instead of being 2 to 5 times as many fatal lung cancer cases as bladder cancer cases (as was cited in NRC's Executive Summary, NRC, 1999, pg. 8 as a qualitative estimate), the combined risk of excess lung and bladder cancer were thought to be only about twice that of bladder cancer risk. EPA noted that, while the new risks were higher than the bladder cancer risk in the proposal, the monetized benefits of lung cancer would fall within the lung cancer benefits range estimated using the ''What-If'' analysis (*e.g.*, $19.6 million—$224 million yearly for an MCL of 10 μg/L) in the proposal (65 FR 38888 at 38959; EPA, 2000m).

In the NODA, EPA also explained that the docket for the proposed rule had the November 1999 version (EPA, 1999o) of ''Technologies and Costs for the Removal of Arsenic from Drinking Water'' rather than the April 1999 version of the document that was the primary source for the treatment technology cost equations used to generate the national cost estimate. The national cost estimate was presented in the ''Proposed Arsenic in Drinking Water Rule Regulatory Impact Analysis'' (EPA, 2000h). The NODA therefore announced the availability of the ''Technologies and Costs for the Removal of Arsenic from Drinking Water,'' dated April 1999 (EPA,1999b). The NODA also noted that commenters interested in reproducing the waste disposal curves should consult the ''Small Water System Byproducts Treatment and Disposal Cost Document'' (EPA, 1993a) and ''Water System Byproducts Treatment and Disposal Document (EPA, 1993b).'' In addition to placing these documents in the docket, the NODA also specified that an electronic copy of the treatment technology and waste disposal equations used in the development of the RIA could be found in the docket.

EPA made the April 1999 version of the document, ‘‘Technologies and Costs for the Removal of Arsenic from Drinking Water’’ (EPA,1999b) available on its arsenic webpage.

The cost methodology and cost estimates were clearly stated and explained in the proposal for public review and consideration. Through a technical oversight, we incorrectly attributed the source for the cost curves to the November version of the document placed in the docket (EPA, 1999o). As a result, people could not replicate the precise analysis we did, should a commenter desire to do so. More specifically, although the inputs, assumptions, and model methodology were clearly explained, we incorrectly cited the sources of an intermediate step of deriving specific cost curves from those assumptions. Based upon the proposal’s detailed discussion of inputs, assumptions and associated methodology, EPA believes the public was fully able to review, understand, and comment on the Agency’s estimate of potential impacts. EPA discusses the cost curves further in section III.E.1 of this preamble.

C. Does This Regulation Apply to My Water System?

The final regulation on arsenic in drinking water promulgated today applies to all CWSs and NTNCWSs. The regulation not only establishes an MCLG and MCL for arsenic, but also lists feasible technologies and affordable technologies for small systems that can be used to comply with the MCL. However, systems are not required to use the listed technologies in order to meet the MCL.

D. What are the Final Drinking Water Regulatory Standards for Arsenic (Maximum Contaminant Level Goals and Maximum Contaminant Levels)?

In today’s rule, the MCLG is 0 µg/L, and the enforceable MCL is 0.01 mg/L, which is the same as 10 micrograms per liter (µg/L) or 10 parts per billion (ppb). EPA based the MCL on total arsenic, because drinking water contains almost entirely inorganic forms, and the analytical methods for total arsenic are readily available and capable of being performed by certified laboratories at an affordable cost.

E. Will There be a Health Advisory?

A health advisory for arsenic is not part of today’s rulemaking. EPA will be considering whether or not to issue a health advisory after evaluating the recommendations of the Science Advisory Board (SAB) (EPA, 2000q). The purpose of an advisory would be to provide useful information to water providers between issuance and implementation of this rule.

F. What are the Best Available Technologies For Removing Arsenic From Drinking Water?

Section 1412(b)(4)(E) of the Safe Drinking Water Act states that each National Primary Drinking Water Regulation (NPDWR) which establishes an MCL shall list the technology, treatment techniques, and other means that 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:

(1) The capability of a high removal efficiency;

(2) A history of full-scale operation;

(3) General geographic applicability;

(4) Reasonable cost based on large and metropolitan water systems;

(5) Reasonable service life;

(6) Compatibility with other water treatment processes; and

(7) The ability to bring all of the water in a system into compliance.

EPA identified BATs in this section using the listed criteria. Their removal efficiencies and a brief discussion of the major issues surrounding the usage of each technology are also given in this section. More details about the treatment technologies and costs can be found in ‘‘Technologies and Costs for the Removal of Arsenic From Drinking Water’’ (EPA, 2000t).

1. BAT technologies

EPA reviewed several technologies as BAT candidates for arsenic removal, e.g., ion exchange, activated alumina, reverse osmosis, nanofiltration, electrodialysis reversal, coagulation assisted microfiltration, modified coagulation/filtration, modified lime softening, greensand filtration, conventional iron and manganese removal, and several emerging technologies. The Agency determined that, of the technologies capable of removing arsenic from source water, only the technologies in Table I.F–1 fulfill the requirements of SDWA for BAT determinations for arsenic. The maximum percent of arsenic removal that can be reasonably obtained from these technologies is also shown in the table. These removal efficiencies are for arsenic (V) removal.

TABLE I.F–1.— BEST AVAILABLE TECHNOLOGIES AND REMOVAL RATES

Treatment Technology	Maximum Percent Removal[1]
Ion Exchange (sulfate ≤ 50 mg/L)	95
Activated Alumina	95
Reverse Osmosis	>95
Modified Coagulation/Filtration	95
Modified Lime Softening (pH > 10.5)	90
Electrodialysis Reversal	85
Oxidation/Filtration (20:1 iron:arsenic)	80

[1] The percent removal figures are for arsenic (V) removal. Pre-oxidation may be required.

2. Preoxidation

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 ($H_2AsO_4{}^{\text{minus;}}$ and $H_2AsO_4{}^{2\text{ minus;}}$) 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.

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 byproducts 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 POU and POE devices, central chlorination may be required for oxidation of As (III).

3. Factors affecting listing technologies

Ion Exchange (IX) can effectively remove arsenic using anion exchange resins. It is recommended as a BAT primarily for sites with low sulfate because sulfate is preferred over arsenic. Sulfate will compete for binding sites resulting in shorter run lengths. Due to much shorter run lengths than activated alumina, anion exchange must be regenerated because it is not cost effective to dispose of the resin after one use. Column bed regeneration frequency is a key factor in the cost of the process and affects the volume of waste produced by the process. The proposed rule preamble noted that anion exchange may be practical up to approximately 120 mg/L of sulfate (Clifford, 1994). The upper-bound sulfate concentration for the final rule is 50 mg/L. The selection of this upper bound is based on several factors, including cost and the ability to dispose of the brine stream.

The proposed rule listed three mechanisms to dispose of the brine stream used for regeneration. The options were: sanitary sewer, evaporation pond, and chemical precipitation. Many comments on the proposed rule were based on the assumption that the waste streams generated would be considered hazardous waste. Waste streams containing less than 0.5% solids are evaluated against the toxicity characteristic directly to determine if the waste is hazardous. Arsenic in the regeneration brine will likely exceed 5 mg/L for most systems with arsenic above 10 µg/L and sulfate below 50 mg/L. Since the brine stream would likely be considered hazardous, EPA eliminated the evaporation pond and the chemical precipitation options from the decision tree as options for disposal of anion exchange wastes. The Agency retained discharge to a sanitary sewer because domestic sewage and any mixture of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works (POTW) for treatment is excluded from consideration as solid waste (40 CFR 261.4). Domestic sewage means untreated sanitary wastes that pass through a sewage system. Discharges meeting the previously stated criteria are excluded from regulation as hazardous waste. However, these assumptions were reviewed to substantially reduce projections of brine wastes going to POTWs from those that were used in support of the proposed rule.

Discharge to a sanitary sewer can be limited by technically based local limits (TBLLs) for arsenic or total dissolved solids. Since anion exchange is regenerated more frequently than activated alumina, the total dissolved solids increase can be significant. Many comments indicated that significant increases in total dissolved solids would be unacceptable, especially in the Southwest where water resources are scarce. Salt is used for regeneration of anion exchange resins. The upper bound of 50 mg/L sulfate for anion exchange is based on projected increases of total dissolved solids using the quantity of salt needed for regeneration and the frequency of regeneration (based on sulfate). The sulfate upper bound for the final rule is significantly lower than the upper bound from the proposed rule. Due to the potential for an increase in total dissolved solids, anion exchange would be favored in areas other than the Southwest where the volume of brine is very small relative to the total volume of wastewater being treated at the POTW. Systems that need to treat only a few entry points or can blend a significant portion of the water to meet the MCL may produce a smaller brine stream to allow the brine to be discharged to a POTW. Water systems should check with the POTW to ensure that the brine stream will be accepted before selecting this option.

Activated Alumina (AA) is an effective arsenic removal technology; however, the capacity of activated alumina to remove arsenic is very pH sensitive. High removals can be achieved over a broad range of pH, but shorter run lengths will be observed at higher pH. Activated alumina can be operated in one of two ways. The activated alumina can either be disposed of or regenerated after the media is exhausted. Under the regeneration option, strong acids and bases are used to remove arsenic from the media so that it can be used again to remove arsenic. Because arsenic is strongly adsorbed to the media, only about 50–70% of the adsorbed arsenic is removed. The brine stream produced by the regeneration process then requires disposal. The proposed rule listed discharge to a sanitary sewer as the disposal mechanism for the brines. Many comments on the proposed rule noted that TBLLs for arsenic or total dissolved solids might restrict discharge of brine streams to the sanitary sewer. Since activated alumina run lengths (i.e., number of bed volumes (BV) per run) are much longer than anion exchange, the arsenic concentrations in the brine stream would likely be much higher. Regeneration of activated alumina media is not recommended for larger systems because: (1) Disposal of the brine may be difficult, (2) the regeneration process is incomplete which reduces subsequent run lengths, and (3) for most systems it will be cheaper to replace the media rather than regenerate it. The option of replacing the spent media with new media is called disposable activated alumina.

The disposable activated alumina option can be operated both at the optimal pH of 6 and at higher natural water pH values. It is expected that larger systems would adjust pH to take advantage of the longer run lengths. EPA developed several disposable activated alumina options for the final rule. Two options were based on operating the process at the natural pH of the water (no pH adjustment). These options are intended primarily for smaller systems, although larger systems may also be able to operate at the natural pH if it is low enough to get sufficiently long run lengths. Two options where the pH was adjusted to pH 6 were also examined. The longer run length is based on using sulfuric acid to lower the pH. However, sulfate can compete for adsorption sites with arsenic. It was recommended that hydrochloric acid be used to obtain a longer run length (Clifford et al., 1998). When pH is adjusted to pH 6, post-treatment corrosion control will be necessary.

In our analysis, we assumed that spent media could be safely disposed of in a non-hazardous landfill. The preamble to the proposed rule described results from testing of activated alumina media used to remove arsenic in drinking water systems with arsenic above 50 µg/L. The results from the Toxicity Characteristic Leaching Procedure (TCLP) on these samples was typically less that 50 µg/L. 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 (5000 µg/L) and is listed in 40 CFR 261.24(a). The TC regulatory level is one hundred times higher than the results from the activated alumina samples.

Reverse Osmosis (RO) can provide removal efficiencies of greater than 95% when operating pressure is ideal. Water rejection (on the order of 20–25%) may be an issue in water-scarce regions and may prompt systems employing RO to seek greater levels of water recovery. Water recovery is the volume of drinking water produced by the process divided by the influent stream (product water/influent stream). Increased water recovery is often more expensive, since it can involve recycling of water through treatment units to allow more efficient separation of solids from water. This can also produce more concentrated solid wastes. However, the waste stream will generally not be as concentrated as anion exchange brines, so it should be easier to dispose of. Based on the cost of the process, it is unlikely that reverse osmosis would be installed solely for arsenic removal. Blending a treated portion with an untreated portion and still meeting the MCL would make reverse osmosis more cost effective. If blending is not an option, post-treatment corrosion control would be necessary. Since a large portion of the water is wasted, water quantity could be an issue, especially in the Western U.S. It should be noted that while reverse osmosis is listed as a BAT, it was not used to develop national costs because other options are more cost effective and have much smaller waste streams.

Modified Coagulation/Filtration (C/F) is an effective treatment process for removal of As (V) according to laboratory, pilot-plant, and full-scale tests. The type of coagulant and dosage used affects the efficiency of the process. 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. Systems may need to lower pH or add more coagulant to achieve higher removals.

Modified Lime Softening (LS), operated within the optimum pH range of greater than 10.5 is likely to provide a high percentage of As removal. Systems operating lime softening at lower pH will need to increase the pH to achieve higher removals of arsenic.

Coagulation/Filtration and Lime Softening are unlikely to be installed solely for arsenic removal. Systems considering installation of one of these technologies should design the process to operate in the optimal pH range if high removal efficiencies are needed for compliance.

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 and typically operates at a recovery of 70 to 80%. Since a large portion of the water is wasted, water quantity could be an issue, especially in the Western U.S. It should be noted that while electrodialysis reversal is listed as a BAT, it was not used to develop national costs because other options are more cost effective and have much smaller waste streams.

Oxidation/Filtration (including greensand filtration) has an advantage in that there is not as much competition with other ions. Arsenic is co-precipitated with the iron during iron removal. Sufficient iron needs to be present to achieve high arsenic removals. One study recommended a 20:1 iron to arsenic ratio (Subramanian et al., 1997). Removals of approximately 80% were achieved when iron to arsenic ratio was 20:1. When the iron to arsenic ratio was lower (7:1), removals decreased below 50%. 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. When the arsenic is present as As(III), sufficient contact time needs to be provided to convert the As(III) to As(V) for removal by the oxidation/filtration process. An additional pre-oxidation step is not required for this process as long as there is sufficient contact time. In developing national cost estimates, EPA assumed that systems would opt for this type of technology only if more than 300 μg/L of iron was present. The Agency assumed a removal percentage of 50% when estimating national costs because the 20:1 ratio could not be verified due to limitations in the co-occurrence database. However, EPA assumed a removal percentage of 80% as part of a sensitivity analysis. At proposal EPA indicated that oxidation filtration was not being listed as BAT because it has a low removal efficiency, which might not be appropriate for an MCL of 5. However, the Agency also noted that this technology may be appropriate for systems that do not require high arsenic removal and had high iron in their source water. Because this is an inexpensive technology that is particularly effective for high-iron, low-arsenic waters, EPA is listing oxidation/filtration as a BAT with a footnote that the iron-to-arsenic ratio must be at least 20:1. Systems with greater than 300 μg/L of iron will also see benefits in the aesthetic quality of the water as the iron can be reduced below the secondary standard. EPA's inclusion of oxidation/filtration as a BAT in today's final rule is based upon further evaluation of all available information and studies as well as on public comments.

4. Other technologies evaluated, but not designated as BAT

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 that are consistently below 2 μg/L. Critical operating parameters are iron dose, mixing energy, detention time, and pH (Clifford, 1997). Coagulation and microfiltration as separate processes have both been installed full scale, but the combined coagulation/microfiltration process does not have a full-scale operation history. 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. EPA used this option in developing the national cost estimate because we believe coagulation/microfiltration is an appropriate technology that will be used by certain water systems to comply with this rule, even though it is not currently listed as BAT for the reasons mentioned.

Granular ferric hydroxide is a technology that may combine very long run length without the need to adjust pH. The technology has been demonstrated for arsenic removal full scale in England (Simms et al., 2000). A pilot-scale study for activated alumina was also conducted on that water and showed run lengths much longer than observed in pilot-scale studies in the United States. Due to the lack of published data showing performance for a range of water qualities, granular ferric hydroxide was not designated a BAT. In addition, there is little published information on the cost of the media, so it is difficult to evaluate cost. Granular ferric hydroxide is being investigated in several ongoing studies and may be an effective technology for removing arsenic. Systems may wish to investigate it and other adsorption technologies such as modified activated alumina and other iron-based media. Many of these other new adsorptive media are also being investigated in several ongoing studies.

5. Waste disposal

Waste disposal will be an important issue for both large and small drinking water 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 Tables I.G–1, I.G–5, and I.G–6.

The preamble to the proposed rule summarized toxicity characteristic leaching procedure (TCLP) data on residuals from different arsenic removal technologies. 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 were mixed—the residuals from an arsenic removal plant were below 0.05 mg/L, but the residuals from another iron coagulation plant were above 1 mg/L. However, this is still below the TC regulatory level of 5 mg/L. Based on these 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. Options where the brine stream could be hazardous were eliminated from the final decision tree. For the purposes of the national cost estimate, it was assumed that solid residuals would be disposed of at nonhazardous landfills.

G. Treatment Trains Considered For Small Systems

1. Can my water system use point-of-use (POU), point-of-entry (POE), or bottled water to comply with this regulation?

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 or equal to 500; (2) population of more than 500, but less than or equal to 3,300; and (3) population of more than 3,300, but less than or equal to 10,000. Owners and operators may choose any technology or technique that best suits their conditions, as long as the MCL is met.

The technologies examined for BAT determinations were also evaluated as small system compliance technologies. Several other alternatives that are solely small system options were also evaluated as compliance technologies. Central treatment is not the only option available to small systems. One of the provisions included in the SDWA Amendments of 1996 allows the use of POU and POE devices as compliance technologies for small systems. 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 maintenance and compliance with the MCL or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems (§ 1412(b)(4)(E)).

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 such as at many NTNCWSs. 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. However, there will be higher administrative costs associated with POU and POE options. For POU options, the trade-off is lower treatment cost since only 1% of the water is treated, but higher administrative and monitoring costs occur. Centrally managed POU options, even with the higher monitoring and administrative costs, are less expensive than central treatment for populations up to 150 to 250 people depending upon the technology and number of households.

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 may require special regulations regarding customer responsibilities as well as water utility responsibilities. The water system or person under contract to the system is responsible for maintaining the devices in customers' homes. This responsibility cannot be delegated to the customer. Use of POU/POE systems does not reduce the need for a well-maintained water distribution system. Increased monitoring may be necessary to ensure that the treatment units are operating properly. Monitoring POU/POE systems is also more complex because compliance samples need to be taken after each POU or POE unit rather than at the entry point to the distribution system to be reflective of treatment.

EPA examined three technologies as POU and POE devices for the proposed rule. EPA assumed that systems would more likely choose to use POU activated alumina (AA) or reverse osmosis (RO), and POE AA in the proposed rule. POU and POE ion exchange (IX) and POE RO were considered, but not included as compliance technologies in the proposed rule. Activated alumina and ion exchange units face a breakthrough issue. If the activated alumina is not replaced on time, there is a potential for significantly reduced arsenic removal. However, if the anion exchange resin is not replaced or regenerated on time, the previously removed arsenic can be driven off the resin by sulfate. Tap water arsenic concentrations can be higher than the source water. This is called chromatographic peaking. Due to the potential for chromatographic peaking and run lengths that would typically be less than six months, anion exchange was not listed as a compliance technology in the proposed rule. POE ion exchange also may present problems with total dissolved solids since the resin would need to be regenerated. Since all sites within the system would need treatment, the total dissolved solids increase from a centrally managed POE ion exchange system would be similar to that from a central treatment ion exchange system. EPA did not list POE RO units as compliance technologies because it could create corrosion control problems. In addition, water recovery would be no higher than central treatment, so water quantity issues associated with central treatment reverse osmosis would be applicable to POE RO.

The proposed rule included POE AA as a small system compliance technology. Arsenic removal by AA is very sensitive to the pH. The finished water pH will typically be higher than the optimal pH of 6 to meet the corrosion control requirements of the lead and copper rule. A finished water pH for many systems would be in the range of pH 7 to pH 8. Using data on activated alumina run length and pH, it was determined that viable run lengths were likely only when the finished water pH was at or below pH 7.5 (Kempic, 2000). Even in this pH range, the media may need to be replaced more frequently than once a year, which would make the option very expensive especially compared to the POU AA option. The run length data used for this analysis were from a site with very little competing ions (Simms and Azizian, 1997). Studies at other sites with higher levels of competing ions have much lower run lengths (Clifford et al., 1998). Based on the limited finished water pH range where POE AA might be effective and the fact that the POU media needs replacing much less frequently due to lower water demand, POE AA has not been listed as a compliance technology in the final rule. POE devices utilizing media that are less sensitive to pH adjustment may be listed as compliance technologies in the future once data on their performance are generated.

The effect of pH was also examined on POU AA. Under the POU AA option, the volume of water requiring treatment is much smaller. The unit will be installed at the kitchen tap and only the water being used for cooking and consumption is being treated for arsenic removal. Since the ratio of the daily volume of water being treated to the size of the unit is much smaller, POU units can be operated for longer periods of time before the media needs to be replaced. The replacement frequency assumed for the costs is every six months. Viable run lengths for the POU option were greater than one year up to pH 8 (Kempic, 2000). This analysis assumed a large daily usage volume of 24 liters per day. The average consumption per person per day is just over 1 liter. Even if competing ions reduced the run length significantly, systems with tap water at or below pH 8 should meet the MCL of 10 μg/L using a six-month replacement frequency for the media. POU AA is a compliance technology when the tap water pH is at or below pH 8.

POU RO was listed as a compliance technology in the proposed rule and it is being listed as a compliance technology in the final rule as well. Several comments indicated that water rejection would be an issue with POU devices. Since only about 1% of the total water used in the household is being treated, POU RO is unlikely to create water quantity problems. If the water rejection rate was 10:1, this would only increase the total household water demand by about 10 percent. Where availability of additional water is limited, systems may want to consider other alternatives to meet the MCL.

In order to be consistent with 1996 SDWA Amendments, EPA issued a **Federal Register** notice on June 11, 1998 (EPA, 1998f) that deleted the prohibition on the use of POU devices as compliance technologies. This prohibition was in 40 CFR 141.101. This section now states that public water systems shall not use bottled water to achieve compliance with an MCL. Bottled water may be used on a temporary basis to avoid unreasonable risk to health. Therefore, bottled water cannot be used as a compliance technology for the arsenic rule.

Likely treatment trains are shown in Table I.G–1. These trains represent a wide variety of solutions, including BATs, that small systems 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. While systems could install lime softening at pH > 10.5 or optimized coagulation/filtration solely for arsenic removal, EPA does not view this as a likely option. Reverse osmosis and electrodialysis reversal are also not included in this table because other options are more cost effective for arsenic removal and do not reject a large volume of water like these two technologies. RO and EDR may be cost-effective options if removal of other contaminants is needed and water quantity is not a concern.

TABLE I.G–1.— TREATMENT TECHNOLOGY TRAINS FOR CONSIDERATION BY SMALL SYSTEMS IN COMPLYING WITH FINAL RULE INCLUDING BATS

Train #	Treatment Technology Trains for Consideration by Small Systems
1	Add pre-oxidation [if not in-place] and modify in-place Lime Softening (pH > 10.5) and modify corrosion control.
2	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration and modify corrosion control.
3	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level ≤ 20 mg/L.
4	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level: 20 mg/L < sulfate ≤ 50 mg/L.
5	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add mechanical dewatering/non-hazardous landfill waste disposal.
6	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add non-mechanical dewatering/non-hazardous landfill waste disposal.
7	Add Oxidation/Filtration (Greensand) (20:1 iron: arsenic) and add POTW for backwash stream.
8	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 7 ≤ pH < pH 8.
9	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 8 ≤ pH ≤ pH 8.3.
10	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 23,100 BV.
11	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 15,400 BV.
12	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
13	Add pre-oxidation [if not in-place] and add POU Activated Alumina. (Finished water pH ≤ pH 8.0)

Pre-oxidation costs are given as a separate component because they will be incurred only by some systems. In estimating national costs, it was assumed that only systems without pre-oxidation in place would need to add the necessary equipment. It is expected that no surface water systems will need to install pre-oxidation for arsenic removal and 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 ascertain if pre-oxidation is necessary by determining if the arsenic is present as As (III) or As (V). Ground water systems with predominantly As (V) will probably not need pre-oxidation to meet the MCL.

2. What are the affordable treatment technologies for small systems?

The 13 treatment trains listed in Table I.G–1 were compared against the national-level affordability criteria to determine the affordable treatment trains. The Agency's national-level affordability criteria were published in the August 6, 1998 **Federal Register** (EPA, 1998h). In this notice, EPA discussed the procedure for affordable treatment technology determinations for the contaminants regulated before 1996.

The preamble to the proposed arsenic rule described the derivation of the national-level affordability criteria (65 FR 38888 at 38926; EPA, 2000i). A very brief summary follows: First an ''affordability threshold'' (*i.e.*, the total annual household water bill that would be considered affordable) was calculated. The total annual water bill includes costs associated with water treatment, water distribution, and operation of the water system. In developing the threshold of 2.5% median household income, EPA considered the percentage of median household income spent by an average household on comparable goods and services and on cost comparisons with other risk reduction activities for drinking water such as households purchasing bottled water or a home treatment device. 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'' (EPA, 1998l).

The Variance Technology Findings document also describes the derivation of the baselines for median household income, annual water bills, and annual household consumption. Data from the Community Water System Survey (CWSS) were used to derive the annual water bills and annual water consumption values for each of the three small system size categories. The Community Water System Survey data on zip codes were used with the 1990 Census data on median household income to develop the median household income values for each of the three small-system size categories. The median household-income values used for the affordable technology determinations are not based on the national median income. The value for each size category is a national median income for communities served by small water systems within that range. Table I.G–2 presents the baseline values for each of the three small-system size categories. Annual water bills and median household income are based on 1995 estimates.

TABLE I.G–2.—BASELINE VALUES FOR SMALL SYSTEMS CATEGORIES

System size category (population served)	Annual household consumption (1000 gallons/yr)	Annual water bills ($/yr)	Median household income ($)
25–500	72	$211	$30,785
501–3,300	74	184	27,058
3,300–10,000	77	181	27,641

For each size category, the threshold value was determined by multiplying the median household income by 2.5%. The annual household water bills were subtracted from this value to obtain the available expenditure margin. Projected treatment costs will be compared against the available expenditure margin to determine if there are affordable compliance technologies for each size category. The available expenditure margin for the three size categories is presented in Table I.G–3.

TABLE I.G–3.—AVAILABLE EXPENDITURE MARGIN FOR AFFORDABLE TECHNOLOGY DETERMINATIONS

System size category (population served)	Available expenditure margin ($/household/year)
25–500	559
501–3,300	492
3,301–10,000	510

The size categories specified in SDWA for affordable technology determinations are different than the size categories typically used by EPA in the Economic Analysis. A weighted average procedure was used to derive design and average flows for the 25–500 category using design and average flows from the 25–100 and 101–500 categories. A similar approach was used to derive design and average flows from the 501–1000 and 1001–3300 categories for the 501–3300 category. The Variance Technology Findings document (EPA, 1998l) describes this procedure in more detail. Table I.G–4 lists the design and average flows for the three size categories.

TABLE I.G–4.— DESIGN AND AVERAGE DAILY FLOWS USED FOR AFFORDABLE TECHNOLOGY DETERMINATIONS

System size category (population served)	Design flow (mgd)	Average flow (mgd)
25–500	0.058	0.015
501–3,300	0.50	0.17
3,301–10,000	1.8	0.70

Capital and operating and maintenance costs were derived for each treatment train using the flows listed previously and the cost equations in the Technology and Cost Document. Several conservative assumptions were made to derive the costs. The influent arsenic concentration was assumed to be 50 µg/L, which was the MCL for arsenic prior to this rule. The treatment target was 8 µg/L, which is 80% of the MCL. Thus, little blending could be performed to reduce costs. Capital costs were amortized using the 7% interest rate preferred by OMB for benefit-cost analyses of government programs and regulations rather than a 3% interest rate.

The annual system treatment cost in dollars per year was converted into a rate increase using the average daily flow. The annual water consumption values listed in Table I.G–2 were multiplied by 1.15 to account for water lost due to leaks. Since the water lost to leaks is not billed, the water bills for the actual water used were adjusted to cover this lost water by increasing the household consumption. The rate increase in dollars per thousand gallons used was multiplied by the adjusted annual consumption to determine the annual cost increase for the household for each treatment train. Several comments on affordability presented household cost increases that were derived by dividing the annual system cost by the number of households. That is an inappropriate method because residential customers would not only be paying for the water that they use, but also all the water used by non-residential customers of the system..

Of the 13 treatment trains in Table I.G–1, the ones identified in Table I.G–5 are deemed to be affordable for systems serving 25–500 people as the annual household cost was below the available expenditure margin. The two trains using coagulation-assisted microfiltration are not affordable for this size category. All 13 treatment trains are deemed to be affordable for systems serving 501–3,300 and 3,301–10,000 people and are presented in Table I.G–6. 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, POU and POE devices are also compliance technology options for the smaller systems.

TABLE I.G–5.— AFFORDABLE COMPLIANCE TECHNOLOGY TRAINS FOR SMALL SYSTEMS WITH POPULATION 25–500

Train No.	Treatment Technology Trains
1	Add pre-oxidation [if not in-place] and modify in-place Lime Softening (pH > 10.5) and modify corrosion control.
2	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration and modify corrosion control.
3	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level ≤ 20 mg/L.
4	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level: 20 mg/L < sulfate ≤ 50 mg/l.
7	Add Oxidation/Filtration (Greensand) (20:1 iron: arsenic) and add POTW for backwash stream.
8	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 7 ≤pH < pH 8.
9	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 8 ≤ pH ≤ pH 8.3.
10	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 23,100 BV.
11	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 15,400 BV.
12	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
13	Add pre-oxidation [if not in-place] and add POU Activated Alumina. (Finished water pH ≤ pH 8.0)

TABLE I.G–6.— AFFORDABLE COMPLIANCE TECHNOLOGY TRAINS FOR SMALL SYSTEMS WITH POPULATIONS 501–3,300 AND 3,301 TO 10,000

Train No.	Treatment Technology Trains
1	Add pre-oxidation [if not in-place] and modify in-place Lime Softening (pH > 10.5) and modify corrosion control.
2	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration and modify corrosion control.
3	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level ≤ 20 mg/L.
4	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level: 20 mg/L < sulfate ≤ 50 mg/l.
5	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add mechanical dewatering/non-hazardous landfill waste disposal.
6	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add non-mechanical dewatering/non-hazardous landfill waste disposal.
7	Add Oxidation/Filtration (Greensand) (20:1 iron: arsenic) and add POTW for backwash stream.
8	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 7 ≤pH < pH 8.
9	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 8 ≤ pH ≤ pH 8.3.
10	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 23,100 BV.
11	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 15,400 BV.
12	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
13	Add pre-oxidation [if not in-place] and add POU Activated Alumina. (Finished water pH ≤ pH 8.0)

3. Can My Water System Get a Small System Variance From an MCL Under Today's Rule?

Section 1415(e)(1) of SDWA allows States to grant variances to small water systems (i.e., systems having 10,000 customers or less) 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. EPA has determined that affordable technologies exist for all three system size categories and has therefore not identified a variance technology for any system size or source water quality combination. Small system variances are not available for the final arsenic MCL.

H. Can My System Get a General Variance or Exemption From the MCL Under Today's Rule?

General variances may be granted in accordance with section 1415(a)(1)(A) of SDWA and EPA's regulations. General variances are available to public water systems that have installed or agree to install the BAT but, due to source water quality, are or will be unable to comply with the national primary drinking water standard. The general variance provisions of SDWA are narrowly focused on addressing those rare circumstances where some unusual characteristic of the source water available to a system will result in less effective performance of the BAT. Exemptions may be granted in accordance with section 1416(a) of SDWA and EPA's regulations. Exemptions are designed to provide a system facing compelling circumstances, such as economic hardship, additional time to come into compliance.

Under section 1415(a)(1)(A) of the SDWA, a State that has primary enforcement responsibility (primacy), or EPA as the primacy agency, may grant variances from MCLs to those public water systems of any size that cannot comply with the MCLs because of characteristics of the water sources. The primacy agency may grant general variances to a system on condition that the system install the best available technology, treatment techniques, or other means, and provided that alternative sources of water are not reasonably available to the system. At the time this type of variance is granted, the State must prescribe a schedule for compliance with its terms and may require the system to implement additional control measures. Furthermore, before EPA or the State may grant a general variance, it must find that the variance will not result in an unreasonable risk to health (URTH) to the public served by the public water system.

Under section 1413(a)(4), States that choose to issue general variances must do so under conditions, and in a manner, that are no less stringent than section 1415. Of course, a State may adopt standards that are more stringent than the EPA's standards. EPA specifies BATs for general variance purposes. EPA may identify as BAT different treatments under section 1415 for variances other than the BAT under section 1412 for MCLs. The BAT findings for section 1415 may vary depending on a number of factors, including the number of persons served by the public water system, physical conditions related to engineering feasibility, and the costs of compliance with MCLs. In this final rule, EPA is not specifying different BAT for variances under section 1415(a).

Under section 1416(a), EPA or a State may exempt a public water system from any requirements related to an MCL or treatment technique of an NPDWR if it finds that: (1) Due to compelling factors (which may include a variety of ''compelling'' factors, including economic factors such as qualification of the PWS as serving a disadvantaged community), the PWS is unable to comply with the requirement or implement measure to develop an alternative source of water supply; (2) the exemption will not result in an URTH; (3) the PWS was in operation on the effective date of the NPWDR, or for a system that was not in operation by that date, only if no reasonable alternative source of drinking water is available to the new system; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress or measures to develop an alternative source of water supply) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(b)(2)(A), the schedule prescribed shall require compliance as expeditiously as practicable (to be determined by the State), but no later than 3 years after the compliance date for the regulations established pursuant to section 1412(b)(10). For public water systems serving 3,300 people or less and needing financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods, but not to exceed a total of six years, if the system establishes that it is taking all practicable steps to meet certain requirements specified in the statute. Thus, the maximum possible duration of a small systems exemption is nine years beyond the 5-year compliance schedule specified in today's rule.

A public water system shall not be granted an exemption unless it can establish that either: (1) The system cannot meet the standard without capital improvements that cannot be completed prior to the date established pursuant to section 1412(b)(10); (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance pursuant to section 1452 or any other Federal or State program; or (3) the system has entered into an enforceable agreement to become part of a regional public water system.

EPA believes that exemptions will be an important tool to help States address the number of systems needing financial assistance to achieve compliance with the arsenic rule (and other rules) with the available supply of financial assistance. About 2,300 CWSs and about 1,100 NTNCWSs will need to install treatment to achieve compliance with today's final rule. CWSs and not-for-profit NTNCWSs are eligible for assistance from the Drinking Water State Revolving Fund (DWSRF). Between its inception in Federal Fiscal Year 1997 and June 2000, the DWSRF program has provided assistance to about 1,100 systems. Given the many competing demands being placed on financial assistance programs, the ability to extend the period of time available for a system to receive financial assistance will provide important flexibility for States and systems. Exemptions provide an opportunity to extend the period of time during which a system can achieve compliance, thus providing needy systems with additional time to qualify for financial assistance. Under today's action, all systems have 5 years to achieve compliance. Exemptions for an additional 3 years can be made available to qualified systems. For those qualified systems serving 3,300 persons or less, up to 3 additional 2-year extensions to the exemption are possible, for a total exemption duration of 9 years. When added to the 5 years provided for compliance by the rule, this allows up to 14 years for small systems serving up to 3,300 people to achieve compliance.

EPA will issue guidance in the near future on considerations involved in granting exemptions under the arsenic rule, including making findings of no URTH where exemptions are offered.

I. What Analytical Methods are Approved for Compliance Monitoring of Arsenic and What are the Performance Testing Criteria for Laboratory Certification?

1. Approved Analytical Methods

Today's rule lists four analytical technologies that are approved for compliance determinations of arsenic at the MCL of 0.01 mg/L (see Table I.I–1). As noted in the June 22, 2000 proposed rule (65 FR 38888, EPA, 2000i), the methods listed in Table I.I–1 are the same analytical technologies that were approved for arsenic when the MCL was 0.05 mg/L, with the exception of the methods that use Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP–AES) measurement technology. EPA is withdrawing two ICP–AES methods (EPA Method 200.7 and SM 3120B) because their detection limits (0.008 mg/L and 0.050 mg/L respectively) are too high to reliably determine compliance with an MCL of 0.01 mg/L. In the June 2000 proposed rule, EPA noted that the ICP–AES methods were rarely used to obtain laboratory certification when analyzing low level challenge samples for arsenic. Therefore, we believe withdrawal of the availability of the ICP–AES methods for compliance determinations of arsenic in drinking water will not affect laboratory capacity. EPA did not receive any adverse comment on the proposal to withdraw approval of these two methods, and today's final rule amends the CFR to effect this withdrawal.

TABLE I.I–1.—APPROVED ANALYTICAL METHODS (40 CFR 141.23) FOR ARSENIC AT THE MCL OF 0.01 MG/L

Methodology	Reference method
Inductively Coupled Plasma Mass Spectroscopy (ICP–MS)	200.8 (EPA)
Stabilized Temperature Platform Graphite Furnace Atomic Absorption (STP–GFAA)	200.9 (EPA)
Graphite Furnace Atomic Absorption (GFAA)	3113B (SM) D–2972–93C (ASTM)
Gaseous Hydride Atomic Absorption (GHAA)	3114B (SM) D–2972–93B (ASTM)

2. Performance Testing Criteria for Laboratory Certification

For purposes of drinking water laboratory certification, the Agency specifies pass/fail (acceptance) limits for a successful analysis of the required annual challenge sample, i.e., a performance evaluation (PE) or performance testing (PT) sample. These acceptance limits have been historically derived using one of two different approaches:

(a) Variable acceptance limits uniquely derived for each PE study from a regression analysis of the performance of all laboratories that participate in that PE-study, or

(b) Fixed acceptance limits derived from a regression analysis of the laboratory PE sample analysis results in several PE studies.

Variable acceptance limits are analogous to ''grading on a curve'' which means that the pass/fail limit can vary from PE study to study depending on the quality and experience of the laboratories participating in the study. These limits are specified in the CFR as plus or minus two sigma (2) where sigma is the standard deviation of the analytical results reported in the PE study. EPA specifies variable acceptance limits when a method or measurement technology is new enough that an insufficient number of experienced laboratories have participated in the PE studies or when only a few PE studies have been conducted.

EPA prefers the fixed acceptance limits approach because it is the better indicator of laboratory performance averaged over time and several different concentrations of the target analyte. Fixed limits also provide the same pass/fail benchmark in each PE study. As discussed in the proposed rule, EPA has a large base of PE-study data from which to derive a practical quantitation limit (PQL) and a fixed PE-study acceptance limit for arsenic. Thus, as proposed in the June 2000 rule, today's final rule amends § 141.23(k)(3)(ii) to specify an acceptance limit of ±30% in PE (now known as PT) samples spiked with arsenic at the PQL of 0.003 mg/L or greater. For a brief discussion of the derivation of the PQL for arsenic, see section III.B.1, What is the feasible level?

J. How Will I Know if My System Meets the Arsenic Standard?

This section summarizes changes to the arsenic monitoring and compliance determination requirements. The Agency is also changing the methods used by a system to determine if it is in violation of an MCL for all of the regulated inorganic contaminants (IOCs), synthetic organic contaminants (SOCs), and volatile organic contaminants (VOCs). See section I.J.3. for more information regarding violation determinations.

1. Sampling Points and Grandfathering of Monitoring Data

In today's rule, the Agency is moving the requirements associated with arsenic into § 141.23(c) making it consistent with the requirements for IOCs regulated under the standardized monitoring framework. All CWS and NTNCWSs must monitor for arsenic at each entry point to the distribution system. In some cases, § 142.11(1) allows States to establish regulations that ''vary from comparable regulations set forth in part 141 of this chapter, and demonstrate that any different State regulation is at least as stringent as the comparable regulation contained in part 141.'' Using this authority, States may allow systems to collect samples at an alternative location (e.g., the first point of drinking water consumption in the distribution system) if the State justifies in its primacy program that the alternative location is equally or more protective. States could implement the change in sampling location once the primacy package is approved.

The MCL compliance elements of the rule become effective in 2006. Some ground water systems will collect samples to comply with the sampling requirements for all regulated IOCs (including arsenic) in 2005 in accordance with the State monitoring plan. This sampling event will satisfy the monitoring requirements for the 2005–2007 compliance period, but the revised arsenic MCL will not become effective until 2006. Ground water systems may use grandfathered data collected after January 1, 2005 to satisfy the sampling requirements for the 2005–2007 compliance period. The grandfathered data must report results from analytical methods approved for use by this final rule (e.g., the method detection limit must be substantially less than the revised MCL of 10 µg/L). Data collected using unacceptably high detection levels (e.g. using ICP–AES technology) will not be eligible for grandfathering. If the grandfathered data are used to comply with the 2005–2007 compliance period and the analytical result is greater than 10 µg/L, that system will be in violation of the revised MCL on the effective date of the rule. If systems do not use grandfathered data, then surface water systems must collect a sample by December 31, 2006 and ground water systems must collect a sample by December 31, 2007 to demonstrate compliance with the revised MCL.

2. Compositing of Samples

Compositing of samples is allowed under the standardized monitoring framework. The States that allow compositing of samples use the methodology in the Phase II/V regulations as specified in § 141.23(a)(4). In today's rule, CWSs and NTNCWSs will still be allowed to composite samples; however, if arsenic is detected above one-fifth of the revised MCL (2 µg/L), then a follow-up sample must be taken within 14 days at each sampling point included in the composite as described in § 141.23(a)(4). Compliance determinations must be based on the follow up sample result. Water systems may composite samples (temporally and spatially) until a contaminant (arsenic or any other contaminant regulated in the Phase II/V regulations) is detected. Once a contaminant has been detected in a composited sample at concentrations greater than one-fifth of the MCL, the system(s) must discontinue the practice of compositing samples for all future monitoring.

3. Calculation of Violations

In today's rule, the Agency is clarifying the compliance determination section for the IOCs (including arsenic), the SOCs, and the VOCs in §§ 141.23(i), 141.24(f)(15), and 141.24(h)(11), respectively.

Systems will determine compliance based on the analytical result(s) obtained at each sampling point. If any sampling point is in violation of an MCL, the system is in violation. For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. Systems monitoring annually or less frequently whose sample result exceeds the MCL for any inorganic contaminant in § 141.23(c), or whose sample results exceeds the trigger level for any organic contaminant listed in § 141.24(f) or § 141.24(h), must revert to quarterly sampling for that contaminant the next quarter. Systems are only required to conduct quarterly monitoring at the entry point to the distribution system at which the sample was collected and for the specific contaminant that triggered the system into the increased monitoring frequency. Systems triggered into increased monitoring will not be considered in violation of the MCL until they have completed one year of quarterly sampling. If any sample result will cause the running annual average to exceed the MCL at any sampling point (i.e., the analytical result is greater than four times the MCL), the system is out of compliance with the MCL immediately. Systems may not monitor more frequently than specified by the State to determine compliance unless they have applied to and obtained approval from the State. If a system does not collect all required samples when compliance is based on a running annual average of quarterly samples, compliance will be based on the running annual average of the samples collected. If a sample result is less than the method detection limit, zero will be used to calculate the annual average. States have the discretion to delete results of obvious sampling or analytic errors.

States still have the flexibility to require confirmation samples for positive or negative results. States may require more than one confirmation sample to determine the average exposure over a 3-month period. Confirmation samples must be averaged with the original analytical result to calculate an average over the 3-month period. The 3-month average must be used as one of the quarterly concentrations for determining the running annual average. The running annual average must be used for compliance determinations.

The rule requires that monitoring be conducted at all entry points to the distribution system. However, the State has discretion to require monitoring and determine compliance based on a case-by-case analysis of individual drinking water systems. The Agency cannot address all of the possible outcomes that may occur at a particular water system; therefore, EPA encourages drinking water systems to inform State regulators of their individual circumstances. Some systems have implemented elaborate plans including targeted, increased monitoring that is more representative of the average annual contaminant concentration to which individuals are being exposed (some States use a time-weighted or flow-weighted averaging approach to determine compliance).

Some States require that systems collect samples from wells that only operate for one month out of the year regardless of whether they are operating during scheduled sampling times. The State may determine compliance based on several factors including, but not limited to, the quantity of water supplied by a source, the duration of service of the source, and contaminant concentration.

4. Monitoring and Compliance Schedule

Systems must begin complying with the clarified monitoring and compliance determination provisions of today's rule effective January 22, 2004 for inorganic, volatile organic, and synthetic organic contaminants. These requirements clarify that for §§ 141.23(i)(2), 141.24(f)(15)(ii), and 141.24(h)(11)(ii) compliance will be determined based on the running annual average of the initial MCL exceedance and any subsequent State-required confirmation samples. In addition, the clarifications address calculation of compliance when a system fails to collect the required number of samples. Compliance (determined by the average concentration) will be based on the total number of samples collected. Some systems have purposely not collected the required number of quarterly samples and only incurred monitoring and reporting violations for the uncollected samples. Any systems that avoid required sampling will calculate MCL violations by dividing the summed samples by the actual number of samples taken. This clarification did not change §§ 141.23(i)(1) and 141.24(h)(11)(i) which allow systems to use zero for all non-detects when calculating MCL violations. In addition, if any one sample would cause the annual average to be exceeded, the system is out of compliance immediately.

Also in today's rule, the Agency is moving the arsenic monitoring and compliance requirements from §§ 141.23(l) to (q) to the standardized monitoring framework in § 141.23 for other IOCs. States may grant systems nine-year monitoring waivers using the conditions in § 141.23(c) for arsenic. The criteria for developing a State waiver program were published in the Phase II/V rules, and as noted in section IV.B. of this rule, the Agency is not modifying the waiver criteria in today's rulemaking. However, the revised arsenic rule is not effective until January 23, 2006 (see section I.M. for a more detailed discussion regarding the effective date of the rule.). States and utilities supported moving arsenic into the standardized monitoring framework.

To use compliance data after the effective date of the 10 µg/L MCL, systems must use an approved method with a method detection limit substantially less than the revised arsenic MCL of 10 µg/L. This means that after December 31, 2006 and December 31, 2007 all surface water systems and groundwater systems, respectively, may not use analytical methods using the ICP–AES technology, because the detection limits for these methods are 8 µg/L or higher. This restriction means that two ICP–AES methods that were approved when the MCL was 50 µg/L may not be used for compliance determinations at the revised MCL of 10 µg/L. The two methods are EPA Method 200.7 and SM 3120B. Prior to 2005, systems may have compliance samples analyzed with these less sensitive methods. However, EPA advises systems to have compliance samples analyzed and reported at the laboratory minimum detection limit.

If sampling demonstrates that arsenic exceeds the MCL, a CWS will be triggered into quarterly monitoring for that sampling point ''in the next quarter after the violation occurred.'' 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 two consecutive ground water, or four consecutive surface water samples, have been collected (§ 141.23(c)(8)).

The Agency is not promulgating a reduced monitoring approach similar to the revised radionuclides final rule published on December 7, 2000 (65 FR 76708; EPA, 2000p). As noted above, all systems have to collect IOC samples once a year or once every three years, depending on the source water, unless they have a waiver. The Agency believes that very few States issue waivers for IOCs because the analysis is relatively inexpensive and most IOCs are naturally occurring elements that may be found in concentrations above the method detection limit. Therefore, the majority of systems must collect routine samples for the regulated IOCs; and most of the methods used for analysis of these contaminants will measure arsenic as well as antimony, beryllium, cadmium, chromium, copper, and nickel.

K. What do I Need to tell My Customers?

1. Consumer Confidence Reports

a. General requirements. In 1998, EPA promulgated the Consumer Confidence Report Rule (CCR) (codified at 40 CFR part 141, subpart O), a final rule requiring community water systems to issue annual water quality reports to their customers (63 FR 44512; EPA, 1998i). The reports are due each year by July 1, and provide a snapshot of water quality over the preceding calendar year. The reports include information on levels of detected contaminants and if the system has violated an MCL or a treatment technique, must also include information on the potential health effects of contaminants from appendix A to subpart O. When they have such violations, systems must also include in their report an explanation of the violation and remedial measures taken to address it. The arsenic health effects language is currently required when arsenic levels exceed 25 µg/L, one-half the existing MCL of 50 µg/L, required under § 141.154(b).

EPA is today retaining the health effects language for arsenic issued with the final CCR Rule and updating appendix A to subpart O to include the MCL and MCLG as revised in this rule, together with special arsenic-specific reporting requirements.

In addition to the standard reporting of arsenic detects and arsenic MCL violations, EPA is today finalizing a requirement (proposed at § 141.154(b); finalized at § 141.154(f)) that CWSs that detect arsenic between the revised and existing MCL (i.e., above 10 µg/L and up to and including 50 µg/L) prior to the effective date for compliance with the revised MCL, include the CCR Rule health effects language in their reports. This action is required even though, technically, the systems are not in violation of the regulations. This requirement will be effective for the five years after promulgation, when systems are not yet required to comply with the revised MCL. Then, beginning January 23, 2006, systems out of compliance must report violations of the revised arsenic MCL under § 141.153(d)(6) to the public.

Based on stakeholder and commenter input, the Agency decided in the final CCR Rule that it would use authority granted in SDWA section 1414(c)(4)(B)(vi) to require inclusion of health effects language for arsenic exceedances before the compliance date. That section allows the Administrator to require inclusion of health effects language for ''not more than three regulated contaminants'' other than those found to violate an MCL. The Agency used this authority for total trihalomethanes in the Stage 1 Disinfectants and Disinfection Byproducts Rule (63 FR 69390). The Agency is now using this same authority for arsenic, because it believes that it is important to provide customers with the most current understanding of the risk presented by this contaminant as soon as possible after establishing a new standard. This provision provides systems the flexibility to put this health effects information into context and to explain to customers that the system is complying with existing standards.

EPA modified the language it proposed on June 22, 2000 to reflect the MCL promulgated today and to clarify what language a system must include in its report. Systems subject to § 141.154(f) must begin including the arsenic health effects language in the report due by July 1, 2002.

b. Special informational statement. In addition, in the CCR Rule, the Agency decided to require that CCRs include additional information about certain contaminants, one of which was arsenic. As explained in the preamble to the CCR Rule (63 FR 44512 at 44514; EPA, 1998i), because of commenters' concerns about the adequacy of the current MCL, EPA decided that systems that detect arsenic between 25 µg/L and the current MCL must include some information regarding the arsenic standard (§ 141.154(b)). This informational statement is different from the health effects language required for an MCL violation. EPA noted in the CCR rule and in the arsenic proposal that the informational statement requirement would be deleted upon promulgation of a revised MCL.

In view of the fact that EPA is today finalizing an MCL somewhat higher than the technologically feasible MCL, and that some commenters expressed concern about the risk that a higher-than-feasible MCL might present to certain consumers, EPA is today retaining and revising an existing § 141.154(b) requirement that systems which find arsenic below the MCL must provide additional information to their customers. EPA believes that consumers should be aware of the uncertainties surrounding the risks presented even by very low levels of arsenic. While EPA addressed many of the sources of uncertainty in its risk analysis of arsenic in support of the final rule, several sources of uncertainty remain. Chief among these is the mode of action (i.e., the shape of the dose-response curve). EPA continues to research the effects of arsenic (according to an arsenic research plan required by the 1996 SDWA Amendments and submitted to Congress) and should have a better understanding of these effects as the relevant research is completed. EPA believes that this uncertainty adequately justifies retaining the existing requirement to provide consumers with information about low levels of arsenic.

The existing § 141.154(b) requirement is today updated in two ways. First, the arsenic level that triggers the additional information is reset from 25 µg/L (half the existing MCL) to 5 µg/L (half the revised MCL). In the preamble to the CCR Rule, we explained that ''[many] commenters agreed that half the MCL would be an appropriate threshold for requiring additional risk-related information.'' EPA continues to believe that half the MCL is an appropriate trigger for special information about certain contaminants. Beginning with the report due by July 1, 2002, CWSs that find arsenic above 5 µg/L and up to and including 10 µg/L must include § 141.154(b) special health information about arsenic in their consumer confidence reports.

Second, the suggested text of the special information is updated. Rather than stating that ''EPA is reviewing the drinking water standard for arsenic . . .,'' the statement announces clearly that the consumer's water meets EPA's new standard while also noting the cost-benefit trade-off involved in setting that standard. The suggested text further notes that there are uncertainties (described in section III.F of this notice) surrounding the risks of low levels of arsenic. Systems retain the flexibility, as defined in the existing requirement, to adjust this language in consultation with the Primacy Agency.

2. Public Notification

On May 4, 2000, EPA issued the final Public Notification Rule (PNR) to revise the minimum requirements that public water systems must meet for public notification of violations of EPA's drinking water standards (65 FR 25982; EPA, 2000e). Water systems must begin to comply with the revised 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 drinking water regulation on arsenic affects public notification requirements and amends the PNR as part of its rulemaking.

Today's final rule will require CWSs and NTNCWSs 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. The new arsenic MCL will become effective January 23, 2006. CWSs and NTNCWSs must provide public notification to consumers for any violations after the effective date of the revised arsenic MCL. The PNR requires owners and operators of public water systems to give notice to persons they serve for all violations when they are operating under a variance or exemption (or violate conditions of the variance or exemption).

L. What Financial Assistance is Available for Complying With This Rule?

There are two major sources of Federal financial assistance available for water systems: the Drinking Water State Revolving Fund (DWSRF) and the Water and Waste Disposal Loan and Grant Program of the Rural Utilities Service (RUS) of the U. S. Department of Agriculture.

The 1996 SDWA Amendments authorized (*i.e.*, approved spending) $9.6 billion for the DWSRF program. To date, Congress has appropriated (*i.e.*, provided) $4.2 billion, which includes $825 million for the program in Fiscal Year 2001. By the end of September 2000, States had been awarded $3.2 billion in capitalization grants and, from that, had provided more than $2.8 billion in assistance to eligible drinking water systems. The Federal capitalization grant, together with State matching funds, is currently making available about $1 billion per year. States have considerable discretion in designing their DWSRF program, and have the option of offering special assistance to systems that the State considers to be disadvantaged. Special assistance may include principal forgiveness, a negative interest rate, an interest rate lower than that charged to non-disadvantaged systems, and extended repayment periods of up to 30 years. Federal law allows DWSRF assistance to be provided to water systems of both public ownership and private ownership, although some States are unable or choose not to provide assistance to privately owned systems.

EPA recognizes that public water systems and States face a significant challenge in implementing new requirements that are needed to ensure the continued provision of safe drinking water. While the DWSRF program is proving to be a significant source of funding, it cannot be viewed as the only source of funding. It will take a concerted effort on the part of Federal, State and local governments, private business, and utilities to address the significant infrastructure needs identified by public water systems. In order to ensure that the DWSRF program is used to focus attention on the highest priority needs, all States must give priority to those drinking water infrastructure improvement projects that will have the greatest public health benefit or ensure compliance with SDWA. State DWSRF programs are currently making loans available to the highest ranked projects on their lists and are also using a portion of the grants to support other important drinking water program activities.

The RUS program is focused on providing a safe, reliable water supply and wastewater treatment to residents of rural America. The program offers a combination of low interest loans and grants to systems serving rural areas and cities and towns of up to 10,000 persons and which are publicly owned (including Native American systems) or operated as not-for-profit corporations. In recent years the RUS program has typically offered assistance totaling about $1.3 billion per year, about 60% of which is directed to drinking water projects. Thus, about $780 million per year is available for rural drinking water systems from this program. Together with the approximately $1 billion per year being made available through the DWSRF, this results in a total of about $1.78 billion per year of Federal financial assistance available for drinking water.

Other Federal financial assistance programs exist that may help systems with SDWA compliance related expenditures. However, these other programs are not generally as large or focused on drinking water as are the DWSRF and RUS programs. EPA's Environmental Financial Advisory Board has developed a ''Guidebook of Financial Tools'' (EPA, 1999c), which offers a comprehensive summary of public and private programs and mechanisms for paying for drinking water and other environmental systems. The handbook is available through EPA's web site at: *http://www.epa.gov/efinpage/guidbk98/index.htm*.

The Federal financial assistance programs described previously clearly face numerous, competing demands on their resources. EPA's 1995 Drinking Water Infrastructure Needs Survey (EPA, 1997a) identified a total 20-year need for all systems of $138.4 billion. The single largest category of need (accounting for over half of the total need) is installation and rehabilitation of transmission and distribution systems. Treatment needs constitute the second largest category of need, accounting for over ¼ of total needs. Storage and source rehabilitation and development constitute the remaining major categories of needs. Thus, systems seeking financial assistance for installation of arsenic treatment are competing for resources with systems seeking assistance for compliance with other rules and with systems seeking resources for basic infrastructure repair and replacement. In seeking to meet these numerous and competing needs, the Agency recognizes the importance of priority setting for financial assistance programs. Systems having the financial capability to secure funding through the capital markets should do so, leaving the Federal financial assistance programs to assist the truly needy systems. Since the demand for assistance will likely outstrip the supply of assistance, States may wish to consider exemptions, which will provide additional time for systems to secure financial assistance.

M. What is the Effective Date and Compliance Date for the Rule?

In the proposed rule, EPA made a finding that all small systems (*i.e.*, systems serving 10,000 people or less) would be granted a 2-year capital improvement extension which extends the MCL effective date for purposes of compliance with the new MCL to January 23, 2006. EPA proposed the 2-year capital improvement extension for small systems because of the time required for systems to plan, finance, design and construct new treatment systems.

Large systems were not provided this additional time because of the greater resources these systems have to perform capital improvements in a timely manner. However, upon consideration of information submitted by commenters, EPA has determined that large systems will also require an additional 2 years to complete the capital improvements necessary to comply with the arsenic MCL. While large systems (*i.e.*, systems serving more than 10,000 people) do have greater resources to implement capital improvements, (*e.g.*, engineering and construction management staff to manage the projects), these systems generally also have more entry points to the distribution system that will require treatment.

A number of treatment technologies are listed as BAT for the proposed rule: ion exchange, activated alumina, reverse osmosis, modified coagulation/filtration, modified lime softening and electrodialysis reversal. There are also several emerging technologies for arsenic removal, such as nanofiltration and granular ferric hydroxide. To ensure cost effective compliance with the arsenic MCL, systems will need to evaluate their treatment technology options as a first step. This planning step may include pilot studies with potential treatment systems, or it may be limited to an evaluation of the raw water characteristics. Systems choosing to conduct pilot testing may take a year or more to contract with vendors and to perform pilot testing.

Once the planning step is completed systems must design and construct the treatment systems. Design and permitting of the treatment systems can take an additional year, and construction of the treatment system can take another year. Because systems will also need time to: obtain funding, obtain local government approval of the project, or acquire the land necessary to construct these technologies, it is likely that most large systems will need additional time beyond the three-year effective date for compliance with the new MCL that EPA proposed.

Based upon these considerations, EPA determined, in accordance with section 1412(b)(10) of SDWA, that the compliance date for the new arsenic MCL, regardless of system size, will be 5 years from the date of promulgation of the standard. See section I.H. for more information regarding variance and exemptions.

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

EPA met extensively with a broad range of groups during the development of the arsenic proposal, both at EPA-sponsored meetings and at other organizations' meetings. The **Federal Register** published notices about EPA's arsenic meetings, and we made conference call lines available for those who chose not to attend in person. In addition, EPA notified people about regulatory actions via the three **Federal Register** notices (proposal, notice of data availability, and correction notice), by mail and e-mail. Over 600 people asked to be on the mailing list during the regulatory development period.

EPA held arsenic stakeholders meetings September 11–12, 1997 in Washington, DC; February 25, 1998 in San Antonio, Texas; May 5, 1998 in Monterey, California; June 2–3, 1999 in Washington, DC; and August 9, 2000 in Reno, Nevada. For each of these meetings we invited representatives of States, tribal groups, associations, utilities and environmental groups. The docket for the proposed rule (W–99–16) contains the meeting discussion papers, agendas, participants lists, presentation materials, and executive meeting summaries. All the meeting materials, except the presentations and attendance list, are also available on EPA's arsenic in drinking water web page, *www.epa.gov/safewater/arsenic.html.*

EPA also presented sessions on drinking water regulations (including arsenic) at the National Indian Health Board Annual Conference in Anchorage, Alaska in September 1998. The Inter-tribal Council of Arizona hosted a consultation for EPA with Tribes February 24–25, 1999 in Las Vegas, NV at which an overview of the proposed arsenic regulation was presented. EPA also conducted a series of workshops at the Annual Conference of the National Tribal Environmental Council May 18–20, 1999 in Eureka, California. The Council distributed materials and gathered comments on EPA's drinking water regulations from all recognized Tribal governments.

In addition to the general stakeholder meetings, EPA also had targeted meetings with States' representatives. In May 1999, State regulatory representatives from California, Nevada, Michigan, Illinois, Texas, Indiana, New Mexico, and Louisiana joined EPA in a discussion on the development of the cost of compliance decision tree. In August 1999, State regulatory representatives from Illinois, Indiana, New Mexico, and Texas joined EPA workgroup members in a discussion of the NRC study use, review of the occurrence work, treatment technology update, and regulatory changes. The interaction from these meetings with State colleagues improved the regulatory language and the preamble.

In May 2000, EPA presented a summary of the rule to the National Governors' Association. In May 2000, EPA held a dialogue in Washington, DC with State officials and the associations that represent elected officials. Presentations on arsenic and other drinking water rules under development were given to representatives of the National Association of Towns and Townships, National Governors' Association, National Association of Counties, National League of Cities, Association of State Drinking Water Administrators, Environmental Council of the States, Florida Department of Environmental Protection, Drinking Water Section, Association of State and Territorial Health Officials, and the International City/County Management. The purpose of the dialogue was to consult on the expected compliance and implementation costs of these rules for State, county, and local governments and gain a better understanding of the views of representatives of State, county, and local governments and their elected officials. The meeting materials are in the docket for the proposed rule.

In addition to the various special meetings and discussions mentioned previously, EPA representatives delivered arsenic regulatory development presentations at a variety of meetings held by other organizations. These included the American Water Works Association (AWWA) Inorganic Contaminants Meetings in February, 1998 in San Antonio, TX and in February, 2000 in Albuquerque, NM; meetings of the Association of State Drinking Water Administrators (ASDWA) in February and October 1998, March and October 1999, and in October 2000; meetings of the Association of Metropolitan Water Agencies (AMWA) in January and March 1998; and a meeting of the Association of California Water Agencies in March 1998. EPA also gave several technical presentations and regulatory updates at the AWWA annual meetings as well as at the AWWA Water Quality and Technology Conferences in 1998, 1999, and 2000. EPA participated in the Society of Toxicology arsenic workshop in Philadelphia, PA in March 2000. Finally, EPA co-sponsored and participated in the four International Conferences on Arsenic Exposure and Health Effects in July 1993, June 1995, July 1998, and June 2000.

After the proposal was published in the **Federal Register**, EPA notified all persons on its electronic mailing list for the arsenic rule of its availability and sent information. The Regulatory Impact Analysis went on the arsenic web page a week after the proposal publication. Similarly, EPA also notified the individuals and organizations on this mailing list about the NODA and the correction notice.

II. Statutory Authority

Section 1401 of SDWA requires a ‘‘primary drinking water regulation’’ to specify a MCL if it is economically and technically feasible to measure the contaminant and to include testing procedures to insure compliance with the MCL and proper operation and maintenance. An 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 must also list affordable technologies that achieve compliance with the MCL or treatment technique for three categories of small systems: those serving 10,000 to 3301 persons, 3300 to 501 persons, and 500 to 25 persons. EPA can list modular (packaged) and POE and POU 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 NAS, other Federal agencies, and interested public and private entities. The amendments allowed EPA to enter into cooperative agreements for research. On October 27, 2000, Public Law 106–377, the bill which included Fiscal Year 2001 appropriations for EPA, amended the statutory deadline to direct EPA to promulgate a final arsenic standard by no later than June 22, 2001.

Section 1412(a)(3) requires EPA to propose an MCLG simultaneously with the NPDWR. 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 NPDWR will specify an 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. As required by the statute, EPA issued a HRRCA for arsenic (EPA, 2000i) as section XIII of the June 22, 2000 arsenic proposal (65 FR 38888 at 38957).

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 this obligation, EPA must specify, among other things,

> peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data (section1412(b)(3)(B)(v)).

Section 1413(a)(1) allows EPA to grant States primary enforcement responsibility (primacy) 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 granted. 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 an NPDWR has primacy enforcement authority for the new regulation while EPA action on the revision is pending (section 1413(c)). Section 1451(a) allows EPA to grant primacy enforcement responsibility to Federally recognized Indian Tribes, providing grant and contract assistance, using the procedures applied to States.

III. Rationales for Regulatory Decisions

A. What Is the MCLG?

The proposed rule suggested that an MCLG of zero be established for arsenic in view of the fact that we are currently unable to specify a safe threshold level due to uncertainty about the mode of action for arsenic. Today's rule establishes a final MCLG for arsenic of zero. After full consideration of public comments, EPA continues to believe that the most scientifically valid approach, given the lack of critical data, is to use the linear approach to assessing the mode of action. This approach results in an MCLG of zero. In the proposal and the NODA, EPA noted that the available data point to several potential carcinogenic modes of action for arsenic (EPA also requested additional data on the mode of action). However, which mode(s) of action is operative is unknown. For this reason, while the Agency recognizes that the dose-response relationship may be sublinear, the data do not provide any basis upon which EPA could reasonably construct this relationship. Thus, EPA has no basis upon which to depart from its assumption of linearity. The NRC report noted that available data that could help determine the shape of the dose-response curve are inconclusive and do not meet EPA's stated criteria for departure from the default assumption of linearity (NRC, 1999). See section III.D.1 for a thorough discussion of the dose-response assessment.

Because the postulated mode of action for arsenic cannot specifically be described and the key events are unknown, the Agency lacks sufficient available, peer-reviewed information to estimate quantitatively a non-linear mode of action. The Agency has thus decided not to depart from the assumption of linearity in selecting an MCLG of zero.

B. What Is the Feasible Level?

1. Analytical Measurement Feasibility

In the development of a drinking water regulation, EPA derives a practical quantitation limit (PQL) to estimate or evaluate the minimum, reliable quantitation level (concentration) that most laboratories can be expected to meet during day-to-day operations. The PQL accounts for the limits of current measurement technologies and the laboratories that use the methods written around these analytical technologies. The PQL was defined in a November 13, 1985 rule (50 FR 46906, EPA, 1985b) as ''the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions.'' A PQL is determined either through use of interlaboratory studies or, in absence of sufficient studies, through the use of a multiplier of 5 to 10 times the method detection limit (MDL). Interlaboratory data are obtained from water supply (WS) studies that are conducted by EPA to certify drinking water laboratories. The WS studies require a candidate laboratory to measure the concentration of the target analyte within specified limits (e.g., ±30%) of the amount spiked into a PE (now called PT) challenge sample. Using graphical or linear regression analysis of the WS data, the Agency sets a PQL at a concentration where at least 75% of experienced laboratories (generally EPA and State laboratories) could perform within this acceptable limit for accuracy, e.g., ±30%.

As discussed in the June 22, 2000 proposed rule for arsenic, the Agency determined that the PQL (i.e., the feasible level of measurement) for arsenic in drinking water is 0.003 mg/L with an acceptance limit of ±30%. The derivation of the PQL for arsenic is consistent with the process used to determine PQLs for other metal contaminants regulated under SDWA and takes into consideration the recommendations from EPA's SAB (EPA, 1995). Using acceptance limits of ±30% and linear regression analysis of six recent WS studies, EPA derived a PQL of 0.00258 mg/L for arsenic, which was rounded to 0.003 mg/L at the ±30%. While the PQL represents a relatively stringent target for laboratory performance, based on the WS data used to derive the PQL for arsenic, the Agency believes most laboratories (using appropriate quality assurance and quality control procedures) can achieve this level on a routine basis.

2. Treatment Feasibility

EPA has determined that 3 μg/L is technologically feasible for large systems based on peer-reviewed treatment information. EPA has listed seven BATs for arsenic in the final rule. They are: ion exchange when sulfate ≤50 mg/L, activated alumina, reverse osmosis, modified coagulation/filtration, modified lime softening at pH >10.5, electrodialysis reversal, and oxidation/filtration when the iron to arsenic ratio is at least 20:1. Bench, pilot and full-scale data were examined to determine the capabilities of the treatment processes. The treatment performance data are summarized in ''Technologies and Costs for the Removal of Arsenic from Drinking Water'' (EPA, 2000t).

C. How Did EPA Revise its National Occurrence Estimates?

1. Summary of Occurrence Data and Methodology

Our data and methodology for estimating arsenic occurrence are substantially the same as in the proposed rule (65 FR 38888 at 38903; EPA, 2000i). The data and methodology are described in detail in (EPA, 2000r). Following is a summary of our method. All of the elements of this summary are the same as in the proposed rule, except where noted.

Our occurrence database consists of arsenic compliance monitoring samples of finished drinking water, submitted voluntarily by drinking water agencies in 25 States. The 25 States are distributed throughout the U.S., with at least one located in each of the seven geographic regions that we used in our analysis (65 FR 38888 at 38906; EPA, 2000i; EPA, 2000r). In some States we used data only from a subset of years in which detection limits were lowest. For each PWS in our database, we estimated the mean arsenic concentration over time in finished water, by first ''filling in'' non-detected concentrations, using one of two statistical methods (EPA, 2000r), then averaging the detected and filled-in observations from that system. Next, we collected the system mean estimates into State distributions, then merged the State distributions into regional and then national distributions. In combining the regional distributions into a national distribution, we weighted each region by the total number of systems in the region, not just the number of systems in the States in our database. This procedure has the same effect as assigning the regional distributions to the 25 States for which we have no observations in our database.

In addition to the distributions of system means, we estimated nationwide intra-system coefficients of variation (ISCV). For a given water system, the ISCV quantifies the variation of mean arsenic levels at the system's entry points to the distribution system (i.e., sampling points of individual wells and treatment points) around the overall system mean. We estimated a separate ISCV for each ground water (gw) CWS, surface water (sw) CWS, and, unlike in the proposed rule, ground water NTNCWS. Each of these ISCVs is assumed to be constant throughout the U.S.

2. Corrections and Additions to the Data

Some public commenters asked whether our data might have errors in the classification of water samples as treated or untreated. If that were the case, then including untreated samples in our database could cause us to overestimate occurrence in finished water. In order to determine whether and to what extent these problems exist, we solicited additional data sets from drinking water agencies in six States (Alabama, California, Illinois, New Mexico, North Carolina, and Texas) from whom we already had data in our draft data set. All six States responded to our request by submitting additional data, including additional identifiers of untreated observations, as well as some new observations not contained in our draft data base. In California, once the newly identified untreated observations were removed from the data set, the number of surface water observations decreased from 2,488 in the draft data set to 1,280 in the final data set. For ground water, on the other hand, the number of samples in California increased from 5,622 to 9,494. The increase resulted in part from the additional data, and in part because we changed our methodology, as we describe below, to include samples from both treated and untreated ground water in our ground water estimates. Changes in the other five States were of smaller size.

We also updated our data set from Utah. The latest data from Utah include more observations and covers the years 1980 to 1999. The total number of observations from Utah in our data set increased from 2,447 to 4,684.

Table III.C–1 compares the number of observations, systems, and States in our database, by system type and source water type, in the proposed and final rules. Note that our complete database is larger than shown in Table III.C–1, but in some States we excluded data from some years in which analytical detection limits were highest. Table III.C–1 counts only the data from the years that we used to estimate occurrence.

TABLE III.C–1.—SUMMARY OF OCCURRENCE DATABASES FOR THE PROPOSED AND FINAL RULES

System type	Source water	Proposed rule			Final rule		
		# of observations	# of systems	# of States	# of observations	# of systems	# of States
CWS	GW	44,502	15,640	25	53,307	15,931	25
CWS	SW	15,892	2,360	25	16,212	2,228	25
NTNCWS	GW	*6,420	*4,662	*18	7,045	4,382	17
NTNCWS	SW	*420	*150	*14	*409	*118	*15
All	All	67,234	22,812	25	76,973	22,659	25

*Data not used in estimating occurrence.

We also updated our baseline inventory of the public water systems in the U.S. and the populations they serve, by type of system, type of source water, and State. We use this inventory to estimate the numbers of systems and people affected by different MCL options, by multiplying the number of people or systems in a given category by the estimated fraction of systems in that category with mean arsenic greater than the levels of interest. In the proposed rule, the occurrence and regulatory impact analyses used different sets of baseline estimates: occurrence took baseline estimates from EPA's 4th quarter 1997 Safe Drinking Water Information System (SDWIS) database, while the proposal's regulatory impact analysis (RIA) used 4th quarter 1998 SDWIS. The result, as some public commenters pointed out, was that the proposed rule contained two inconsistent sets of estimates of the numbers of people and systems affected by different MCL options (65 FR 38888; EPA, 2000i, Table V–3; EPA, 2000h, Exhibit 4–11). The two estimates of total numbers of systems affected at various MCLs differed by up to 27%. We corrected this inconsistency by adopting, with one modification, the baseline inventory in EPA's Drinking Water Baseline Handbook (EPA, 2000b) throughout this preamble and all supporting documents for the final rule. The inventory in the Baseline Handbook is taken from EPA's 4th quarter 1998 SDWIS database, or the same that was used in the proposed RIA. The only modification we made to the inventory was in Alaska where the Baseline Handbook lists zero NTNCWS and zero population served by NTNCWS. Following public comment from the Alaska Department of Environmental Conservation, we corrected the inventory of NTNCWS in Alaska. The Baseline Handbook and corrected Alaska inventories are shown in Table III.C–2.

TABLE III.C–2.—ALASKA PWS INVENTORIES: BASELINE HANDBOOK AND CORRECTED

System type	Source water	Baseline handbook		Corrected	
		No. of systems	Population served	No. of systems	Population served
CWS	GW	508	227,874	344	175,367
CWS	SW	160	317,155	121	260,792
NTNCWS	GW	0	0	161	51,909
NTNCWS	SW	0	0	35	56,013
All	All	668	545,029	661	544,081

The revised estimates of numbers of systems affected at different arsenic concentrations are shown in Table III.C–6. Since the proposed and final Economic Analysis use the same set of baseline estimates (except for the small correction in Alaska), changes in Table III.C–6 compared to the proposed RIA (EPA, 2000h, Exhibit 4–11) are due to changes in the occurrence estimates in Table III.C–3, which follows. Changes in Table III.C–6 compared to the proposed occurrence analysis (65 FR 38888; EPA, 2000i, Table V–3) are due to changes in occurrence estimates and also correction of the baseline.

3. Changes to the Methodology

In September 1999, EPA sponsored a peer review of our occurrence data and methodology by three independent experts in geochemistry and statistics. In response to that review and public comments, we have made minor revisions to our methodology for estimating occurrence in two ways since the proposed rule.

First, we now estimate the occurrence distribution for ground water NTNCWSs separately from CWSs. In the proposed rule, we used the CWSs distribution as a surrogate for NTNCWSs, for both ground and surface water systems. We now estimate occurrence in ground water NTNCWSs separately, using the same method as for CWSs, as described previously. For ground water NTNCWSs we have data from 17 States, compared to 25 States for CWSs, so there are on average fewer States with data in each region. Moreover we have no data about NTNCWSs from any States in the Southeast region (Alabama, Florida, Georgia, Mississippi, and Tennessee). We therefore used the occurrence distribution for ground water CWSs as a surrogate for ground water NTNCWSs in the Southeast. The revised occurrence estimates for ground water NTNCWSs are shown in Table III.C–3.

We still do not estimate a separate occurrence distribution for surface water NTNCWSs. For surface water NTNCWSs, we did not believe that the 118 systems for which data were provided for NTNCWSs formed as strong a basis for estimating occurrence as the much larger CWS surface water data base, especially in the concentration range of interest. In addition, there is less reason to believe that surface water NTNCWSs will differ from surface water CWSs. We thus believe the surface water CWS estimates provide the soundest basis for estimating impacts given the types of data available.

Second, we have improved our method for estimating intra-system variability. In the proposed rule, we estimated the ISCV by measuring the total amount of variability of arsenic concentrations around the system mean within each system. The problem with that approach is that it fails to distinguish between-source variability (variability of sampling-point means around the system mean) from within-source variability (variability of observations at each sampling point around the sampling-point mean). Within-source variability includes variations in concentrations through time at a source, and analytical variability caused by imprecision of the analytical methods used to measure arsenic in water samples. The ISCV is intended to describe only between-source variability within a system. Following the recommendations of the peer review, we corrected our model of intra-system variation to include separate terms for between-source and within-source variability. As a result, our estimates of the ISCVs decreased, since we separate out the within-source variability. The revised ISCV estimates are shown in Table III.C–7.

A third change to our methodology is that, for ground water systems, we now include observations on both treated and untreated ground water in our analysis. With the exception of iron removal technologies, most treatment in ground water systems has little effect on arsenic, so one might expect arsenic concentrations to be similar in treated and untreated samples. This turns out to be the case in our data: estimates that included untreated samples were either slightly higher or lower than estimates with only treated samples. We therefore decided to include both treated and untreated samples in our ground water occurrence estimates. For surface water estimates, we still use only samples from treated water.

4. Revised Occurrence Results

Table III.C–3 shows our revised estimates of the national distribution of arsenic occurrence, by system type and source water type. The distributions are stated in terms of ‘‘exceedance probabilities,’’ that is, the fraction of systems with mean arsenic equal to or greater than the given concentration, in finished water. The ‘‘weighted point estimate’’ is the combination of State distributions into a national distribution, as described previously. We consider the weighted point estimate to be our best estimate. The ‘‘lognormal fit’’ is the result of fitting a lognormal distribution to the weighted point estimates. The lognormal fit is an approximation to the weighted point estimate, which we use in our cost and benefit analyses (sections III.E and III.F). The lognormal approximation simplifies the simulation studies that we use to derive costs and benefits, by allowing each distribution to be summarized in terms of only two parameters. Table III.C–4 lists the parameters of the fitted lognormal distributions.

TABLE III.C–3.—NATIONAL OCCURRENCE EXCEEDANCE PROBABILITY ESTIMATES

	Percent of systems with mean finished arsenic exceeding concentrations (µg/L) of:				
	3	5	10	20	50
Ground Water CWS					
Weighted point estimate	19.9	12.1	5.3	2.0	0.43
95% confidence interval [1]	[19.3,21.9]	[11.7,13.0]	[5.2,5.9]	[1.9,2.3]	[0.38,0.52]
Lognormal fit	19.7	12.0	5.3	2.0	0.43
Surface Water CWS					
Weighted point estimate	5.6	3.0	0.80	0.32	0.10
95% confidence interval [1]	[4.8,20.6]	[1.8,9.7]	[0.52,1.6]	[0.13,0.82]	[0.02,0.59]
Lognormal fit	5.6	3.0	1.1	0.37	0.067
Ground Water NTNCWS					
Weighted point estimate	24.2	15.6	5.3	2.1	0.47
95% confidence interval [1]					
Lognormal fit	23.4	14.2	6.1	2.2	0.42

[1] Brackets indicate confidence intervals which were computed for the proposed rule and have not been updated. No confidence intervals were computed for NTNCWS.

TABLE III.C–4.—PARAMETERS OF LOGNORMAL DISTRIBUTIONS FITTED TO NATIONAL OCCURRENCE DISTRIBUTIONS

System type	Source water	Log-mean [1]	Log-SD [2]
CWS	GW	−0.25	1.58
CWS	SW	−1.68	1.74
NTNCWS	GW	0.03	1.47

[1] Log-mean = mean of natural logarithm of arsenic concentrations (µg/L).

[2] Log-SD = standard deviation of natural logarithm of arsenic concentrations (µg/L).

Table III.C–3 lists separate distribution estimates for ground and surface water CWS and for ground water NTNCWSs. As we said previously, we believe surface water CWSs provide a more sound basis for estimation.

For CWSs, the estimates in Table III.C–3 have changed only slightly since the proposed rule. For ground water CWSs, the largest change is an increase at 10 µg/L from 5.3% exceedance to 5.4%. For surface water CWSs, the largest change is a decrease at 3 µg/L from 6.0% in the proposed rule to 5.6% in Table III.C–3. This decrease is as expected, since, as we explained previously, our revised database excludes some observations on untreated water that were included in the draft database. Our surface water occurrence estimates did increase slightly at 5 µg/L, however, as Table III.C–8 shows.

For ground water NTNCWSs, our estimated exceedance probabilities increased from 19.9% to 24.2% at 3 µg/L, and from 12.1% to 15.6% at 5 µg/L. The estimates at higher concentrations changed by at most 0.1% point. The estimates changed because we now estimate a separate distribution for ground water NTNCWSs, as we described previously.

The confidence intervals listed in Table III.C–3 were computed for the proposed rule, using a computationally intensive resampling procedure, as described in (EPA, 2000r). Since our data set and point estimates have changed only minimally for the final rule, we did not recompute the confidence intervals.

Table III.C–5 shows occurrence distributions in seven geographic regions presented in the proposal and developed by Frey and Edwards (1997). (The States and names of these geographic regions in Table III.C–5 are based directly on the authors' designations.) As in the proposed rule, we find concentrations to be generally highest in the West, and generally lowest in the Southeast and Mid-Atlantic. In regions where analytical reporting limits in our database were mostly higher than 3 µg/L or 5 µg/L, we did not attempt to estimate occurrence at the lowest concentrations. These cases are indicated by dashes in Table III.C–5. In some regions, we were able to estimate occurrence in fewer States at the lowest concentrations, and this sometimes led to inconsistencies in our estimates. For example, for New England surface water CWSs, we estimated occurrence at 3 µg/L using only Maine, and at 5 µg/L using Maine, New Hampshire, and New Jersey. The introduction of more States at higher concentrations led to inconsistent estimates of 6.2% and 11.7% of New England surface water CWSs with arsenic exceeding 3 µg/L and 5 µg/L, respectively. We did not try to resolve these inconsistencies at the regional level, but note that the national occurrence distributions, listed in Table III.C–3, are consistent.

TABLE III.C–5.—REGIONAL OCCURRENCE EXCEEDANCE PROBABILITY ESTIMATES

	Percent of systems with mean finished arsenic exceeding concentrations (µg/L) of:			
	3	5	10	20
Ground Water CWS				
Mid-Atlantic	(2)	*0.4	0.7	0.0
Midwest	21.2	13.8	6.2	2.4
New England	21.7	20.8	7.0	2.9
North Central	21.3	13.1	6.0	2.4
South Central	18.6	9.7	3.6	1.1
Southeast	0.9	0.4	0.1	0.0
West	31.5	25.2	12.5	5.0
Surface Water CWS				
Mid-Atlantic	(2)	0.1	0.0	0.0
Midwest	3.0	1.6	0.7	0.3
New England	[1] 6.2	11.7	1.0	0.4
North Central	9.1	3.2	0.6	0.1
South Central	3.8	0.9	0.2	0.1
Southeast	0.2	0.1	0.0	0.0
West	12.7	8.2	3.4	1.4
Ground Water NTNCWS				
Mid-Atlantic	(2)	(2)	1.4	0.5
Midwest	26.2	17.1	8.2	3.3
New England	(2)	(2)	2.1	0.6
North Central	29.8	22.8	15.0	9.3
South Central	24.0	14.4	5.9	1.9
Southeast	0.9	0.4	0.1	0.0
West	34.3	21.9	10.5	4.2

[1] Estimate is inconsistent with estimate at the next higher concentration. See text for explanation.

[2] Means not enough data to form an estimate. See text for explanation.

Table III.C–6 shows our estimates of the numbers of systems with mean finished arsenic concentrations in various ranges, by system type and size. As in the proposed rule, we find no evidence of any consistent difference in mean arsenic among systems of different sizes. We conclude that the occurrence distributions shown in Table III.C–3 apply to all categories of system size. In Table III.C–6, therefore, the estimated numbers of systems are computed by multiplying the baseline inventory of all systems of the given size and type, by the corresponding probability of falling within the given range, computed from Table III.C–3 and shown in the ''% of systems'' rows. The estimates for surface water NTNCWSs were computed by applying the occurrence distribution for surface water CWSs to the baseline inventory of surface water NTNCWSs.

TABLE III.C–6.—STATISTICAL ESTIMATES OF NUMBERS OF SYSTEMS WITH AVERAGE FINISHED ARSENIC CONCENTRATIONS IN VARIOUS RANGES

System size (population served)	Number of systems with mean arsenic concentration (µg/L) in the range of:			
	>3 to 5	>5 to 10	>10 to 20	>20
Ground Water CWS				
25 to 500	2,272	1,980	961	584
501 to 3,300	811	706	343	208
3,301 to 10,000	192	167	81	49
10,001 to 50,000	95	83	40	24
>50,000	15	13	6	4
All	3,384	2,949	1,432	870
% of systems	7.8%	6.8%	3.3%	2.0%
Surface Water CWS				
25 to 500	76	68	14	10
501 to 3,300	92	81	17	12
3,301 to 10,000	47	41	9	6
10,001 to 50,000	41	36	8	5
>50,000	15	13	3	2
All	270	239	51	34
% of systems	2.5%	2.2%	0.5%	0.3%
Ground Water NTNCWS				
25 to 500	1,440	1,713	545	348
501 to 3,300	230	274	87	56
3,301 to 10,000	5	6	2	1
10,001 to 50,000	1	1	0	0
>50,000	0	0	0	0
All	1,677	1,995	635	405
% of systems	8.6%	10.3%	3.3%	2.1%
Surface Water NTNCWS				
25 to 500	14	13	3	2
501 to 3,300	5	4	1	1
3,301 to 10,000	1	1	0	0
10,001 to 50,000	0	0	0	0
>50,000	0	0	0	0
All	20	17	4	2
% of systems	2.5%	2.2%	0.5%	0.3%

Numbers do not add up to totals in some cases due to rounding.

Our proposed and final estimates of intra-system coefficients of variation are shown in Table III.C–7. The revised estimates are lower, since, as we described previously, we now better separate out within-source (time and analytical) variability from the variability of source means within a system. The ISCV estimate for ground water NTNCWSs also has changed because we now estimate it separately from that of ground water CWSs.

TABLE III.C–7.—ESTIMATED INTRA-SYSTEM COEFFICIENTS OF VARIATION (ISCV)

System type	Source water	Proposed rule	Final rule	
		ISCV (percent)	ISCV (percent)	95% confidence interval
CWS	GW	62.9	37.1	[33.1,40.8]
CWS	SW	68.4	52.6	[31.4,69.6]
NTNCWS	GW	62.9	25.2	[9.6,34.7]

Table III.C–8 compares our proposed and final national occurrence estimates to estimates from three other studies: the National Arsenic Occurrence Survey (NAOS) (Frey and Edwards, 1997), National Inorganics and Radionuclides Survey (NIRS) (Wade Miller Associates, 1992), and U.S. Geological Survey (USGS) (USGS, 2000). All of the studies in Table III.C–8 evaluated drinking water except for USGS, which evaluated ambient ground water, some of which came from non-drinking water sources. Wade Miller used surface water estimates from the 1978 Community Water System Survey, which we consider now to be out of date, so those estimates are not shown. Note that Frey and Edwards (1997) found significantly different occurrence distributions for small and large systems, so the NAOS estimates are reported separately for small and large systems. The NAOS included samples from all 50 States, but it was a much smaller study (468 samples, compared to about 77,000 in our database), and it analyzed unfinished water samples. Frey and Edwards (1997) applied estimated efficiencies for the treatments known to be in place at the sampling locations, to predict the concentrations in finished water.

TABLE III.C–8.—COMPARISON OF NATIONAL ARSENIC OCCURRENCE ESTIMATES

Study	Type of water	System types	Population served	% of systems with mean arsenic exceeding concentrations (µg/L) of:				
				2	3	5	10	20
Ground Water Systems								
EPA-proposed	raw + finished	CWS	all	27.2	19.9	12.1	5.4	2.1
EPA-final	raw + finished	CWS	all	27.3	19.9	12.1	5.3	2.0
NAOS-small	finished[1]	PWS	≤10,000	23.5	NR	12.7	5.1	NR
NAOS-large	finished[1]	PWS	>10,000	28.8	NR	15.4	6.7	NR
NIRS	finished	CWS	all	17.4	11.9	6.9	2.9	1.1
USGS	raw	PWS	all	25.0	NR	13.6	7.6	3.1
Surface Water Systems								
EPA-proposed	finished	CWS	all	9.9	6.0	2.9	0.8	0.3
EPA-final	finished	CWS	all	9.8	5.6	3.0	0.8	0.3
NAOS-small	finished[1]	PWS	≤10,000	6.2	NR	1.8	0.0	NR
NAOS-large	finished[1]	PWS	>10,000	7.5	NR	1.3	0.6	NR

NR = not reported.

[1] Predicted from raw water, using estimated efficiency of treatment in place.

Table III.C–8 shows that our proposed and final occurrence estimates are only slightly different, with the possible exception of surface water occurrence estimates at 3 µg/L, where our estimate decreased from 6.0% to 5.6% exceedance for the final rule. The difference is explained by the identification and exclusion of samples of untreated water from our database for the final rule, as we described previously. For ground water, our estimates fall within the range reported in the other three studies. For surface water, our estimates are somewhat higher than those of the NAOS.

D. How Did EPA Revise its Risk Analysis?

1. Health Risk Analysis

a. Toxic forms of arsenic. Humans are exposed to many forms of arsenic that have different toxicities. 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). Little is known about the various arsenic species in vegetables, grains, and oils (NRC, 1999). Arsenite (+3) and arsenate (+5) are the most prevalent toxic forms of inorganic arsenic found in drinking water. In general, the inorganic forms of arsenic have been considered to be more toxic than the organic forms. In toxicity tests, the inorganic forms were reported to be more toxic than the organic forms (NAS, 1977) and the trivalent form was more toxic than the pentavalent one (Szinicz and Forth, 1988).

In animals and humans, inorganic pentavalent arsenic is converted to trivalent arsenic that is methylated (*i.e.,* chemically bonded to a methyl group, which is a carbon atom linked to three hydrogen atoms) to monomethyl arsenic (MMA) and dimethyl arsinic acid (DMA), which are organic arsenicals. The primary route of excretion for these four forms of arsenic is in the urine. The organic arsenicals MMA and DMA were once thought to be much less toxic than inorganic arsenicals. 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). However, recent work has shown that the assumption that organic forms that arise during the metabolism of inorganic arsenic are less toxic than inorganic forms may not be correct (Aposhian *et al.,* 2000; Petrick *et al.,* 2000). One reason for this was that earlier toxicity tests were conducted using pentavalent MMA and DMA because it was believed that trivalent MMA(III) and DMA(III) were too transient to be found in urine. Recently, MMA(III) was isolated in human urine (Aposhian *et al.,* 2000). Tests have demonstrated that MMA(III) is more toxic to hepatocytes (*i.e.,* liver cells) that inorganic trivalent arsenic (Petrick *et al.,* 2000; Styblo *et al.,* 2000). These reports indicate that the metabolism of inorganic arsenic is not necessarily a detoxification process. As yet, it is not known which form of arsenic participates in the key events within cells that disrupt cell growth control and initiate or influence tumor formation. The SAB noted that ''[i]t is not possible to consider contributions of different forms of arsenic to the overall response based on the data that are available today'' (EPA, 2000q).

b. 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_{50} of arsenic has been estimated to range from 1 to 4 mg arsenic per kilogram (kg) of body weight (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 U.S. public water supplies in compliance with the current MCL of 50 μg/L. EPA's drinking water regulation addresses the long-term, chronic effects of exposure to low concentrations of inorganic arsenic in drinking water.

c. Non-cancer effects associated with arsenic. A large number of adverse noncarcinogenic effects has 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 (NRC, 1999, pg. 131). They include alterations in pigmentation and the development of keratoses that 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; NRC, 1999).

Chronic exposure to inorganic arsenic is often associated with alterations in gastrointestinal(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 standardized mortality ratios (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. 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 another study in the U.S. (Engel *et al.,* 1994), in Taiwan (Wu *et al.,* 1989) and in 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.

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 <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; Hopenhayn-Rich *et al.*, 2000). After reviewing the available literature on arsenic and reproductive effects, the NRC (1999) wrote that "nothing conclusive can be stated from these studies." Regarding the Hopenhayn-Rich study, the majority of the SAB panel (EPA, 2000q) concluded that while:

> it is generally reasonable to consider that children are generally at greater risk for a toxic response to any agent in water because of their greater drinking water consumption (on a unit-body weight basis), [the SAB does not] believe that this study demonstrates such a heightened sensitivity or susceptibility to arsenic.

The EPA agrees with this conclusion.

d. Cancers 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 hundreds of 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 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 (human studies) 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.

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 (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 administered physical examinations to the study group of over 40,000 residents from 37 villages, as well as to a reference group of 7500 residents reported to be exposed to a median level of 0 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 arsenic per liter (mg/L) 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. In both the EPA 1988 report on skin cancer and the 1999 NRC report, it was noted that grouping individuals into broad exposure groups (rather than grouping into village exposures) limited the usefulness of these studies for quantitative dose-response estimation. 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 (EPA, 1984).

Internal cancers. Exposure to inorganic arsenic in drinking water has also been associated with the development of internal cancers. Chen *et al.* (1985) used 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 prostrate 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 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. The best U.S. study currently available is that of Lewis *et al.* (1999) who conducted a mortality study of a population in Utah whose drinking water contained relatively low concentrations of arsenic. 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 median (mid-point in range) community exposure concentrations of 14 to 166 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. 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.

Tsai *et al.* (1999) estimated SMRs 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. 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 *et al.* (1999) population study had high arsenic content. 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 *et al.* (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.

A small cohort study in Japan of persons exposed to arsenic in drinking water provides evidence of the association of cancer and arsenic among persons exposed for 5 years to 1000 μg/L or more and followed for 33 years after cessation of exposure. The strongest association was for lung and bladder cancer, similar to results in studies in Taiwan and South America (Tsuda *et al.*, 1995).

Kurttio *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 bladder cancer when exposure occurred two to nine years prior to diagnosis. Arsenic exposure occurring greater than 10 years prior to diagnosis was not associated with bladder cancer risk. This raises a question about the significance of the finding about exposures two to nine years since one would expect earlier exposure to have had an effect given the Tsuda *et al.* (1995) study summarized previously.

The two internal cancers consistently seen and best characterized in epidemiologic studies are those of lung and bladder. EPA considers the studies summarized before as confirmation of its long-standing view that arsenic is a known human carcinogen. This rule relies on assessment of lung and bladder cancers for its quantitative risk estimates in support of the MCL. EPA recognizes that other internal cancers as well as skin cancer are important.

Nonetheless, some issues with other cancer endpoints led to their being considered qualitatively rather than quantitatively. EPA has considered skin and liver cancer qualitatively for the following reasons: (1) The skin cancer endpoint is difficult to analyze because, in the U.S., it is considered curable; and (2) the liver cancer endpoint is likely to have been influenced in Taiwan by the prevalence there of viral hepatitis which is a factor in liver cancer.

How does arsenic cause cancer? EPA sponsored an ''Expert Panel on Arsenic Carcinogenicity: Review and Workshop'' in May 1997 (EPA, 1997e). 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 deoxyribonucleic acid (DNA) adducts (*i.e.*, bound to DNA) nor caused point mutations. Thus, indications are that the mode of action does not involve direct reaction with DNA. 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 that suggests interference with DNA repair or cell control instead of direct DNA damage.

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 (*i.e.*, reduced animal fats in the diet would underestimate risk). 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 (EPA, 1997e, 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 (EPA, 1997e, page 31). On the other hand, basing risk estimates on one or two tumor sites may underestimate risk as compared to summing risks for all related health endpoints.

There is much research underway about the mode of action for arsenic. In order to understand the shape of the dose-response relationship in the range of exposure typical of the U.S., that is significantly below the range of observation of epidemiologic studies, one needs to identify which one or more of the possible modes of action is operative. If this can be elucidated, it will become possible to study and quantify the key events within cells that influence cell growth control and how they may quantitatively relate to eventual tumor incidence. Until then the shape of the dose-response relationship and whether there is any threshold cannot be known.

f. What is the quantitative relationship between exposure and cancer effects that may be projected for exposures in the U.S.? The Agency chose to make its quantitative estimates of risk based on the Chen *et al.* (1988; 1992) and Wu *et al.* (1989) Taiwan studies. This choice was endorsed by the NRC and EPA's SAB (EPA, 2000q; NRC, 1999). The database from Taiwan has the following advantages: mortality data were drawn from a cancer registry; arsenic well water concentrations were measured for each of the 42 villages; there was a large, relatively stable study population that had life-time exposures to arsenic; there are limited measured data for the food intake of arsenic in this population; age- and dose-dependent responses with respect to arsenic in the drinking water were demonstrated; the collection of pathology data was unusually thorough; and the populations were quite homogeneous in terms of lifestyle.

EPA recognizes that there are problems with the Taiwan study that introduce uncertainties to the risk analysis such as: the use of median exposure data at the village level; the low income and relatively poor diet of the Taiwanese study population (high levels of carbohydrates, low levels of protein, selenium and other essential nutrients); and high exposure to arsenic via food and cooking water. These are discussed more thoroughly in the following paragraphs. The available studies from Taiwan are ecological studies and have exposure uncertainties that are recognized. Ecological studies are problematic as bases for quantitative risk assessment. Errors in assigning persons to exposures are difficult to avoid. Moreover, all confounding factors that may have contributed to risk may not be adequately accounted for. These uncertainties have to be remembered since they lead to uncertainty in the quantitative dose-response relationship estimated in the observed range of data and in any extrapolation to estimate the potential risk at exposures significantly below the observed range. There is not a way to take all confounding factors into account quantitatively. (see section III.F.)

Notwithstanding these concerns, the Taiwan 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 do not respond to inorganic arsenic exposure in a way that makes them useful as a model for human cancer assessment. Their metabolism of inorganic arsenic is also quantitatively different than humans.

There are issues with the extrapolation of the dose-response from the observed range of exposure in Taiwan to estimate Taiwan cancer risk below the observed data range and application of the same risk estimate to U.S. populations. The following issues have been addressed:

- The Taiwan population ingested more arsenic in food and via cooking with contaminated water than is typical for the U.S. population. This is because the staples of the Taiwan diet were rice and sweet potatoes. Rice and sweet potatoes are high in arsenic and both staples absorb water upon cooking. EPA did a sensitivity analysis of the effect of exposure to arsenic through water used in preparing food in Taiwan. EPA also analyzed the effect of exposure to arsenic through food.
- The Taiwan data on exposure were uncertain because the association of individuals with contaminated wells was made by grouping persons in a village and assuming they had a lifetime of exposure to the median of the concentration of arsenic measured in the wells serving that village. Wells within each village had varying arsenic levels so that people using certain wells had much higher exposures than others in the same village. Not all wells serving all villages were measured. However, all villagers were assigned a single median

concentration for exposure. In addition, moves made from village to village were not accounted for. When villages with only one arsenic measurement were removed from the data set (on the theory that the exposure data were too uncertain), or when village means instead of medians were used for the exposure estimates, there was no statistically significant change in the estimated point of departure, using Model 1 of Morales et al. (2000).

- The Taiwan population was a rural population that was not well nourished, having deficits of selenium, possibly methionine or choline (methyl donors), zinc and other essential nutrients. This malnourishment is not typical of the U.S. population, although some U.S. populations may have one or another of the same deficits. The Taiwanese population may also have some genetic differences from the general U.S. population. These issues cannot be quantitatively accounted for. However, deficits in selenium in the diet, in particular, are a known risk factor for cancer and indicate possible overestimation of risk when the Taiwan data are applied. EPA has qualitatively taken this into account. (See section III.F.)
- The Utah study (Lewis et al., 1999) did not find any excess bladder or lung cancer risk after exposure to arsenic at concentrations of 14 to 166 μg/L. An important feature of the study is that it estimated excess risk by comparing cancer rates among the study population, in Millard County, Utah to background rates in all of Utah. But the cancer rates observed among the study population, even those who consumed the highest levels of arsenic, were lower, in many cases significantly lower, than in all of Utah. This is evidence that there are important differences between the study and comparison populations besides their consumption of arsenic. One such difference is that Millard County is mostly rural, while Utah as a whole contains some large urban populations. Another difference is that the subjects of the Utah study were all members of the Church of Jesus Christ of Latter Day Saints, who for religious reasons have relatively low rates of tobacco and alcohol use. For these reasons, the Agency believes that the comparison of the study population to all of Utah is not appropriate for estimating excess risks. An alternative method of analysis is to compare cancer rates only among people within the study population who had high and low exposures. The Agency performed such an analysis on the Utah data, using the statistical technique of Cox proportional hazard regression (US EPA, 2000x; Cox and Oakes, 1984). The results showed no detectable increased risk of lung or bladder cancers due to arsenic, even among subjects exposed to more than 100 μg/L on average. On the other hand, the excess risk could also not be distinguished statistically from the levels predicted by model 1 of Morales et al. (2000). What these results show is that the Utah study is not powerful enough to estimate excess risks with enough precision to be useful for the Agency's arsenic risk analysis. Furthermore, the SAB noted that "(a)lthough the data provided in published results of the Lewis, et al., 1999 study imply that there was no excess bladder or lung cancer in this population, the data are not in a form that allows dose-response to be assessed dependably" (EPA, 2000q). The indications of Lewis et al. study have been taken into account in the judgments of the impact of scientific uncertainties on the final MCL.

g. Is it appropriate to assume linearity for the dose-response assessment for arsenic at low doses given that arsenic is not directly reactive with DNA? Independent scientific panels (EPA, 2000q; NRC, 1999; EPA, 1997e; EPA, 1988) who have considered the Taiwan study have raised the caution that using the Taiwan study to estimate U.S. risk at lower levels may result in an overly conservative estimation of U.S. risk. The independent panels have each said that below the observed range of the high level of contamination in Taiwan the shape of the dose-response relationship may prove to be sublinear when there is adequate data to characterize the mode of action. If so, an assumption that the effects seen per dose increment remain the same from high to low levels of dose may overstate the U.S. risk. In evaluating the benefits of alternative MCLs, EPA weighed both the qualitative and quantitative uncertainties about risk magnitude (see section III.F.)

The use of a linear procedure to extrapolate from a higher, observed data range to a lower range beyond observation is a science policy approach that has been in use by Federal agencies for four decades. Its basis is both science and policy. The policy objectives are to avoid underestimating risk in order to protect public health and be consistent and clear across risk assessments. The science components include its applicability to generally available data sets (animal tests and human studies) and its basis in the fact that cancer is a consequence of genetic changes coupled with the assumption that direct reaction with DNA is a basic mode of action for chemicals causing important genetic changes (Cogliano et al., eds., 1999).

The linear approach is intended to identify a level of risk that is an upper limit on what the risk might be. There are two biological situations in which the linear approach can be a particularly uncertain estimate of risk. One is when the metabolism and toxicokinetics of the agent being assessed cause a nonlinear relationship between the dose of the active form and the dose of the applied form of the agent. If this is not quantitatively dealt with in the dose part of the dose-response estimation, the linear extrapolation will have added uncertainties. In the case of arsenic, it is known that metabolism and toxicokinetics are complex, but the active form(s) is not known. The resulting complexities of estimating dose cannot, therefore, be accounted for in dose-response modeling.

The other situation is when the mode of action of the agent is indirect; that is, when there is not a one-to-one reaction between the active form of the agent and DNA, but, instead, the active form affects other cell components or processes that, in turn, causes genetic change. In such cases, the rates of these secondary processes are limiting, not the dose of the active form. With few exceptions, the rates of these secondary processes are thought not to be a linear function of applied dose. In the case of arsenic, it is known that arsenic does cause genetic changes in short-term tests, but these are indirect genetic changes (not one-to-one reactions between arsenic and DNA).

If there are both complex toxicokinetics and secondary effects, the upper-limit risk estimate from the linear approach provides may be overly conservative. However, there simply are not sufficient data to quantify the effect of these two features of arsenic on risk. While some commenters assert that the Agency can simply use models that have sublinear structures to address the issue of secondary nature of effects, the Agency does not agree. There are no data on the effects of arsenic that may be precursors to cancer. Without such biological data, the exercise of blindly applying models has no anchor, in EPA's judgment. Such modeled extrapolations could take numerous shapes and there is no way to decide how shallow or steep the curve would be or where on the dose gradient the zero risk level might be, given the hundreds of possibilities. There are also certain modes of action that do not involve DNA reactivity, but are thought to be linear in dose response, such as effects on growth-control signals within cells. Since we do not know what the mode of action of arsenic is, we cannot in fact rule out linearity. Therefore, in accordance with the 1986 cancer guidelines, and subsequent guidance discussed later, the Agency cannot reasonably use anything other than a linear mode of action to estimate the upper bound of risk associated with arsenic exposure. Nevertheless, the uncertainties about both of these facets (the toxicokinetics and secondary effects) of risk estimation have been taken into account qualitatively in the Agency's final decision as a perspective on the linear dose-response estimation (see section III.F.).

The Agency considered mode-of-action information as a basis for departing from the assumption of linearity and in the process, developed a framework for judging the adequacy of mode of action data (EPA, 1996a). This framework has been reviewed and supported by the SAB (EPA, 1997f; EPA, 1999g). The framework was applied to the assessment of chloroform (EPA, 2000d).

In order to decide whether a particular mode of action is operative for an agent, the database on mode of action must be rich and able to both describe the sequence of key events in the putative mode of action and demonstrate it experimentally. The elements of the framework analysis include:

- Summary description of postulated mode of action (the postulated sequence of cellular/physiological events leading to cancer must be described.)
- Identification of key events (the specific events that are key to carcinogenesis must described in order to be experimentally examined.)
- Strength, consistency, specificity of association (the experimental observation of the key events and their relationship to tumor development must be described.)
- Dose-response relationship (the dose-response relationship between the key events and tumor incidence must be described and evaluated.)
- Temporal relationship (the key events must be shown to precede tumor development.)
- Biological plausibility and coherence (the postulated mode of action and the data must be in accord with general, accepted scientific evidence about the causes of cancer.)
- Other modes of action (alternative modes of action that are suggested must be examined and their contribution, if any, described.)
- Conclusion (an overall conclusion is made as to whether the postulated mode of action is accurate given the results of evaluation of the evidence under the previous elements.)
- Human relevance, including subpopulations (if the evidence of mode of action of carcinogenicity is from animal studies, its human relevance is examined.)

In the case of chloroform, there was sufficient information to describe key events and undertake mode of action analysis. In the case of arsenic, the postulated mode of action cannot be specifically described, the key events are unknown, and no analysis of the remaining elements of the mode of action framework can be made. Several possible influences of arsenic on the carcinogenic process have been postulated, but there are insufficient experimental data either to show that any one of the possible modes is the influence actually at work or to test the dimensions of its influence as the framework requires.

For chloroform there are extensive data on metabolism that identify the likely active metabolite. The key events—cell toxicity followed by sustained cell proliferation and eventually tumor effects—have been extensively studied in many experiments. The key events have been empirically demonstrated to precede and consistently be associated with tumor effects. In sum, a very large number of studies have satisfied the requirements of the framework analysis. By contrast, the arsenic database fails to even be able to satisfy the first element of the framework; the key events are unknown. While there are a number of possible modes of action implied by existing data, none of them has been sufficiently studied to be analyzed under the Agency's framework. For this reason the comparison of the ''best available, peer reviewed data'' for arsenic and chloroform shows quite different results. There are not sufficient data on arsenic to describe a mode of action as there were for chloroform. This was also the conclusion of the SAB review of arsenic (EPA, 2000q).

Overall, the NRC and SAB reports agreed that the best available science provides no alternative to use of a linear dose-response process for arsenic because a specific mode (or modes) of action has not been identified. Unlike chloroform, the Agency lacks sufficient available, peer-reviewed information on arsenic to estimate quantitatively a non-linear mode of action. The Agency thus has decided not to depart from the assumption of linearity in selecting an MCLG of zero.

2. Risk factors/bases for upper- and lower-bound analyses

EPA calculated upper- and lower-bound risk estimates for the U.S. population exposed to arsenic concentrations. The approach for this analysis included five components. First, we developed relative exposure factor distributions, which incorporate data from the recent EPA water consumption study with age, sex, and weight data. Second, the Agency calculated the arsenic occurrence distributions for the population exposed to arsenic levels above 3 μg/L. Third, we chose risk distributions for bladder and lung cancer for the analysis from Morales et al. (2000). Fourth, EPA developed estimates of the projected bladder and lung cancer risks faced by exposed populations using Monte-Carlo simulations, bringing together the relative exposure factor, occurrence, and risk distributions. These simulations resulted in upper bound estimates of the risks faced by U.S. populations exposed to arsenic concentrations at or above 3 μg/L in their drinking water. Finally, EPA made adjustments to the lower-bound risk estimates to reflect exposure to arsenic in cooking water and in food in Taiwan. A more detailed description of the risk methodology is provided in Appendix B of the Economic Analysis (EPA, 2000o).

a. Water consumption. EPA recently updated its estimates of per capita daily average water consumption (EPA, 2000c). 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, multi-stage area probability sample of the entire U.S. and is conducted to survey the food and beverage intake of the U.S. 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 the 90th percentile of daily average per capita consumption of total water is 2.3 liters/person/day. In other words, current consumption data indicate that 90% of the U.S. population consumes approximately 2 liters/person/day, or less.

Water consumption estimates for selected subpopulations in the U.S. are described in the CSFII, 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 and sex were used in the computation of the relative exposure factors discussed later.

b. Relative Exposure Factors. Lifetime male and female relative exposure factors (REFs) for each of the broad age categories used in the water consumption study were calculated, where the life-long REFs indicate the sensitivity of exposure to an individual relative to the sensitivity of exposure of an ''average'' person weighing 70 kilograms and consuming 2 liters of water per day, a ''high end'' water consumption estimate according to the EPA water consumption study referred to previously (EPA, 2000c). In these calculations, EPA combined the water consumption data with data on population weight from the 1994 Statistical Abstract of the U.S. Distributions for both community tap water and total water consumption were used because the community tap water estimates may underestimate actual tap water consumption. The weight data included a mean and a distribution of weight for male and females on a year-to-year basis. The means and standard deviations of the life-long REFs derived from this analysis are shown in Table III.D–1.

TABLE III.D–1.—LIFE-LONG RELATIVE EXPOSURE FACTORS

	Community water consumption data	Total water consumption data
Male	Mean = 0.60 s.d. = 0.61	Mean = 0.73 s.d. = 0.62
Female	Mean = 0.64 s.d. = 0.6	Mean = 0.79 s.d. = 0.61

c. Arsenic occurrence. EPA recently updated its estimates of arsenic occurrence, and calculated separate occurrence distributions for arsenic found in ground water and surface water systems. These occurrence distributions were calculated for systems with arsenic concentrations of 3 µg/L or above. Arsenic occurrence estimates are described in more detail in section III.C.

d. Risk distributions. 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 had comparable risks to those ''in Taiwan at comparable levels of exposure'' (NRC, 1999). The NRC also examined the implications of applying different statistical analyses to the newly available Taiwanese data for the purpose of characterizing bladder cancer risk. 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 the June 22, 2000 proposed rule, EPA calculated bladder cancer risks and benefits using the bladder cancer risk analysis from the NRC report (NRC, 1999). We also estimated lung cancer benefits in a ''What If'' analysis based on the statement in the 1999 NRC report 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).

In July, 2000, a peer reviewed article by Morales *et al.* (2000) was published, which presented additional analyses of bladder cancer risks as well as estimates of lung and liver cancer risks for the same Taiwanese population analyzed in the NRC report. EPA summarized and analyzed the new information from the Morales *et al.* (2000) article in a NODA published on October 20, 2000 (65 FR 63027; EPA, 2000m). Although the data used were the same as used by the NRC to analyze bladder cancer risk in their 1999 publication, Morales *et al.* (2000) considered more dose-response models and evaluated how well they fit the Taiwanese data for both bladder cancer risk and lung cancer risk. Ten risk models were presented in Morales *et al.* (2000) used with and without one of two comparison populations. After consultation with the primary authors (Morales and Ryan), EPA chose Model 1 with no comparison population for further analysis.

EPA believes that the models in Morales *et al.* (2000) without a comparison population are more reliable than those with a comparison population. Models with no comparison population estimate the arsenic dose-response curve only from the study population. Models with a comparison population include mortality data from a similar population (in this case either all of Taiwan or part of southwestern Taiwan) with low arsenic exposure. Most of the models with comparison populations resulted in dose-response curves that were supralinear (higher than a linear dose response) at low doses. The curves were ''forced down'' near zero dose because the comparison population consists of a large number of people with low risk and low exposure. EPA believes, based on discussions with the authors of Morales *et al.* (2000), that models with a comparison population are less reliable, for two reasons. First, there is no basis in data on arsenic's carcinogenic mode of action to support a supralinear curve as being biologically plausible. To the contrary, the conclusion of the NRC panel (NRC, 1999) was that the mode of action data led one to expect dose responses that would be either linear or less than linear at low dose. However, the NRC indicated that available data are inconclusive and '' * * * do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity.'' (NRC, 1999)

Second, models that include comparison populations assume that the study and comparison populations are the same in all important respects except for arsenic exposure. Yet Morales *et al.* (2000) agree that ''[t]here is reason to believe that the urban Taiwanese population is not a comparable population for the poor rural population used in this study.'' Moreover, because of the large amount of data in the comparison populations, the model results are sensitive to assumptions about this group. Evidence that supports these arguments are that the risks in the comparison groups are substantially lower than in similarly exposed members of the study group and the shape of the estimated dose-response changes sharply as a result. For these reasons, EPA believes that the models without comparison populations are more reliable than those with them. Of the models that did not include a comparison population, EPA believes that Model 1 best fits the data, based on the Akaike Information Criterion (AIC), a standard criterion of model fit, applied to Poisson models. In Model 1, the relative risk of mortality at any time is assumed to increase exponentially with a linear function of dose and a quadratic function of age.

Morales *et al.* (2000) reported that two other models without comparison populations also fit the Taiwan data well: Model 2, another Poisson model with a nonparametric instead of quadratic age effect, and a multi-stage Weibull (MSW) model. Under Model 2, the points of departure for male and female bladder and lung cancer are from 1% to 11% lower than under Model 1, but within the 95% confidence bounds from Model 1. Model 2 therefore implies essentially the same bladder and lung cancer risks as Model 1. Under the MSW model, compared to Model 1, points of departure are 45% to 60% higher for bladder cancer and for female lung cancer, and 38% lower for male lung cancer. EPA did not consider the MSW model for further analysis, because this model is more sensitive to the omission of individual villages (Morales *et al.*, 2000) and to the grouping of responses by village (NRC, 1999), as occurs in the Taiwanese data. However, if the MSW model were correct, it would imply a 14% lower combined risk of lung and bladder cancers than Model 1, among males and females combined.

Considering all of these results, the Agency decided that the more exhaustive statistical analysis of the data provided by Morales *et al.* (2000), as analyzed by EPA, would be the basis for the new risk calculations for the final rule (with further consideration of additional risk analyses) and other pertinent information. The Agency views the results of the alternative models described above as an additional uncertainty which was considered in the decision concerning the selection of the final MCL (see section III.F. of today's preamble).

e. Estimated risk reductions. Estimated risk reductions for bladder and lung cancer at various MCL levels were developed using Monte-Carlo simulations. Monte-Carlo analysis is a technique for analyzing problems where there are a large number of combinations of input values which makes it impossible to calculate every possible result. A random number generator is used to select input values from pre-defined distributions. For each set of random numbers, a single scenario's result is calculated. As the simulation runs, the model is recalculated for each new scenario that continues until a stopping criteria is reached. These simulations combined the distributions of relative exposure factors (REFs), occurrence at or above 3 μg/L, and risks of bladder and lung cancer taken from the Morales *et al.* (2000) article. The simulations resulted in upper-bound estimates of the actual risks faced by populations exposed to arsenic concentrations at or above 3 μg/L in their drinking water.

f. Lower-bound analyses. Two adjustments were made to the risk distributions resulting from the simulations described previously, reflecting uncertainty about the actual arsenic exposure in the Taiwan study area. First, the Agency made an adjustment to the lower bound risk estimates to take into consideration the effect of exposure to arsenic through water used in preparing food in Taiwan. The Taiwanese staple foods were dried sweet potatoes and rice (Wu *et al.*, 1989). Both the 1988 EPA ''Special Report on Ingested Inorganic Arsenic'' report (EPA,1988) and the 1999 NRC report assumed that an average Taiwanese male weighed 55 kg and drank 3.5 liters of water daily, and that an average Taiwanese female weighed 50 kg and drank 2 liters of water daily. Using these assumptions, along with an assumption that Taiwanese men and women ate one cup of dry rice and two pounds of sweet potatoes a day, the Agency re-estimated risks for bladder and lung cancer, using one additional liter water consumption for food preparation (*i.e.*, the water absorbed by hydration during cooking). This adjustment was discussed and used in the October 20, 2000 NODA (65 FR 63027; EPA, 2000m).

Second, an adjustment was made to the lower-bound risk estimates to take into consideration the relatively high arsenic concentration in the food consumed in Taiwan as compared to the U.S. The food consumed daily in Taiwan contains about 50 μg of arsenic, versus about 10 μg in the U.S. (NRC, 1999, pp. 50–51). Thus the total consumption of inorganic arsenic (from food preparation and drinking water) is considered, per kilogram of body weight, in the process of these adjustments. To carry them out, the relative contribution of arsenic in the drinking water that was consumed as drinking water, on a μg arsenic per kilogram body weight per day (μg/kg/day) basis, was compared to the total amount of arsenic consumed in drinking water, drinking water used for cooking, and in food, on a μg/kg/day basis.

Other factors contributing to lower bound uncertainty include the possibility of a sub-linear dose-response curve below the point of departure. The NRC noted ''Of the several modes of action that are considered most plausible, a sub-linear dose response curve in the low-dose range is predicted, although linearity cannot be ruled out.'' (NRC, 1999). The recent Utah study (Lewis *et al.*, 1999), described in section V.G.1(b), provides some evidence that the shape of the dose-response curve may well be sub-linear at low doses. Because sufficient mode of action data were not available, an adjustment was not made to the risk estimates to reflect the possibility of a sub-linear dose-response curve. Additional factors contributing to uncertainty include the use of village well data rather than individual exposure data, deficiencies in the Taiwanese diet relative to the U.S. diet (selenium, choline, etc.), and the baseline health status in the Taiwanese study area relative to U.S. populations. The Agency did not make adjustments to the risk estimates to reflect these uncertainties because applicable peer-reviewed, quantitative studies on which to base such adjustments were not available.

Estimated risk levels for bladder and lung cancer combined at various MCL levels are shown in Tables III.D–2(a-c). The risk estimates without adjustments for exposure uncertainty through cooking water and food are shown Table III.D–2 (a). These estimates incorporate occurrence data, water consumption data, and male and female risk estimates. Lower bounds show estimates using community water consumption data; upper bounds show estimates using total water consumption data. Table III.D–2 (b) shows estimated risk levels for bladder and lung cancer combined at various MCL levels with adjustments for exposure uncertainty through cooking water and food. These estimates incorporate occurrence data, water consumption data, and male risk estimates, with lower bounds reflecting community water consumption data and upper bounds reflecting total water consumption data. There are no adjustments for other factors which contribute to uncertainty, such as the use of village well data as opposed to individual exposure data. Tablet III.D–2 (c) is a combination of Table III.D–2(a) and Table III.D–2 (b), with the lower bounds taken from Table III.D–3 (b), and the upper bounds taken from Table III.D–2 (a). Thus Table III.D–2(c) reflects the range of estimates before and after the exposure uncertainty adjustments for cooking water and for food, along with the incorporation of water consumption data, occurrence data, and cancer risk estimates. These estimates were used to estimate the range of potential cases avoided at the various MCL levels.

The lower-bound risk estimates in Tables III.D–2(a-c) reflect the following:

—The community (tap) water consumption from the EPA water consumption study (EPA, 2000c)
—The occurrence distributions of arsenic in U.S. ground and surface water systems
—Male risk estimates from Morales *et al.* (2000)
—Arsenic exposure from cooking water in Taiwan
—Arsenic exposure from food in Taiwan

The upper-bound risk estimates in Tables III.D–2(a-c) reflect the following:

—The total water consumption estimates from the EPA water consumption study (EPA, 2000c)
—The occurrence distributions of arsenic in U.S. ground and surface water systems
—Male and female risk estimates from Morales *et al.* (2000)

TABLE III.D–2(a).—CANCER RISKS FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT [1,2]

[without adjustment for arsenic in food and cooking water]

MCL (µg/L)	Mean exposed population risk	90th percentile exposed population risk
3	$0.93–1.25 \times 10^{-4}$	$1.95–2.42 \times 10^{-4}$
5	$1.63–2.02 \times 10^{-4}$	$3.47–3.9 \times 10^{-4}$
10	$2.41–2.99 \times 10^{-4}$	$5.23–6.09 \times 10^{-4}$
20	$3.07–3.85 \times 10^{-4}$	$6.58–8.37 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume that the probability of illness from arsenic exposure in the U.S. is equal to the probability of death from arsenic exposure among the arsenic study group.

[2] The estimated risks are male and female risks combined.

TABLE III.D–2(B).—CANCER RISKS FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT 1, 2

[without adjustment for arsenic in food and cooking water]

MCL (µg/L)	Mean exposed population risk	90th percentile exposed population risk
3	$0.11–0.13 \times 10^{-4}$	$0.22–0.26 \times 10^{-4}$
5	$0.27–0.32 \times 10^{-4}$	$0.55–0.62 \times 10^{-4}$
10	$0.63–0.76 \times 10^{-4}$	$1.32–1.54 \times 10^{-4}$
20	$1.1–1.35 \times 10^{-4}$	$2.47–2.89 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume that the probability of illness from arsenic exposure in the U.S. is equal to the probability of death from arsenic exposure among the arsenic study group.

[2] The estimated risks are for males.

TABLE III.D–2(c).—CANCER RISKS FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT [1,2]

[lower bound with food and cooking water adjustment, upper bound withough food and cooking water adjustment]

MCL (µg/L)	Mean exposed population risk	90th percentile exposed population risk
3	$0.11–1.25 \times 10^{-4}$	$0.22–2.42 \times 10^{-4}$
5	$0.27–2.02 \times 10^{-4}$	$0.55–3.9 \times 10^{-4}$
10	$0.63–2.99 \times 10^{-4}$	$1.32–6.09 \times 10^{-4}$
20	$1.1–3.85 \times 10^{-4}$	$2.47–8.37 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume that the probability of illness from arsenic exposure in the U.S. is equal to the probability of death from arsenic exposure among the arsenic study group.

g. Cases avoided. The lower and upper bound risk estimates from Table III.D–2(c) were applied to the exposed population to generate cases avoided for CWSs serving less than a million customers. Because the actual arsenic occurrence was known for the very large systems (those serving over a million customers), their system-specific arsenic occurrence distributions could be directly computed. The system-specific arsenic distributions allowed direct calculation of avoided cancer cases. The process, described in detail in the Economic Analysis (EPA, 2000o), utilizes the same risk estimates from Morales et al. (2000) that were used in deriving the number of cases avoided in smaller CWSs. Cases avoided for NTNCWSs were also computed separately, utilizing factors developed to account for the intermittent nature of the exposure. These factors are described in the Economic Analysis.

An upper-bound adjustment was made to the number of bladder cancer cases avoided to reflect a possible lower mortality rate in Taiwan than was assumed in the risk assessment process described earlier. We also made this adjustment in the June 22, 2000 proposal. In the Taiwan study area, information on arsenic-related bladder and lung cancer deaths was reported. In order to use these data to determine the probability of contracting bladder and lung cancer as a result of exposure to arsenic, a probability of mortality, given the onset of arsenic-induced bladder and lung cancer among the Taiwanese study population, must be assumed. The study area in Taiwan is a section where arsenic concentrations in the water are very high by comparison to those in the U.S., and an area of low incomes and poor diets, where 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 probability of contracting bladder cancer was relatively close to the probability of dying from bladder cancer (i.e., that the bladder cancer incidence rate was equal to the bladder cancer mortality rate).

We do not have data on the rates of survival for bladder cancer in the Taiwanese villages in the study 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 (WHO, 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 (*i.e.*, 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. 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 previous discussion, we think bladder cancer incidence could be no more than two-fold bladder cancer mortality; and that an 80% mortality rate would be plausible. Thus, we have adjusted the upper bound of cases avoided, which is used in the benefits analysis, to reflect a possible mortality rate for bladder cancer of 80 percent. Because lung cancer mortality rates are quite high, about 88% in the U.S. (EPA, 1998n), the assumption was made that all lung cancers in the Taiwan study area resulted in fatalities.

The total number of bladder and lung cases avoided at each MCL is shown in Table III.D–3. These cases avoided include CWSs and NTNCWSs cases. The number of bladder and lung cancer cases avoided ranges from 57.2 to 138.3 at an MCL of 3 μg/L, 51.1 to 100.2 at an MCL of 5 μg/L, 37.4 to 55.7 at an MCL of 10 μg/L, and 19.0 to 19.8 at an MCL of 20 μg/L. The cases avoided were divided into premature fatality and morbidity (*i.e.,* illness) cases based on U.S. mortality rates. 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 (EPA, 1999j). 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 was 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% from 1973 to 1996. For lung cancer, mortality rates are much higher. The comparable mortality rate for lung cancer in the U.S. is 88% (EPA, 1998n).

TABLE III.D–3.—ANNUAL TOTAL (BLADDER AND LUNG) CANCER CASES AVOIDED FROM REDUCING ARSENIC IN CWSS AND NTNCWS

Arsenic level (μg/L)	Reduced mortality cases[1]	Reduced morbidity cases[1]	Total cancer cases avoided
3	32.6–74.1	24.6–64.2	57.2–138.3
5	29.1–53.7	22.0–46.5	51.1–100.2
10	21.3–29.8	16.1–25.9	37.4–55.7
20	10.2–11.3	8.5–8.8	19.0–19.8

[1] Based on U.S. mortality rates given in the text.

3. Sensitive Subpopulations

The 1996 SDWA amendments include specific provisions in section 1412(b)(3)(C)(i)(V) that require EPA to assess the effects of a contaminant not just on the general population but on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations 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 subcommittee noted that there is a marked variation in susceptibility to arsenic-induced toxic effects that may be influenced by factors such as genetic polymorphisms (especially in metabolism), life stage at which exposures occur, sex, nutritional status, and concurrent exposures to other agents or environmental factors. 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. EPA agrees with the NRC that there is not enough information to make risk conclusions on any specific subpopulations.

4. Risk Window

EPA has historically considered 10^{-4} to 10^{-6} as a target risk range protective of public health in its drinking water program. However, the risk-range represents a policy goal for EPA, and is not a statutory factor in setting an MCL. Note that the procedure EPA uses to estimate such risks provides an upper-bound estimate. In the case of arsenic, EPA performed a benefit-cost analysis as required by the statute. This analysis is discussed in more detail in section III.F.

E. What Are the Costs and Benefits at 3, 5, 10, and 20 µg/L?

In accordance with section 1412 (b)(3)(C) of SDWA, EPA must analyze the costs and benefits of a proposed NPDWR. To comply with this provision, EPA included the complete analysis in the proposed rule. Also, in accordance with Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the arsenic rule in an Economic Analysis in conjunction with publishing the final rule. EPA has prepared an Economic Analysis to comply with the requirements of this Order. This section provides a summary of the information from the Arsenic Economic Analysis (EPA, 2000o).

1. Summary of Cost Analysis

National cost estimates of compliance with the arsenic rule were derived from estimates of utility treatment costs, monitoring and reporting costs, and start-up costs for both CWS and NTNCWSs. Utility treatment costs were derived using occurrence data, treatment train unit costs, and decision trees. The occurrence data provide a measure of the number of systems that would need to install treatment in each size category. The treatment train unit cost estimates provide a measure of how much a technology will cost to install. Decision trees vary by system size and are used as a prediction of the treatment technology trains facilities would likely install to comply with options considered for the revised arsenic standard. Detailed descriptions of the methodologies used in determining the costs of this rule are found in the ‘‘Technologies and Cost for Removal of Arsenic in Drinking Water’’ document (EPA, 2000t) and also the ‘‘Arsenic Economic Analysis’’ (EPA, 2000o), both of which are in the docket for this final rulemaking.

a. Total national costs. Under the MCL of 10 µg/L, the Agency estimates that total national costs to CWSs are $172.3 million (1999 dollars) annually at a 3% discount rate. This total national cost includes annual treatment costs ($169.6 million), annual monitoring and administrative costs ($1.8 million), and annual State costs ($0.9 million). Assuming a 7% discount rate, total national costs to CWSs are estimated at $196.6 million annually.

Total national costs to NTNCWSs are estimated at $8.1 million annually at a 3% discount rate. This includes annual treatment costs ($7.0 million), annual monitoring and administrative costs ($0.9 million), and annual State costs ($0.1 million). Total national costs to NTNCWSs, assuming a 7% discount rate, are estimated at $9.1 million annually.

Table III.E–1 shows the total national cost breakdown for the arsenic MCL and also for three other arsenic levels considered in the proposed rule. Expected system costs include treatment costs, monitoring costs, and administrative costs of compliance. State costs include monitoring and administrative costs of implementation. As expected, aggregate arsenic compliance costs increase with decreasing arsenic MCL levels as more systems are affected.

TABLE III.E–1.—TOTAL ANNUAL NATIONAL SYSTEM AND STATE COMPLIANCE COSTS

[$ millions, 1999]

Discount rate	CWS		NTNCWS		Total	
	3 percent	7 percent	3 percent	7 percent	3 percent	7 percent
MCL = 3 µg/L						
System Costs	$668.1	$759.5	$28.2	$31.0	$696.3	$790.4
Treatment	665.9	756.5	27.2	29.6	693.1	786.0
Monitoring/Administrative	2.2	3.0	1.0	1.4	3.2	4.4
State Costs	1.4	1.6	0.1	0.2	1.5	1.7
Total [1]	669.4	761.0	28.3	31.1	697.8	792.1
MCL = 5 µg/L						
System Costs	396.4	451.1	17.3	18.9	413.5	470.2
Treatment	394.4	448.3	16.3	17.6	410.6	466.1
Monitoring/Administrative	2.0	2.8	1.0	1.3	2.9	4.1
State Costs	1.1	1.3	0.1	0.2	1.2	1.4
Total [1]	397.5	452.5	17.3	19.1	414.8	471.7
Final MCL = 10 µg/L						
System Costs	171.4	195.5	7.9	8.9	179.4	204.4
Treatment	169.6	193.0	7.0	7.6	176.7	200.6
Monitoring/Administrative	1.8	2.5	0.9	1.3	2.7	3.8
State Costs	0.9	1.0	0.1	0.2	1.0	1.2
Total [1]	172.3	196.6	8.1	9.1	180.4	205.6
MCL = 20 µg/L						
System Costs	62.4	71.4	3.5	4.1	65.9	75.5
Treatment	60.7	69.0	2.6	2.8	63.3	71.8
Monitoring/Administrative	1.7	2.4	0.9	1.3	2.6	3.7

TABLE III.E–1.—TOTAL ANNUAL NATIONAL SYSTEM AND STATE COMPLIANCE COSTS—Continued

[$ millions, 1999]

Discount rate	CWS		NTNCWS		Total	
	3 percent	7 percent	3 percent	7 percent	3 percent	7 percent
State Costs	0.7	0.8	0.1	0.2	0.9	1.0
Total[1]	63.2	72.3	3.6	4.2	66.8	76.5

[1] Total may not match detail due to rounding.

b. Household costs. Table III.E–2 shows mean annual costs per household for those households that are served by systems that may need to treat under today's rule. As discussed in Table III.C–6 of today's preamble and Table 8–2 of the Economic Analysis, of the approximately 74,000 systems that are covered by today's rule, EPA estimates that only about 3,433 of these systems will require treatment. Table III.E–2 refers only to the households served by systems expected to need treatment. The average household cost increase resulting from today's rule is $31.85. However, due to economies of scale, costs per household are higher in the smaller size categories, and lower in the larger size categories. For today's rule (10 µg/L), costs are expected to be $326.82 per household for systems serving <100 people, and $162.50 per household for systems serving 101–500 people. Costs per households in systems larger than those are substantially lower: From $70.72 to $0.86 per household. As shown in Table III.E–2, the costs per household do not vary dramatically across MCL options although Table III.E–1 shows that total national costs are significantly different. This divergence is attributable to the total number of households affected by each MCL level and not the cost of treatment. For example, approximately eleven million households would be affected by an MCL of 3 µg/L compared to approximately three million affected by the today's final rule MCL of 10 µg/L. In addition, the household costs change relatively little among MCL options because while each progressively lower MCL option brings in a larger number of systems subject to the rule, the majority of those systems generally need only minimal removal of arsenic. This fact offsets, to an extent, the increased costs as a result of more systems covered at lower MCL options. A more detailed discussion of household costs can be found in Chapter 6 of the ''Arsenic Economic Analysis'' document (EPA, 2000o).

TABLE III.E–2.—MEAN ANNUAL COSTS PER HOUSEHOLD

[in 1999 dollars][1]

System size	3 µg/L	5 µg/L	10 µg/L	20 µg/L
<100	$317.00	$318.26	$326.82	$351.15
101–500	166.91	164.02	162.50	166.72
501–1,000	74.81	73.11	70.72	68.24
1,001–3.300	63.76	61.94	58.24	54.36
3.301–10,000	42.84	40.18	37.71	34.63
10,001–50,000	38.40	36.07	32.37	29.05
50,001–100,000	31.63	29.45	24.81	22.63
100,001–1,000,000	25.29	23.34	20.52	19.26
>1,000,000	7.41	2.79	0.86	0.15
All categories	41.34	36.95	31.85	23.95

[1] Only households served by those systems expected to install treatment.

2. Summary of Benefits Analysis

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, and neurological, endocrine effects. A complete list of the arsenic-related health effects reported in humans is discussed in section III. D of this preamble. Current research on arsenic exposure has only been able to provide enough information to conduct a quantitative assessment of bladder and lung cancers. The other health effects and possible non-health benefits remain unquantified in this analysis but are discussed qualitatively. It is important to note that if the Agency were able to quantify additional arsenic-related health effects and non-health effects, the quantified benefits estimates may be significantly higher than the estimates presented in this analysis. In addition, the SDWA amendments of 1996 require that EPA fully consider both quantifiable and non-quantifiable benefits that result from drinking water regulations and has done this for today's arsenic rule.

a. Primary analysis. Quantifiable benefits. Although arsenic in drinking water has been associated with numerous health effects (see section III.D), the quantified benefits that result from today's rule are associated only with reductions in arsenic-related bladder and lung cancers. A complete discussion of risk assessment methodology and assumptions can be found in Chapter 5 of the ''Arsenic Economic Analysis'' document (EPA, 2000o).

The quantified benefits for today's rule for both CWSs and NTNCWSs range from $140 million to $198 million and consider both lower- and upper-bound risk levels. Specifically, the benefits to the CWSs are approximately $138.2 million to $193.2 million and $1.4 million to $4.5 million for NTNCWSs. Table III.E–3 shows the complete range of quantified benefits for the other MCL levels considered by the Agency. Section III.D.2. of this preamble explains the derivation of the upper- and lower-bound estimates

In order to monetize the benefit from the bladder and lung cancers cases avoided, the Agency used two different values. First, a value of statistical life (VSL) estimate was applied to those cancer cases that result in a mortality. EPA assumed a 26% mortality rate for bladder cancer and an 88% mortality rate for lung cancer (EPA, 1999j; EPA, 1998n). The current VSL value used by the Agency is $6.1 million, in 1999 dollars. This value of $6.1 million does not reflect any adjustments to account for national real income growth that occurred subsequent to the completion of the wage-risk studies on which EPA's VSL estimate is derived. Were the Agency to adjust the VSL to account for this growth in real income, the VSL would be approximately $6.77 million (assuming a 1.0 income elasticity).

Second, a willingness-to-pay value (WTP) is used to monetize the cancer cases that do not result in a mortality. The WTP value for avoiding a non-fatal cancer is not currently available; therefore, the Agency used a WTP estimate to reduce a case of chronic bronchitis as a proxy. The use of this value may understate the true benefit if the WTP to avoid a nonfatal cancer is greater than the WTP to avoid a case of chronic bronchitis. The mean value of this WTP estimate is $607,000 (in 1999 dollars). A complete discussion of the VSL and WTP values and how they are calculated can be found in Chapter 5 for the ''Arsenic Economic Analysis'' document (EPA, 2000o).

—Non-quantifiable benefits. There are a number of important non-quantified benefits that EPA considered in its analysis. Chief among these are certain health impacts known to be caused by arsenic, though, while they may be substantial, the extent to which these impacts occur at levels below 50 μg/L is unknown. These additional health effects include cancers, other than bladder and lung cancers, as well as non-cancer health effects. In addition, EPA has identified non-health benefits that may result from today's rule, which are discussed next.

EPA was not able to quantify many of the health effects potentially associated with arsenic due to data limitations. These health effects include other cancers such as skin and prostate cancer and non-cancer endpoints such as cardiovascular, pulmonary, and neurological impacts. These health effects and the relevant studies linking these health effects to arsenic in drinking water are discussed in section III.D. of today's rule. For example, 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.

Other potential benefits not quantified or monetized in today's rule include reduced uncertainty about becoming ill from consumption of arsenic in drinking water and the ability for some treatment technologies to eliminate multiple contaminants. The reduced uncertainty concept depends on several factors including consumer's degree of risk aversion, their perceptions about the drinking water quality (degree to which they will be affected by the regulatory action), and the expected probability and severity of human heath effects associated with arsenic contamination of drinking water. Another non-quantified benefit is the effect on those systems that install treatment technologies that can address multiple contaminants. For example, membrane systems, such as reverse osmosis, can be used for arsenic removal but can also remove many other contaminants that EPA is in the process of regulating or considering regulating. Therefore, by installing a reverse osmosis system, a system may not have to make any additional changes to comply with these future regulations.

TABLE III.E–3.—ESTIMATED BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER

[$ millions 1999]

Arsenic level (μg/L)	Total quantified health benefits [1]	Potential non-quantified health benefits includes reductions in:
3	$213.8–$490.9	• Skin Cancer. • Kidney Cancer. • Cancer of the Nasal Passages. • Liver Cancer. • Prostate Cancer. • Cardiovascular Effects. • Pulmonary Effects. • Immunological Effects. • Neurological Effects. • Endocrine Effects.
5	$191.1–$355.6	
10	$139.6–$197.7	
20	$66.2–$75.3	

[1] Benefits from reduction in bladder and lung cancer. The range represents both a lower and upper bound risk as discussed in section III. D. of this preamble.

b. Sensitivity analysis on benefits valuation. For the final rulemaking analysis, some commenters have argued that the Agency should consider an assumed time lag or latency period in its benefits calculations. The term ''latency'' can be used in different ways, depending on the context. For example, health scientists tend to define latency as the period beginning with the initial exposure to the carcinogen and ending when the cancer is initially manifested (or diagnosed), while others consider latency as the period between manifestation of the cancer and death. Latency, in this case, refers to the difference between the time of initial exposure to environmental carcinogens and the actual mortality. Use of such an approach might reduce significantly the present value of health risk reduction benefits estimates.

In the proposed arsenic rule, the Agency included qualitative language on the latency issue, including descriptions of other adjustments which may influence the estimate of economic benefits associated with avoided cancer fatalities. The Agency also agreed to ask the SAB to conduct a review of the benefits' transfer issues and possible adjustment factors associated with economic valuation of mortality risks. A summary of the SAB's recommendations is shown in the following section.

c. SAB recommendations. EPA brought this issue before the Environmental Economics Advisory Committee (EEAC) of EPA's SAB in a meeting held on February 25, 2000 in Washington, DC. The SAB submitted a final report on its findings and recommendations to EPA on July 27, 2000. The Panel's report made a number of recommendations on the adjustment factors and benefit-cost analysis in general. A copy of the final SAB report (EPA, 2000j) is in the record for this rulemaking.

The SAB Panel noted that benefit-cost analysis, as described in the Agency's Guidelines for Preparing Economic Analysis (EPA, 2000k), is not the only analytical tool nor is efficiency the only appropriate criterion for social decision making. The SAB Panel also stated that it is important to carry out such analyses in an unbiased manner with as much precision as possible. In its report, the SAB recommended that the Agency continue to use a wage-risk-based VSL as its primary estimate; any appropriate adjustments that are made for timing (*e.g.*, latency) and income growth should be part of the Agency's main analysis while any other proposed adjustments should be accounted for in sensitivity analyses to show how results would change if the VSL were adjusted for some of the major differences in the characteristics of the risk and of the affected populations. The SAB recommended including only adjustments for latency and income growth in the main analysis because it did not believe any of the other proposed adjustments were adequately supported in the literature at the present time. Specifically, the SAB report recommended that (1) Health benefits brought about by current policy initiatives (*i.e.*, after a latency period) should be discounted to present value using the same rate that is used to discount other future benefits and costs in the primary analysis; and any other proposed adjustments should be accounted for in a sensitivity analysis including adjustments to the VSL for a ''cancer premium,'' voluntariness and controllability, altruism, risk aversion, and ages of the affected population. No adjustment should be made to the VSL to reflect health status of persons whose cancer risks are reduced. (2) Estimates of VSLs accruing in future years should be adjusted in the primary analysis to reflect anticipated income growth, using a range of income elasticities.

After considering the SAB's recommendations, EPA has developed a sensitivity analysis of the latency structure and associated benefits for the arsenic rule, as described in the next section and in the Economic Analysis for the final rule. This analysis consists of health risk reduction benefits that reflect adjustments for discounting, incorporation of a range of latency period assumptions, adjustments for growth in income, and incorporation of other factors such as voluntariness and controllability. Although the SAB recommended accounting for latency in a primary benefits analysis, the Agency believes that, in the absence of any sound scientific evidence on the duration of particular latency periods for arsenic related cancers, discounted benefits estimates for arsenic are more appropriately accounted for in a sensitivity analysis. Sensitivity analyses are generally reserved for examining the effects of accounting for highly uncertain factors, such as the estimation of latency periods, on health risk reduction benefits estimates.

Defining a latency period is highly uncertain because the length of the latency period is often poorly understood by health scientists. In some cases, information on the progression of a cancer is based on animal studies, and extrapolation to humans is complex and uncertain. Even when human studies are available, the dose considered may differ significantly from the dose generally associated with drinking water contaminants (*e.g.*, involve a high level of exposure over a short time period, rather than a long term, low level of exposure). The magnitude of the dose, may in turn, affect the resulting latency period. Information on latency may be unavailable in many cases or, if available, may be highly uncertain and vary significantly across individuals. The Agency recognizes, however, that despite significant uncertainty in the latency period associated with arsenic exposure through drinking water, it is unlikely that all cancer reduction benefits would be realized immediately upon exposure reduction. To the extent that there are delays due to latency in the realization of these benefits, monetized cancer reduction benefits would be discounted; although, as discussed above, this may be offset by other adjustments.

d. Analytical approach. For the latency sensitivity analysis, the health benefits have been broken into separate treatments of morbidity and mortality. The mortality component of the total benefits is examined in this analysis because a cancer latency period (*i.e.*, the time period between initial exposure to environmental carcinogens and the actual fatality) impacts arsenic-related fatalities to a greater extent than arsenic-related morbidity. For purposes of this analysis, the Agency examined the impacts of various latency period assumptions, adjustments for income growth, and incorporation of other adjustments such as a voluntariness and controllability, on bladder and lung cancer fatalities associated with arsenic in drinking water (EPA, 2000k).

Because the latency period for arsenic related bladder and lung cancers is unknown, EPA has assumed a range of latency periods from 5 to 20 years. While both lung and bladder cancer have relatively long, average latencies, the lower end of the latency period is substantially less. As can be seen by inspection of the Surveillance, Epidemiology, and End Results (SEER) data of the National Cancer Institute, significant incidence of both cancers occurs in individuals in the 15–19 year old age groups (NCI, 2000). This strongly indicates a short latency period for whatever the cause of the cancer may have been.

Moreover, the mode of action for arsenic is suspected to be one that operates at a late stage of the cancer process that may advance the expression of cancers initiated by other causes (sometimes referred to as ''promoting out'' the cancerous effect). Therapeutic treatment with the drug cyclophosphamide, which causes cell toxicity, has been seen to induce bladder cancer in as little as 7 months to 15 years in affected patients. This was of course a high dose treatment, but the example serves to illustrate the ability of an agent to advance the development of cancer.

For these reasons, we believe latency periods of 5, 10, and 20 years serve as reasonable approximations, in the absence of definitive data on arsenic-induced cancers, of the latency periods for the sensitivity analysis.

Table III.E–4 shows the sensitivity of the primary analysis VSL estimate ($6.1 million, 1999 dollars) to changes in latency period assumptions and also with the incorporation of an adjustment to reflect changes in WTP based on real income growth and other adjustment factors. As is shown in Table III.E–4, the adjusted VSL is greater than the primary VSL ($6.77 million versus $6.1 million) at an income elasticity of 1.0, with adjustments for income growth only. Assuming a 3% discount rate, the lowest adjusted VSL value ($3.44 million) is yielded over a 20-year latency period that includes discounting and income growth only (income elasticity = 0.22). Assuming a 7% discount rate, the highest adjusted VSL is also $6.77 million (adjusted for income growth only (income elasticity = 1.0)). The lowest adjusted VSL is $1.61 million (discounted over 20 years).

TABLE III.E–4.— SENSITIVITY OF THE PRIMARY VSL ESTIMATE TO CHANGES IN LATENCY PERIOD ASSUMPTIONS, INCOME GROWTH, AND OTHER ADJUSTMENTS

[$ millions, 1999]

Adjustment factor	Latency period (Years)		
	5	10	20
3% Discount Rate			
Primary Analysis (No VSL Adjustment)	6.1	6.1	6.1
Adjusted for Income Growth: [1]			
elasticity = 0.22	6.22	6.22	6.22
elasticity = 1.0	6.77	6.77	6.77
Adjusted for Income Growth [1] and Discounting:			
elasticity = 0.22	5.37	4.63	3.44
elasticity = 1.0	5.84	5.04	3.75
Adjusted for Income Growth,[1] Discounting, and 7% Increase for Voluntariness and Controllability;			
elasticity = 0.22	5.74	4.95	3.69
elasticity = 1.0	6.25	5.39	4.01
Break-Even for Other Characteristics (as a percentage of the primary VSL estimate);			
elasticity = 0.22	6 percent	19 percent	40 percent
elasticity = 1.0	−2 percent	12 percent	34 percent
7% Discount Rate			
Primary Analysis (No VSL Adjustment)	6.1	6.1	6.1
Adjusted for Income Growth:[1]			
elasticity = 0.22	6.22	6.22	6.22
elasticity = 1.0	6.77	6.77	6.77
Adjusted for Income Growth [1] and Discounting:			
elasticity = 0.22	4.44	3.16	1.61
elasticity = 1.0	4.83	3.44	1.75
Adjusted for Income Growth, [1] Discounting, and 7% Increase for Voluntariness and Controllability:			
elasticity = 0.22	4.75	3.38	1.72
elasticity = 1.0	5.17	3.68	1.87
Break-Even for Other Characteristics (as a percentage of the primary VSL estimate):			
elasticity = 0.22	22 percent	45 percent	72 percent
elasticity = 1.0	15 percent	40 percent	69 percent

[1] This adjustment reflects the change in WTP based on real income growth from 1990 to 1999.

The first row of both the 3% and 7% discount rate panels in Table III.E–4 shows the VSL used in the primary analysis. Because this value has not been adjusted for discounting over an assumed and unknown latency period, this value does not deviate from the original $6.1 million used in the primary benefits analysis. The second and third rows of both the 3 and 7 percent panels show the adjustments to the primary VSL to account for changes in WTP for fatal risk reductions associated with real income growth from 1990 to 1999. As real income grows, the WTP to avoid fatal risks is also expected to increase at a rate corresponding to the income elasticity of demand, as discussed below. This income growth, from the years 1990 to 1999, accounts for the differences in incomes of the VSL study population versus the population affected by the arsenic rule. This does not include any income adjustments over a latency period because of methodological issues that have not yet been resolved. However, pending the resolution of these issues, EPA may include an adjustment for income growth over a latency period in future analyses, as recommended by the SAB.

The fourth and fifth rows of both the 3% and 7% panels illustrates the impacts of adjusting the primary VSL for discounting and WTP changes based on real income growth over a range of assumed latency periods. As is shown in Table III.E–4, this value decreases from $5.84 million assuming a five-year latency period to $3.75 million assuming a 20-year latency period (at a 3% discount rate and income elasticity of 1.0). At a 7% discount rate, this value decreases from $4.83 million to $1.75 million.

The sixth and seventh rows of the 3% and 7% panels illustrate the effects of incorporating a 7% increase for voluntariness and controllability. The 7% adjustment is based on a study by Cropper and Subramanian (1999) that indicates individuals may place a slightly higher Willingness to Pay (WTP) on risks where exposure is neither voluntary nor controllable by the individual.

In adjusting for WTP changes based on real income growth, EPA used a range of income elasticities from the economics literature. Income elasticity is the % change in demand for a good (in this case, WTP for fatal risk reductions) for every 1% change in income. For example, an income elasticity of 1.0 implies that a 10 percent higher income level results in a 10% higher WTP for fatal risk reductions. In a recent study (EPA, 2000l), EPA reviewed the literature related to the income elasticity of demand for the prevention of fatal health impacts. Based on data from cross-sectional studies of wage premiums, a range of elasticity estimates for serious health impacts was developed, ranging from a lower-end estimate of 0.22 to an upper-end estimate of 1.0.

There are several other characteristics that differ between the VSL estimates used in the primary analysis and an ideal estimate specific to the case of cancer risks from arsenic. These might include a cancer premium, differences in risk aversion, altruism, age of the individual affected, and a morbidity component of the VSL mortality estimate. Very little empirical information is available on the impact that these characteristics have on VSL estimates so they are not accounted for directly in this sensitivity analysis. A more complete discussion of the other characteristics identified by economists as having a potential impact on willingness to pay to reduce mortality risks can be found in chapter seven of the Agency's ''Guidelines for Preparing Economic Analyses'' (EPA 2000k), which is available in the docket for this final rulemaking.

However, it is possible to use a different type of analysis to address the question: what would the impact on VSL of these additional characteristics need to be to produce the $6.1 million VSL used in the primary benefits analysis? (See primary benefits analysis in section III.E.2.a of today's rule.) The last two rows of the 3% and 7% panels of Table III.E–4 attempt to answer this question in percentage terms. For example, at a 3% discount rate over a 10-year latency period, income elasticity of 1.0, and a 7% adjustment for controllability and voluntariness, a factor of 12% (as shown in the bottom row of the 3% panel of Table III.E–4) indicates that if accounting for these characteristics would increase VSL by more than 12% then the primary analysis will tend to understate the value of risk reductions. If accounting for these characteristics would not increase VSL by at least 12%, then the primary analysis may overstate benefits (a negative % indicates that the primary analysis understates benefits unless the combined impact of these additional characteristics actually reduces VSL estimates).

Some researchers believe that the value of some of these characteristics will substantially add to the unadjusted VSL (one study suggests that a cancer premium alone may be worth an additional 100% of primary VSL value (Revesz, 1999)). Some researchers also believe that some of these characteristics have a negative effect on VSL, suggesting that some of these factors offset one another. Until we know more about these various factors we cannot explicitly make adjustments to existing VSL estimates. The SAB noted in its report that these characteristics require more empirical research prior to incorporation into the Agency's primary benefits analysis, but could be explored as part of a sensitivity analysis.

e. Results. Table III.E–5 illustrates the impacts of changes in VSL adjustment factor assumptions on the estimated benefits for the range of fatal bladder and lung cancer cases avoided in the final arsenic rule, assuming a 3% discount rate. The results of this analysis at a 7% discount rate are given in Table III.E–6. These results were calculated by applying the adjusted VSL from Table III.E–4 to the lower- and upper-bound estimates of fatal bladder and lung cancer cases avoided as shown in Table III.E–3 in section III.D.2 of today's rule. For purposes of this sensitivity analysis, EPA presented combined bladder and lung cancer cases avoided in Tables III.E–5 and III.E–6. Health risk reduction benefits attributable to reduced arsenic levels in both CWSs and NTNCWSs are presented in these tables as well.

It is important to note that the monetized benefits estimates shown in this section reflect quantifiable benefits only. As shown in section III.E.2.a, there may be a number of nonquantifiable benefits associated with regulating arsenic in drinking water. Were EPA able to quantify some of the currently nonquantifiable health effects and other benefits associated with arsenic regulation, monetized benefits estimates would be higher than what is shown in the table. A more complete discussion of how risks from arsenic in drinking water and the corresponding health benefits were calculated is provided in the ''Arsenic Economic Analysis'' (EPA, 2000o), which is available in the docket for this final rulemaking.

TABLE III.E–5.—SENSITIVITY OF COMBINED ANNUAL BLADDER AND LUNG CANCER MORTALITY BENEFITS ESTIMATES TO CHANGES IN VSL ADJUSTMENT FACTOR ASSUMPTIONS

[$ millions, 1999, 3% discount rate][1]

Arsenic Level (μg/L)	3	5	10	20
5-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	176–328	130–182	62–69
Adjusted for Income Growth[2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth[2] and Discounting:				
E = 0.22	175–398	156–288	114–160	55–61
E = 1.0	190–433	170–314	124–174	60–66
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	187–425	167–308	122–171	59–65
E = 1.0	204–463	182–336	133–186	64–71
10-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	176–328	130–182	62–69
Adjusted for Income Growth:[2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth,[2] and Discounting:				
E = 0.22	151–343	135–249	99–138	47–52
E = 1.0	164–373	147–271	107–150	51–57
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	161–367	144–266	105–148	50–56
E = 1.0	176–399	157–289	115–161	55–61

Table III.E–5.—Sensitivity of Combined Annual Bladder and Lung Cancer Mortality Benefits Estimates to Changes in VSL Adjustment Factor Assumptions—Continued

[$ millions, 1999, 3% discount rate] [1]

Arsenic Level (µg/L)	3	5	10	20
20-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	176–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth [2] and Discounting:				
E = 0.22	112–255	100–185	73–103	35–39
E = 1.0	122–278	109–201	80–112	38–42
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	120–273	107–198	79–110	38–42
E = 1.0	131–297	117–215	85–119	41–45

[1] The lower- and upper-bound benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble.

[2] This adjustment reflects the change in WTP based on real income growth from 1990 to 1999. E = income elasticity.

Table III.E–6.—Sensitivity of Combined Annual Bladder and Lung Cancer Mortality Benefits Estimates to Changes in VSL Adjustment Factor Assumptions

[$ millions, 1999, 7% discount rate] [1]

Arsenic Level (µg/L)	3	5	10	20
5-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	178–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth,[2] and Discounting:				
E = 0.22	145–329	129–238	95–132	45–50
E = 1.0	157–358	141–259	103–144	50–55
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	155–352	138–255	102–142	49–54
E = 1.0	168–383	150–278	110–154	53–58
10-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	178–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth [2] and Discounting:				
E = 0.22	103–234	92–170	67–94	32–36
E = 1.0	112–255	100–185	73–103	35–39
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	110–251	98–182	72–101	35–38
E = 1.0	120–273	107–198	78–110	38–42
20-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	178–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth [2] and Discounting:				
E = 0.22	53–119	47–86	34–48	16–18
E = 1.0	57–130	51–94	37–52	18–20
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	56–127	50–92	37–51	18–20
E = 1.0	61–139	54–100	40–56	19–21

[1] The lower- and upper-bound benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble.

[2] This adjustment reflects the change in WTP based on real income growth from 1990 to 1999. E = income elasticity.

As shown in Tables III.E–5 and III.E–6, the highest range of adjusted benefits estimates at the 10 µg/L MCL ($144–$202 million) are yielded when benefits are adjusted for changes in WTP based on real income growth only with an income elasticity of 1.0. The lowest adjusted benefits estimates at the 10 µg/L MCL ($73–$103 million at 3%, $34–$48 million at 7%) are yielded under the assumption of a 20-year latency period that includes adjustments for discounting and WTP changes based on real income growth (income elasticity = 0.22). These results indicate the high degree of sensitivity of benefits estimates to different assumptions of a latency period, discount rate, and income elasticity and also the inclusion of adjustments for income growth and voluntariness and controllability.

3. Comparison of Costs and Benefits

This section presents a comparison of quantifiable total national costs and benefits for each of the arsenic regulatory options considered. Three separate analyses are considered, including a direct comparison of aggregate national costs and benefits, a summary of benefit-cost ratios and net benefits, and the results of a cost-effectiveness analysis of each regulatory option.

a. Total national costs and benefits. Table III.E–7 shows the annual costs and benefits associated with the 10 µg/L MCL and also with three other arsenic levels considered in the proposed rule. Both costs and benefits increase as arsenic levels decrease. Costs increase over decreasing arsenic levels because of the increasing number of systems that must treat to lower arsenic levels. Benefits estimates increase as arsenic levels decrease due to the greater number of both fatal and non-fatal cancer cases avoided at lower arsenic levels. Additionally, other potential non-quantifiable health benefits are summarized in Table III.E–7.

TABLE III.E–7 ESTIMATED ANNUAL COSTS AND BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER

[1999, $ millions]

Arsenic level (µg/L)	Total national costs to CWSs and NTNCSs[1]	Total bladder cancer health benefits[2]	Total lung cancer health benefits[2]	Total combined cancer health benefits[2]	Potential nonquantifiable health benefits
3	697.8–792.1	58.2–156.4	155.6–334.5	213.8–490.9	Skin Cancer; Kidney Cancer; Cancer of the Nasal Passages; Liver Cancer; Prostate Cancer; Cardiovascular Effects; Pulmonary Effects; Immunological Effects; Neurological Effects; Endocrine Effects.
5	414.8–471.7	52.0–113.3	139.1–242.3	191.1–355.6	
10	180.4–205.6	38.0–63.0	101.6–134.7	139.6–197.7	
20	66.8–76.5	20.1–21.5	46.1–53.8	66.2–75.3	

[1] Costs include treatment, monitoring, O&M, and administrative costs to CWSs and NTNCWSs 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.

[2] The lower- and upper-bound bladder, lung, and combined cancer benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble; these estimates include both mortality and morbidity.

b. National net benefits and benefit-cost ratios. Table III.E–8 describes the quantifiable net benefits and the benefit-cost ratios under various regulatory levels for both CWSs and NTNCWSs at 3% and 7% discount rates. The net benefits and benefit-cost ratios do not include any of the potential nonquantifiable health benefits that are listed in the previous table. As shown in Table III.E–8, under both the lower- and upper-bound estimates of avoided lung and bladder cancer cases, the net benefits decrease as the arsenic rule MCL options become increasingly more stringent. Similarly, the benefit-cost ratios decrease with each more stringent MCL option. Costs outweigh the quantified benefits for the lower-bound benefits estimates under all four MCL options. Benefit-cost ratios are equal to or greater than 1.0 for the upper-bound benefits estimates (at both 3% and 7% discount rates) for arsenic levels of 10 µg/L and 20 µg/L.

TABLE III.E—8. SUMMARY OF NATIONAL ANNUAL NET BENEFITS AND BENEFIT-COST RATIOS, COMBINED BLADDER AND LUNG CANCER CASES

[1999, $ millions][1] [2] [3]

		Arsenic level (µg/L)			
		3	5	10	20
3% Discount Rate					
Lower Bound	Net Benefits	(484.0)	(223.7)	(40.8)	(0.6)
	B/C Ratio	0.3	0.5	0.8	1.0
Upper Bound	Net Benefits	(206.8)	(59.2)	17.3	8.5
	B/C Ratio	0.7	0.9	1.1	1.1
7% Discount Rate					
Lower Bound	Net Benefits	(578.3)	(280.6)	(66.0)	(10.3)
	B/C Ratio	0.3	0.4	0.7	0.9
Upper Bound	Net Benefits	(301.1)	(116.1)	(7.9)	(1.2)

TABLE III.E—8. SUMMARY OF NATIONAL ANNUAL NET BENEFITS AND BENEFIT-COST RATIOS, COMBINED BLADDER AND LUNG CANCER CASES—Continued

[1999, $ millions][1] [2] [3]

		Arsenic level (µg/L)			
		3	5	10	20
	B/C Ratio	0.6	0.8	1.0	1.0

[1] Costs include treatment, monitoring, O&M, and administrative costs to CWSs and NTNCWSs 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.

[2] The lower- and upper-bound bladder, lung, and combined cancer benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble; unquantified benefits are not included.

[3] Numbers in parentheses indicate negative numbers.

c. Incremental costs and benefits. Incremental costs and benefits are those that are incurred or realized in reducing arsenic exposures from one level to the next more stringent level (*e.g.*, from 20 µg/L to 10 µg/L). Estimates of incremental costs are useful in developing estimates of the cost-effectiveness of successively more stringent requirements.

Table III.E–9 shows the incremental total national risk reduction, arsenic mitigation costs, and monetized health benefits for the various arsenic levels valued using discount rates of three and seven percent.

TABLE III.E–9—ESTIMATES OF THE ANNUAL INCREMENTAL RISK REDUCTION, COSTS, AND BENEFITS OF REDUCING ARSENIC IN DRINKING WATER

[$ millions, 1999]

Benefit-cost element	Arsenic level (µg/L)			
	20	10	5	3
Incremental Risk Reduction:				
Fatal Cancers Avoided per Year [1]	10.2–11.3	11.1–18.5	7.8–23.9	3.5–20.4
Incremental Risk Reduction:				
Non-Fatal Cancers Avoided per Year [1]	8.5–8.8	7.6–17.1	5.9–20.6	2.6–17.7
Annual Incremental Monetized Benefits [2]	$66.2–$75.3	$73.4–$122.4	$51.5–$157.9	$22.7–$135.4
Annual Incremental Costs (3%) [3]	$66.8	$113.6	$234.4	$283.0
Annual Incremental Costs (7%) [3]	$76.5	$129.1	$266.0	$320.5

[1] Total fatal and non-fatal cancer cases avoided are discussed in section III.D.2 of this preamble.

[2] The lower- and upper-bound combined cancer benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble.

[3] Costs include treatment, monitoring, O&M, and administrative costs to CWSs and NTNCWSs and State costs for administration of water programs.

d. Cost-per-case avoided. Cost-per-case avoided is a commonly used measure of the economic efficiency with which regulatory options are meeting the intended regulatory objectives. Table III.E–10 shows the results of an analysis in which the average national cost of achieving each unit of reduction in cases of bladder and lung cancer avoided, was calculated. The average annual cost per case avoided was computed at each MCL option for both 3% and 7% discount rates.

As shown in Table III.E–10, the cost per bladder and lung cancer case avoided ranges from $4.8 million down to $3.2 million at the 10 µg/L MCL, assuming a 3% discount rate. At a 7% discount rate, the cost per bladder and lung cancer case avoided ranges from $5.5 million down to $3.7 million at the 10 µg/L MCL. As expected, the cost per bladder and lung cancer case avoided decreases with increasing arsenic levels. This is due to lower compliance costs at higher levels for the standard.

TABLE III.E–10.—ANNUAL COST PER CANCER CASE AVOIDED FOR THE FINAL ARSENIC RULE—COMBINED BLADDER AND LUNG CANCER CASES

$ millions, 1999]

Arsenic level (µg/L)	Lower-bound estimate [1]	Upper-bound estimate [1]
3 % Discount Rate		
3	12.2	5.0
5	8.1	4.1
10	4.8	3.2
20	3.5	3.4
7 % Discount Rate		
3	13.8	5.7
5	9.2	4.7
10	5.5	3.7
20	4.0	3.9

[1] The lower- and upper-bound cost per cancer case avoided corresponds to the range of combined cancer benefits estimates as shown in Table III.E–3.

4. Affordability

As noted previously, section 1412(b)(4)(E)(ii) of SDWA, as amended, requires EPA, when promulgating a national primary drinking water regulation which establishes a maximum contaminant level (MCL), to list technology (considering source water quality) that achieves compliance with the MCL and is affordable for systems in three specific population size categories: 25–500, 501–3300, and 3301–10,000. If, for any given size category/source water quality combination, an affordable compliance technology cannot be identified, section 1412(b)(15)(A) requires the Agency to list a variance technology. Variance technologies may not achieve full compliance with the MCL but they must achieve the maximum contaminant reduction that is affordable considering the size of the system and the quality of the source water. In order for the technology to be listed, EPA must determine that this level of contaminant reduction is protective of public health.

A determination of national level affordability is concerned with identifying, for each of the given size categories, some central tendency or typical circumstance relating to their financial abilities. The metric EPA selected for this purpose is the median household income (MHI) for communities of the specified sizes. The household is thus the focus of the national-level affordability analysis. EPA considers treatment technology costs affordable to the typical household if they represent a percentage of MHI that appears reasonable when compared to other household expenditures. This approach is based on the assumption that the affordability to the median household served by the CWS can serve as an adequate proxy for the affordability of technologies to the system itself. The national-level affordability criteria have two major components: current annual water bills (baseline) and the affordability threshold (total % of MHI directed to drinking water). Current annual water bills were derived directly from the 1995 Community Water System Survey. Based on 1995 conditions, 0.75–0.78% of MHI is being directed to water bills for systems serving fewer than 10,000 persons.

The fundamental, core question in establishing national-level affordability criteria is: what is the threshold beyond which drinking water would no longer be affordable for the typical household in each system size category? Based upon careful analysis EPA believes this threshold to be 2.5% of MHI. In establishing this threshold, the Agency considered baseline household expenditures (as documented in the 1995 Consumer Expenditure Survey, Bureau of Labor Statistics) for piped water relative to expenditure benchmarks for other household goods, including those perceived as substitutes for piped water treated to higher standards, such as bottled water and point-of-use and point-of-entry devices. Based on these considerations, EPA concluded that current household water expenditures are low enough, relative to other expenditures, to support the cost of additional risk reductions. The detailed rationale for the selection of 2.5% MHI as the affordability threshold is provided in the guidance document entitled ''Variance Technology Findings for Contaminants Regulated Before 1996.'' The difference between the affordability threshold and current water bills is the available expenditure margin. This represents the dollar amount by which the water bill of the typical (median) household could increase before exceeding the affordability threshold of 2.5% of MHI.

By definition, the MHI is the income value exactly in the middle of the income distribution. The median is a measure of central tendency; its purpose is to help characterize the nature of a distribution of values. In the case of income, which tends not to be evenly distributed, the median is a much better indicator of central tendency than the mean, or arithmetic average, that could be significantly skewed by a few large values. The Agency recognizes that there will be half the households in each size category with incomes above the median, and half the households with incomes below the median. The objective of a national-level affordability analysis is to look across all the households in a given size category of systems and determine what is affordable to the typical, or ''middle of the road'' household.

The Agency recognizes that baseline costs change over time as water systems comply with new regulations and otherwise update and improve their systems. To take account of this upward movement in the baseline, the Agency plans to adjust the baseline it employs in its calculation in two ways. First, actual changes in the baseline will be measured approximately every 5 years by the Community Water System Survey. These changes will reflect not only the increased costs resulting from EPA drinking water rules, but also any changes resulting from other factors that could affect capital or operating and maintenance costs. Second, to the extent practical and appropriate during the period between Community Water System Surveys, the baseline will be adjusted to reflect the cost of rules promulgated during that period.

MHI also changes from year to year, generally increasing in constant dollar terms. For example, since 1995 MHI has increased (in 1999$) by 9.6%. Thus, to determine the available expenditure margin (the difference between the affordability threshold and the baseline) for each successive rule, adjustments would need to be made in both the baseline and the MHI.

Given the narrow and specific purpose for which the national-level affordability criteria are used, the Agency is not adjusting either the baseline or the MHI for its analysis for the final arsenic rule. As noted previously, MHI has increased by 9.6%. The rules, which have been promulgated since the baseline was developed, are the Interim Enhanced Surface Water Treatment Rule, the Stage 1 Disinfectants and Disinfection ByProducts Rule, the revised Radionuclides Rule, the Consumer Confidence Report Rule and the revised Public Notification Rule. The Interim Enhanced Surface Water Treatment Rule applies only to systems serving greater than 10,000 persons, so it has essentially no impact on the baseline costs for smaller systems. The Stage 1 Disinfectants and Disinfection ByProducts Rule does apply to small systems, and it has an impact on only 12% of the nearly 68,200 ground water systems serving $<$10,000 persons; and on 70% of the nearly 5200 surface water systems serving $<$10,000 persons. The revised Radionuclides Rule has limited impact since it, for the most part, reaffirmed long-standing MCLs. The Consumer Confidence Rule and revised Public Notification Rule result in no capital expenditures and only very modest administrative costs.

The Agency believes that, for purposes of assessing national-level affordability of the arsenic rule, the unadjusted baseline and unadjusted MHI are appropriate. Making adjustments to these two factors would not materially alter the outcome of the analysis.

The distinction between national-level affordability criteria and affordability assessments for individual systems cannot be over-emphasized. The national-level affordability criteria serve only to guide EPA on the listing of an affordable compliance technology versus a variance technology for a given system size/source water combination for a given contaminant. In the case of arsenic, EPA has determined that nationally affordable technologies exist for all system size categories and has therefore not identified a variance technology for any system size/source water combination. This means that EPA believes that the typical household in each system size category can afford the costs associated with the listed compliance technologies. EPA recognizes that individual water systems may serve a preponderance of households with incomes well below the median or may face unusually high treatment costs due to some unusual local circumstance.

SDWA provides a number of tools that States can use to address affordability concerns for these individual water systems. Two of these tools are financial assistance under the Drinking Water State Revolving Fund (DWSRF) and extended compliance time-frames under an exemption. SDWA allows States to provide special assistance to water systems that the State determines to be disadvantaged, using State-developed affordability criteria. This special assistance may include forgiveness of principal, a negative interest rate, an interest rate lower than that charged to non-disadvantaged systems, and extended repayment periods of up to 30 years. To date, about half of the States have implemented disadvantaged community programs as part of their DWSRF. Almost one quarter of all loans made under the DWSRF have been made to systems classified as disadvantaged by the States.

In addition to special financial assistance through the DWSRF, as discussed previously, systems facing affordability concerns may also be eligible for extended time to achieve compliance under the terms of a State-issued exemption or may receive assistance under the Rural Utilities Service (RUS) program of the United States Department of Agriculture (see section I.L). Together with the approximately $1 billion per year being made available through the DWSRF, this results in a total of about $1.78 billion per year of Federal financial assistance available for drinking water.

Decisions that a drinking water system makes about how to allocate its costs to users and how to design rates can also have a significant effect on affordability for low-income households. A traditional declining block rate structure would be regressive and might result in the households with the least income subsidizing excessive water use by more affluent households. Numerous alternative rate designs are possible that are more progressive. Of particular interest in addressing affordability concerns is lifeline rates. Lifeline rates are a rate structure applicable to qualified residential customers that includes a specified block of water use priced below the standard charge for the customer class. Such rates are primarily designed to aid the poor in obtaining some minimum level of service at an affordable price.

The basic organizational or institutional structure of the drinking water system is another very important factor that influences the affordability of water service. The key issue here is the extent to which a given organizational or institutional structure is capable of achieving economic and operational efficiency. An especially important element of this efficiency relates to the degree to which a system seeks to work together with other systems. Systems that effectively work together, perhaps by combining management, will realize lower overall costs compared to the same systems working independently.

F. What MCL Is EPA Promulgating and What Is the Rationale for This Level?

1. Final MCL and Overview of Principal Considerations

EPA is today promulgating a final arsenic MCL of 10 µg/L. EPA's selection of this MCL is based on the SDWA statutory requirements for establishing an MCL and reflects the Agency's detailed evaluation and careful consideration of thousands of pages of comments. As part of this process, we have evaluated new data and analysis on occurrence, unit treatment costs, small system impacts, treatment technology availability, waste disposal options, and uncertainties regarding exposure and health effects data. Based on this new information, the Agency has revisited technical analyses, calculations, and judgments underlying the proposed MCL of 5 µg/L. As discussed in section III.E. in this preamble, the Agency has conducted a thorough revaluation of costs and has carefully considered substantial new analysis on this subject submitted by commenters. In addition, EPA has completed a detailed reassessment of the risks of arsenic in drinking water, and has made significant adjustments to provide a more quantitative evaluation of major sources of uncertainty discussed at proposal and emphasized by commenters from a number of different perspectives.

Today's rule, with a final MCL of 10 µg/L, reflects the application of several provisions under SDWA, the first of which 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 SDWA amendments also require that the Administrator determine whether or not the quantifiable and nonquantifiable benefits of an MCL justify the quantifiable and nonquantifiable costs. This determination is to be based on the Health Risk Reduction and Cost Analysis (HRRCA) required under section 1412(b)(3)(C). The HRRCA must include consideration of seven analyses:

(1) The quantifiable and nonquantifiable benefits from treatment to the new MCL;

(2) The quantifiable and non quantifiable benefits resulting from reductions of co-occurring contaminants;

(3) The quantifiable and nonquantifiable costs resulting directly from the MCL;

(4) The incremental costs and benefits at the new MCL and alternatives considered;

(5) The health risks posed by the contaminant, including risks to vulnerable populations;

(6) Any increased risk resulting from compliance, including risks associated with co-occurring contaminants; and

(7) Any other relevant factor, including the uncertainties in the analyses and the degree and nature of risk.

Finally, the 1996 SDWA amendments provide 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)) based on the HRRCA analysis. Today's rule establishing an MCL of 10 µg/L for arsenic is the second time EPA has invoked this new authority. (The first such time was in the final rule for uranium, which was published on December 7, 2000; EPA, 2000p.)

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 and the various comments offered concerning these levels in response to the proposed rule. EPA has determined that a final MCL of 10 µg/L more appropriately meets the relevant statutory criteria referred to above, particularly after considering the following: Available information relating to the various health effects associated with arsenic; new analysis regarding the projected risk to the population of adverse health effects that would remain after implementation; the revised costs and benefits of the various options; the incremental costs and benefits; and the uncertainties in the benefit-cost and risk analyses. A summary of the results of the Agency's reanalysis of these various factors follows.

2. Consideration of Health Risks

The fifth and seventh HRRCA analyses focus on the health risks to be addressed by a new MCL. 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 associated benefits. 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) requires EPA to set the MCL at a level that ''maximizes health risk reduction benefits at a cost that is justified by the benefits.'' (EPA does not believe the sixth HRRCA analysis, consideration of increased risk likely to result from compliance is a significant factor in connection with selection of a final MCL; rather, we believe that many of the appropriate technologies for reducing arsenic will reduce many other co-occurring inorganic contaminants as well thereby decreasing, rather than increasing risk.)

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 a number of considerations, including the bladder cancer risk analysis developed by the National Research Council (NRC) of the National Academy of Sciences (NRC, 1999); the NRC's qualitative assessment of other possible adverse health effects; the lung cancer risk analysis developed by Morales et al. (2000); and findings of other relevant national and international studies. This information included, but was not limited to, findings from epidemiological studies in South America cited in the NRC report (NRC, 1999) and a study of a population exposed to high levels of arsenic in Millard County, Utah conducted by Lewis, *et al.* (1999).

Among the factors EPA considered in choosing the final MCL was Congress' intent that EPA ''reduce * * * [scientific] uncertainty'' in promulgating the arsenic regulation reflected in section 1412(b)(12) arsenic research plan provisions and the legislative history on the arsenic provision (S. Rep. 104–169, 104th Cong., 1st Sess. at 39–40). The uncertainties in the analyses of costs, benefits and risks are also a factor required to be considered in the HRRCA. All assessments of risk are characterized by an amount of uncertainty. Some of this uncertainty 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 several definable sources of uncertainty that were taken into account. These include, but are not limited to, the following:

- Uncertainty about the exact exposure of individuals in the study population to arsenic in drinking water, water used in cooking, and food;
- Uncertainties associated with applying data from a population in rural Taiwan to the heterogenous population of the U.S. (including differences in health status and diet between the Taiwanese and the U.S. population); and
- Uncertainties concerning precisely how a chemical causes cancer in humans (the mode of action) that affects assessments of the extent and severity of health effects at low doses.

Section III.D. of the preamble to today's final rule provides a detailed explanation of how these uncertainties associated with the risk analysis were taken into account in developing a revised estimate of the risk of arsenic in drinking water. Based on comments and available information, the Agency has focused, in particular, on the first uncertainty bullet, and made two adjustments to its risk analysis to reduce uncertainty and more accurately apply data from the Taiwan study to the U.S. population. EPA has revised its quantified estimate of the risks of arsenic in drinking water to adjust for exposure to arsenic in both cooking water and food in the Taiwanese study and has also developed a risk range for the combined effects of bladder and lung cancer to reflect the scope of uncertainty underlying these estimates. Thus, one of the previously listed uncertainties has specifically been taken into account quantitatively, while others continue to be considered in a qualitative sense.

In EPA's judgment, use of a risk range more clearly supports a qualitative consideration and recognition of the uncertainties that are inherent in any risk analysis that substantially relies upon epidemiological information. EPA believes that the health risk analysis presented in section III.D. of today's rule comprises a plausible range of likely risk associated with various concentrations of arsenic in drinking water. As just suggested, we do not believe it is appropriate to select a central or ''best estimate'' of the risk, due to the uncertainties associated with the underlying health effects studies and the various plausible assumptions used in considering these uncertainties for our risk analysis. This revised analysis of risks was used in recalculating the benefits attributable to reducing arsenic in drinking water from its present levels. EPA also recognizes that the latter two bulleted sources of uncertainty may operate to reduce the risk estimates if it were possible to account for them quantitatively.

3. Comparison of Benefits and Costs

Under HRRCA analyses one and two, the Agency must consider both quantifiable and nonquantifiable health risk reduction benefits. Benefits considered in our analysis include those about which quantitative information is known and can be monetized as well as those which are more qualitative in nature (such as some of the non-cancer health effects potentially associated with arsenic) and which cannot currently be monetized. Important assumptions inherent in EPA's revised analysis of the benefits estimates include the value of a statistical life and willingness to pay to avoid illness. These assumptions and various adjustment factors considered for our benefits analysis are explained in detail in section III.E. of this preamble.

EPA considered the relationship of the monetized benefits to the monetized costs for each the regulatory levels it considered. While strict equality of monetized benefits and costs is not a requirement under section 1412(b)(6)(A), this relationship is an important consideration in the regulatory development process. The monetized costs and monetized benefits of this final rule, and the methodologies used to calculate them, are discussed in detail in section III. E. of this preamble and in the arsenic Economic Analysis.

EPA believes, however, that reliance on only an arithmetic analysis of whether monetized benefits outweigh monetized costs is inconsistent with the statute's instruction to consider both quantifiable and nonquantifiable costs and benefits. The Agency therefore examined and considered qualitative and non-monetized benefits in establishing the final MCL, as well as other factors discussed previously. These benefits are associated with avoiding certain adverse health impacts known to be caused by arsenic at higher concentrations, which may also be associated with low level concentrations, and include skin and prostate cancer as well as cardiovascular, pulmonary, neurological and other non-cancer effects. (These health effects are discussed in Section III.D. of this preamble.)

Other potential benefits not monetized for today's final rule include customer peace of mind from knowing drinking water has been treated for arsenic and reduced treatment costs for contaminants that may be co-treated with arsenic. (For example, increased use of coagulation and micro filtration by surface water systems will offer benefits with respect to removal of microbial contaminants and disinfection byproducts.)

HRRCA analyses three and four require EPA to consider the costs of compliance with the rule and the incremental costs and benefits. EPA has also revised the cost of compliance estimates associated with the various possible regulatory levels considered for today's final rulemaking. The central estimate of costs has risen modestly since the proposed rule based on our further analysis of the information and data provided by commenters. However, in response to comments, we have also performed a sensitivity analysis that addresses a number of variables in our analysis and which indicates that the costs of compliance could exceed our central estimate by as much as 22%.

In comparing monetized costs and benefits, we conducted several types of analyses, including:

- Comparison of total national costs and benefits (Table III.E–7);
- Analysis of incremental costs and benefits (comparing one regulatory option to another) (Table III.E–9);
- Estimates of net benefits (Table III.E–8); and
- Examination of benefit-cost ratios (Table III.E–8).

Detailed descriptions of our analyses appear in section III.E. of this preamble and in the Economic Analysis supporting today's rule. Our consideration of these analyses in support of the rationale for the final MCL is discussed below.

4. Rationale for the Final MCL

The rationale for the final MCL promulgated with today's rule is based on the HRRCA analyses outlined previously and the statutory criteria for setting an alternative (higher than feasible) MCL under section 1412(b)(6). These analyses include:

- A revised risk analysis of arsenic in drinking water;
- A revised analysis of total costs;
- A revised analysis of total benefits;
- A comparison of costs and benefits using various metrics at various MCL options (including incremental costs and benefits); and
- Other pertinent factors (including uncertainties and the degree and nature of risk).

In the proposed rule, EPA indicated a preference for a standard at 5 μg/L, but solicited comment on MCL options of 3 μg/L, 10 μg/L, and 20 μg/L, depending upon how uncertainties were addressed in the risk analysis as well in the calculation of costs and benefits. However, EPA also noted that, between the time of proposal and promulgation of the final rule, it would work to resolve as much of this uncertainty as possible. As described earlier, the principal revised analyses conducted since the rule was proposed and considered in our selection of the final MCL include: A revised analysis of the uncertainties of the health effects that has generated a revised risk range for the various MCL options considered; a revised range of benefits associated with our current estimates of the risks; and a revised analysis of costs, including uncertainty and sensitivity analyses. These revised analyses allow an updated comparison of the costs and benefits for the various regulatory options considered.

a. General considerations. As explained in section III.E. of today's preamble, both our benefits and cost estimates involve ranges, rather than point estimates, due to a variety of factors. Thus, our consideration of costs and benefits involved an examination and comparison of these ranges. As can be seen from Table III.E–7, both total costs and benefits increase as one examines progressively lower (*i.e.,* more stringent) regulatory options compared to higher options. However, the benefits and costs do not increase proportionately across the range of regulatory options as shown by a comparison of net benefits (defined as costs minus benefits). Progressively more stringent regulatory options become considerably more expensive, from a cost standpoint, than the corresponding increases in benefits, as reflected in decreasing net benefits. (see Table III.E–8.)

b. Relationship of MCL to the feasible level (3 μg/L). The MCL must be set as close as feasible to the MCLG, unless EPA invokes its discretionary authority under section 1412(b)(6) of SDWA to set an alternative MCL, which must then be set at a level that maximizes health risk reduction benefits at a cost that is justified by the benefits. As explained earlier in this preamble, the MCLG is zero and the feasible level is 3 μg/L. The Agency believes that there are several important considerations in examining the feasible level. In comparing the benefits and the costs at this level (see Table III.E–7), we note that it has the highest projected total national costs (relative to the other MCL options considered). In addition, while the benefits are highest at this level relative to the other MCL options, both the net benefits and the benefit/cost disparity at the feasible level are the least favorable of the regulatory options considered. For these reasons, we believe benefits of the feasible level do not justify the costs. Almost all commenters agreed with this conclusion in the proposal.

c. Reanalysis of proposed MCL and comparison to final MCL. Based on substantial public comment, EPA has reexamined the proposed MCL of 5 μg/L. In comparing this level to 10 μg/L, we note that both the net benefits and the benefit-cost relationships are less favorable for 5 μg/L as compared to 10 μg/L. Total national costs at 5 μg/L are also approximately twice the costs of an MCL of 10 μg/L. At 10 μg/L, EPA notes that the lung and bladder cancer risks to the exposed population after the rule's implementation are within the Agency's target risk range for drinking water contaminants of 1×10^{-6} to 1×10^{-4} or below. EPA recognizes that there is uncertainty in this quantification of cancer risk (as well as other health endpoints) and this risk estimate includes a number of assumptions, as discussed previously. EPA did not directly rely on the risk range in selecting the final MCL, since it is not part of the section 1412(b)(6) criteria; however, it is an important consideration, because it has a direct bearing on our estimates of the benefits of the rule.

d. Consideration of higher MCL options. EPA does not believe an MCL less stringent 10 μg/L is warranted from the standpoint of benefit-cost comparison. While total national costs associated with 20 μg/L are the lowest of the regulatory options considered, benefits are also the lowest of these options. Both regulatory options of 10 μg/L and 20 μg/L have relatively favorable benefit-cost relationships relative to lower regulatory options but are not significantly different from one another based on this comparison metric. However, the incremental, upper-bound benefits at 10 μg/L are more than twice those of 20 μg/L; and 10 μg/L is clearly the more protective level. Thus, we do not believe that an MCL of 20 μg/L would ''maximize health risk reduction benefits'' as required for an MCL established pursuant to section 1412(b)(6).

e. Conclusion. 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 section 1412(b)(6) of SDWA. However, EPA believes that, based on comparisons of cost and benefits (using the various benefit-cost comparison tools discussed), the monetized benefits of a regulatory level of 10 μg/L best justify the costs. In addition, as discussed in section III.D. and elsewhere in today's preamble, our further qualitative consideration of the various sources of uncertainty in our understanding of arsenic since the proposal (e.g., such as that surrounding the mode of action), has led us to conclude that our estimate of risk (for the risks we have quantified) is most likely an upper bound of risks and that the higher MCL of 10 µg/L is appropriate. Finally, as discussed in section III.E. of this preamble EPA believes that there are a number of not yet quantified adverse health effects and potentially substantial non-monetized benefits at 10 µg/L that increase the overall benefits at this level.

In summary, based on our reanalysis of costs, benefits, and health risk reduction, and factoring in the uncertainties in these analyses and the degree and nature of risk, EPA believes the final MCL of 10 µg/L represents the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits and that the other regulatory options considered in the proposed rule do not satisfy the statutory requirements of section 1412(b)(6) of SDWA. We are therefore exercising our discretionary authority under the statute to establish an MCL at a level higher than the feasible level and setting that level at 10 µg/L.

IV. Rule Implementation

A. What Are the Requirements for Primacy?

States must revise their programs to adopt any part of today's rule that 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. A State's request 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.'' Today's rule does not require States to submit information in § 142.16(e) for primacy revisions associated with the revised arsenic MCL. The final rule notes that § 142.16(e) primacy revision information will only be required for new contaminants, not revisions of existing regulated contaminants.

B. What Are the Special Primacy Requirements?

Today's rule adds special primacy requirements in § 142.16(j) and § 142.16(k) to the State special primacy requirement section. Section 142.16(j) clarifies that for an existing regulated contaminant such as arsenic, States 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 (NPDWRs) for organic and inorganic contaminants (the Phase II/V rules). Alternatively, the State may inform the Agency in its application of any changes to the monitoring plans and waiver procedures.

Section 142.16(k) requires States to establish initial monitoring requirements for new systems and new sources. Many States already have developed monitoring programs for new systems and for systems that are using new sources of water. To meet the requirements of § 142.16(k), States that have existing requirements may simply explain to EPA in their primacy revision package their monitoring schedule and how the State can ensure that all new systems and new sources will comply with the existing MCLs and monitoring requirements. Some States may wish to explain that monitoring for new systems is established on a case-by-case basis. States should explain the factors that are considered as case-by-case determinations are made.

When a State develops or modifies an initial monitoring program for new systems and new sources, it should ensure that the program reflects the contaminant(s) of concern for that State, known contaminant use, historical data, and vulnerability. Because of varying contaminant uses and sources, some contaminants occur at higher levels in some regions of the country than in other regions. Additionally, the concentrations of some contaminants are known to show clear seasonal peaks, while others remain constant throughout the year. For example, some States may be concerned with atrazine and require multiple samples during a specified vulnerable period (*e.g.,* May 1–July 31), while another State may only require one sample for the entire year. Alternatively, another State may be concerned about trichloroethylene and require four quarterly samples.

C. What Are the State Recordkeeping Requirements?

The standard record keeping requirements for States under SDWA apply to the arsenic rule (§ 142.14). Today's rule does not modify or require additional recordkeeping requirements. States with primacy must keep all records of current monitoring requirements and the most recent monitoring frequency decision pertaining to each contaminant, including the monitoring results and other data supporting the decision, and the State's findings based on the supporting data and any additional bases for such decision. These records must be kept in perpetuity or until a more recent monitoring frequency decision has been issued.

D. What are the State Reporting Requirements?

Currently, States with primary enforcement responsibility must report to EPA information under § 142.15 regarding violations, variances and exemptions, and enforcement actions and general operations of State public water supply programs. Today's rule does not modify or require additional reporting requirements. The State reporting requirements that will apply to the arsenic standard are the same as all other regulated inorganic contaminants.

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

To maintain primacy for the Public Water Supply Supervision (PWSS) program and to be eligible for interim primacy enforcement authority for future regulations, States must adopt today's final rule. A State must submit a request for approval of program revisions that adopt the revised MCL and implement regulations within two years of promulgation, unless EPA approves 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.

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

Currently, the Navajo Nation is the only Tribe with primacy for all the National Primary Drinking Water Regulations, and it will be subject to the same requirements as a State. There are no other Federally recognized Indian tribes with primacy to enforce any of the drinking water regulations. EPA's Regions have responsibility for implementing the rules for all Tribes except the Navajo Nation under section 1451(a)(1) of SDWA. To obtain primacy authority for the revised arsenic MCL, Tribes must submit a primacy application to regulate inorganic contaminants (*i.e.*, the Phase II/V rule).

V. Responses to Major Comments Received

A. General Comments

1. Sufficiency of Information and Adequacy of Procedural Requirements To Support a Final Rule

A number of commenters challenged EPA's basis for promulgating a final rule, arguing that (1) there was insufficient technical information provided with the proposed rule, (2) various expert technical evaluations were not adequately considered, or (3) procedural requirements (*e.g.*, Unfunded Mandates Reform Act (UMRA), Small Business Regulatory and Enforcement Flexibility Act (SBREFA)) have not been fully satisfied. EPA respectfully disagrees, and we believe that the record of our actions is sufficient to support a final rulemaking. Other portions of the preamble to today's rule explain the technical evaluations performed in support of the proposed rule and the revised analyses conducted, based on comments and information submitted in response to the proposal. EPA recognizes that various questions about different aspects of this rulemaking have been the subject of an array of analyses and reports by various investigators. This area of investigation has also been dynamic, and there will undoubtedly be additional analyses after promulgation of the final rule that the Agency will need to consider in light of the requirement to periodically review (and revise as appropriate) all final drinking water regulations as provided by section 1412(b)(9) of SDWA. However, we believe that we have fully and appropriately considered all available and relevant information for the final rulemaking and do not need to repropose as several commenters suggest. We also believe that we have fully satisfied the procedural requirements of the pertinent statutory and Executive Order requirements. Section VI. of the preamble to today's final rule discusses these procedural requirements in more detail.

2. Suggestions for Development of an Interim Standard

Several commenters advocated an interim standard in view of the uncertainties associated with the health effects data, the costs of compliance with the final rule, and concerns over the interpretation of the ''anti-backsliding'' provision of SDWA related to review and revision of existing standards (section 1412(b)(9)). While EPA appreciates these concerns, we do not believe that they provide a sufficient basis for concluding that an interim standard be set. We agree with the recommendation of the National Academy of Sciences that there is sufficient information available now to develop a new lower drinking water standard for arsenic. We further believe that available information is sufficient to support a final, rather than an interim, standard. Finally, there is simply no authority in SDWA to establish an interim standard that does not comply with sections 1412(b)(4) and 1412(b)(6). However, we are committed to reviewing and revising, if appropriate, the final standard every six years (or sooner, if pertinent new information becomes available). In so doing, we must ensure that the revised standard provides for ''equal or greater protection to the health of persons'' as compared to the standard it replaces.

3. Public Involvement and Opportunity for Comment

Some commenters questioned whether the extent of public involvement in the development of today's rule was sufficient. Some commenters also suggested that the Agency use a negotiated rulemaking process for the final rule pursuant to the Federal Advisory Committee Act (FACA). EPA believes that public involvement throughout the development of this rule, has been extensive and far-reaching. As discussed in section I.N. earlier in this preamble, during the period 1996–2000, EPA conducted a number of Agency workgroup meetings on arsenic and advertised six stakeholder meetings (held in five locations) in the **Federal Register**. Five States also provided written comments on implementation issues during the workgroup process. Representatives of eight Federal agencies, 19 State offices, 16 associations representing the breadth of the public water system community, 13 corporations, 14 consulting engineering companies, two environmental organizations, three members of the press, 37 public utilities and cities, four universities, and one Indian tribe attended the stakeholder meetings on arsenic. EPA presented an overview of the arsenic rulemaking to over 900 Tribal representatives in 1998 and provided more detailed information in 1999 to 25 Tribal council members and water utility operators from 12 Indian tribes. In addition, EPA provided updates on our rulemaking activities at national and regional meetings of various groups and trade associations. We also participated in the American Water Works Association's (AWWA) technical workgroup meetings. As part of the Small Business Regulatory and Enforcement Flexibility Act (SBREFA) process, EPA also received valuable input from discussions with small entity representatives during SBREFA consultations for the arsenic rule. EPA obtained recommendations from the National Drinking Water Advisory Council (NDWAC) on the rule as a whole as well as on our approach benefits analysis and small systems affordability. We also posted discussion papers produced for our stakeholder interactions on the EPA Office of Ground Water and Drinking Water (OGWDW) Internet site and sent them directly to participants at stakeholder meetings and others who expressed interest. EPA also received over 1,100 comments on the June 22, 2000 proposed rule. EPA took these comments into consideration in developing today's final rule.

EPA agrees that the FACA-negotiated rulemaking process has been an effective one in the past for other complex rulemakings. However, EPA does not believe that a negotiated rulemaking at this point is consistent with the deadlines set by Congress for this rulemaking. We would point out, however, that the Agency has taken a number of active steps to ensure broad-based stakeholder involvement, as described previously, and has solicited expert points of view outside the Agency. Some of these actions included a charge to the National Academy of Sciences (NAS) to fully explore the most current health effects issues. A charge was also given to EPA's Science Advisory Board (SAB) to review key aspects of the proposed rule and EPA's underlying rationale. EPA believes that this combination of actions ensured that full and complete stakeholder involvement occurred, and that further negotiations would be unnecessary.

4. Relation of MCL to the Feasible Level

Several commenters questioned the feasible level of 3 μg/L contained in the proposed rule. Commenters believed that EPA has not accurately assessed the capabilities of laboratories to achieve the practical quantitation level (PQL) or of treatment technologies to reliably and consistently treat down to the feasible level. EPA disagrees and still believes that 3 μg/L is feasible from the standpoints of both analytical methods and treatment technologies. EPA discusses these issues in more detail in section III.B. of the preamble to today's final rule. Many of the comments on the proposed rule were concerned by the close proximity of the proposed standard (5 µg/L) to the proposed feasible level (3 µg/L). However, comments regarding whether or not the proposed standard of 5 µg/L is feasible are not particularly germane to the setting of the final standard, which is well above any level identified by most commenters as being feasible.

5. Relationship of MCL to Other Regulatory Programs

Many commenters expressed concerns about the possible impact of a new revised drinking water standard for arsenic on other regulatory standards for arsenic. In particular, several commenters recommended that EPA consider the prospective costs of future Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) site clean-up actions, RCRA hazardous waste management costs, or national permit discharge elimination system (NPDES) permits to the extent that a new arsenic in drinking water standard leads to more stringent regulatory actions under those respective statutes. EPA disagrees and notes that SDWA specifically excludes from consideration under the HRRCA such prospective, ancillary costs in developing a drinking water standard (see section 1412(b)(3)(C) of SDWA).

6. Relation of MCL to WHO Standard

Several commenters on the proposed rule expressed a concern that the drinking water standard in the U.S. should be no more stringent than the standard developed for the World Health Organization (WHO). This comment dealt primarily with the proposed level of 5 µg/L and does not apply to the final MCL of 10 µg/L, which is identical to the WHO standard. However, while the thrust of the comment is now moot, EPA notes that the basis for the final MCL and the WHO standard are different. EPA's standard is based on consideration of all of the risk management factors required to be evaluated under SDWA (*e.g.*, risk, costs, benefits, treatment technology and analytical method capabilities, small systems affordability, etc.) while the WHO standard is based solely on health effects, without regard to any implementation considerations. Further, the health basis for the WHO standard is primarily an assessment of arsenic-induced skin cancer, whereas there are a number of health endpoints of concern in EPA's analysis including lung and bladder cancer. In summary, the two levels (the WHO standard and EPA's final MCL) happen to be the same but a possible future change in the WHO standard would not necessarily require a revision to EPA's MCL, for the reasons just discussed.

7. Regulation of Non-Transient Non-Community Water Systems (NTNCWSs)

Several commenters objected to the approach outlined in the proposed rule for addressing NTNCWSs (monitoring and reporting only) and pointed out the need for consistency in coverage of NTNCWSs in EPA's rules. These commenters noted that the rules originally promulgated in 1976 (arsenic and radionuclides) have not required coverage of NTNCWSs, whereas more recently promulgated rules have. In addition, EPA's proposed radon rule suggested not covering NTNCWSs and the recently promulgated radionuclides rule did not require coverage of NTNCWSs, but instead deferred this issue for future resolution. EPA agrees that the outcomes of its recent decisions with respect to coverage of NTNCWSs have been different. However, we considered the merits of each rulemaking on a case-by-case basis using a consistent set of criteria, namely the cost/benefit analysis required under section 1412(b)(4).

For the proposed arsenic rule, EPA carefully examined the risks posed by NTNCWSs and concluded preliminarily that the risks were such that, without coverage, consumers of water from NTNCWSs were projected to be within the target risk range. EPA acknowledges, however, that there is uncertainty associated with its information about exposure patterns for consumers of water from NTNCWSs and the demographics of these facilities. Thus, our understanding of the health risks (and associated possible benefits of removal) to consumers of water from NTNCWSs is uncertain. In the case of arsenic, EPA believes the additional uncertainty in the overall risk analysis argues against any finding at this point that these systems are substantially different in terms of exposure than community water systems. EPA also believes the decision to cover these facilities in today's rule is supported by consideration of the risks to certain subpopulations within the general population, such as children who consume water at day care facilities or schools that are served by NTNCWSs.

Concerns were also expressed about whether commenters were provided with sufficient information about the costs of full coverage. These commenters noted that EPA could not, without violating the notice and comment provisions of the Administrative Procedure Act, move to full coverage of these facilities in the final rule. EPA disagrees with this comment. The proposal clearly indicated that full coverage of NTNCWSs was an option on which comment was being requested and the supporting documents provided complete information about the costs of full coverage. (EPA, 2000h, see Table 6–9).

8. Extension of Effective Date for Large Systems

Commenters were generally supportive of EPA's proposed national determination (pursuant to section 1412(b)(10) of SDWA) that water systems covered by the rule, serving less than 10,000 persons, and needing to make capital improvements to comply with the new standard would need more than 3 years from the time of rule promulgation to accomplish this. Thus, the proposed rule suggested allowing a two-year extension for compliance with the new standard, beyond the three years provided after the promulgation date. However, several commenters suggested that this finding and the additional two years for compliance should be applicable to all systems, including those serving more than 10,000 persons, since extensive planning, design, and new equipment will also generally be needed by larger systems in a similar situation to comply with the new standard. EPA was persuaded by these comments, and has, as part of the implementation requirements for today's final rule, elected to apply this two-year extension to all facilities covered by today's rule.

B. Health Effects of Arsenic

1. Epidemiology Data

Many commenters were critical of the Taiwan epidemiologic study as a basis for EPA decision making, quantitative dose-response assessment, extrapolation of the dose-response from the observed range of exposure, and application of the same risk estimate to the U.S. population. No commenters challenged the EPA conclusion that this study and the other epidemiologic studies together show that arsenic is carcinogenic to humans. Some supported the risk analysis in the proposed rule and the notice of data availability (NODA) because it is relatively risk averse; others had criticisms.

The following issues were raised about the use of the Taiwan risk assessment to represent U.S. risk: Arsenic exposure from food and via cooking with contaminated water in Taiwan is higher than is typical for the U.S. population; exposure groupings were made at the village level and were assigned the median of the concentration of arsenic measured in the wells serving that village; not all wells serving all villages were measured and well concentrations varied seasonally; the Taiwan population was a rural population that was not well nourished, having deficits of selenium, possibly methionine or choline (methyl donors), zinc and other essential nutrients; and the Taiwan population may have unknown differences in genetic polymorphisms from the U.S. population. Similar concerns were raised about the South American studies.

Commenters also cited studies in the U.S. (Lewis *et al.*, 1999, Utah population) and Europe (Buchet *et al.*, 1999; Kurttio *et al.*, 1999) as support for the position that the risks from the Taiwan study overestimated the risks in the U.S.

Many commenters were convinced that the Lewis *et al.* (1999) study of a U.S. population is the best study to use in estimating U.S. risk. Since the Utah study did not observe cancer outcomes that one would expect if risks were as large as the Taiwan or South American studies suggest, these commenters believe that risks estimates from studies of populations outside of the U.S. overestimate U.S. risks.

Scientists generally agree that high doses of arsenic are associated with various cancer and noncancer health effects in humans. Epidemiology studies in humans demonstrate that arsenic induces skin and internal (*e.g.,* bladder and lung) cancers and non-cancer effects such as skin keratoses and vascular abnormalities when ingested in drinking water at high doses.

The epidemiologic investigations that have been most thorough in investigating the exposure and effects on humans of ingesting ground water contaminated with arsenic are those of populations in Taiwan (Chen *et al.,* 1985; 1988; 1992; Wu *et al.,* 1989), Argentina (Hopenhayn-Rich *et al.,* 1996; 1998), Chile (Smith *et al.,* 1998), and the U.S. (Lewis *et al.,* 1999). All of these and other, smaller studies have been considered in the Agency's deliberations on this rule.

The studies from Taiwan, Chile, Argentina and the U.S. employed the proper endpoints, selected correct study groups and grouped the people into discrete exposure groups. They also used acceptable methods and accounted for some known confounders. These studies, due to their relative sizes, varied in their statistical power to detect differences. The Utah study (Lewis *et al.,* 1999) contained 4,000 people while the Taiwan study had approximately 40,000 people and the two South American studies each had over 200,000 people. All of these epidemiology studies were ecological and retrospective studies. The Taiwan and South American studies had no individual exposure data. The Utah study associated persons with wells that had measured concentrations though exposure was calculated based on both level of arsenic and length of exposure. The Utah study followed exposed individuals to discern causes of later disease through carefully kept church records.

The Agency chose to make its quantitative estimates of risk based on the Taiwan study. This choice was endorsed by the EPA Science Advisory Board (SAB, 2000q; NRC, 1999). The database from Taiwan has the following advantages: Mortality data were drawn from a cancer registry; arsenic well water concentrations were measured for each of the 42 villages; there was a large, relatively stable study population that had life-time exposures to arsenic; there are limited measured data for the food intake of arsenic in this population; age- and dose-dependent responses with respect to arsenic in the drinking water were demonstrated; the collection of pathology data was unusually thorough; and the populations were quite homogeneous in terms of lifestyle. Studies in Argentina and Chile also showed lung and bladder risk of similar magnitude at comparable levels of exposure. EPA recognizes that there are problems with the Taiwan study that introduce uncertainties to the risk analysis such as: the ecological study design; the use of median exposure data at the village level; the low income and relatively poor diet of the Taiwanese study population (high levels of carbohydrates, low levels of protein, selenium and other essential nutrients); and high exposure to arsenic via food and cooking water.

As urged by many commenters, the Agency has considered and made adjustments in its dose-response assessment to reflect the quantitative effect of the high Taiwanese exposure to arsenic via food and cooking water. The Agency made an adjustment to the lower bound risk estimates to take into consideration the effect of exposure to arsenic through water used in preparing food in Taiwan. In addition, an adjustment was made to the lower bound risk estimates to take into consideration the relatively high arsenic concentration in the food consumed in Taiwan as compared to the U.S. We also considered several additional factors qualitatively in our final decision. These included the effect of the median well exposure data from the Taiwan study and the effects of nutritional factors such as selenium and methyl donors. However, we did not feel that there were sufficient data to account for these factors quantitatively.

The U.S. population cannot be considered to be made up entirely of well-nourished, genetically uniform persons. People of the Asian and Pacific Islander group make up about 4% (approximately 11 million) of the more than 270 million people in the U.S. (U.S. Census Bureau, 2000). In addition, there is a significant portion of the U.S. population living in poverty with poor nutrition. Thus, the Agency continues to believe that the Taiwan study is appropriate as a basis for risk assessment. The fact that the whole of the Taiwanese population was nutritionally vulnerable is a factor that the Agency has considered qualitatively as an uncertainty in risk assessment that may on average lead to overestimation of risk when applied to the U.S.

The Utah study (Lewis *et al.,* 1999) did not find any excess bladder or lung cancer risk after exposure to arsenic at concentrations of 14 to 166 µg/L. An important feature of the study is that it estimated excess risk by comparing cancer rates among the study population in Millard County, Utah to background rates in all of Utah. But the cancer rates observed among the study population, even those who consumed the highest levels of arsenic, were significantly lower than in all of Utah. This is evidence that there are important differences between the study and comparison populations besides their consumption of arsenic. One such difference is that Millard County is mostly rural, while Utah as a whole contains some large urban populations. Another difference is that the subjects of the Utah study were all members of the Church of Jesus Christ of Latter Day Saints, who for religious reasons have relatively low rates of tobacco and alcohol use. For these reasons, the Agency believes that the comparison of the study population to all of Utah is not appropriate for estimating excess risks. An alternative method of analysis is to compare cancer rates only among people within the study population who had high and low exposures. The Agency performed such an analysis on the Utah data, using the statistical technique of Cox proportional hazard regression (U.S. EPA, 2000x; Cox and Oakes, 1984). The results showed no detectable increased risk of lung or bladder cancers due to arsenic, even among subjects exposed to more than 100 µg/L on average. On the other hand, the excess risk could also not be distinguished statistically from the levels predicted by model 1 of Morales *et al.* (2000). These results show that the Utah study is not powerful enough to estimate excess risks with enough precision to be useful for the Agency's quantitative arsenic risk analysis. Furthermore, the SAB noted that ''(a)lthough the data provided in published results of the Lewis, *et al.,* 1999 study imply that there was no excess bladder or lung cancer in this population, the data are not in a form that allows dose-response to be assessed dependably'' (EPA, 2000q). Other studies in the U.S. (Morton *et al.,* 1976; Valentine *et al.,* 1992; Wong *et al.,* 1992) and Europe (Buchet *et al.,* 1999; Kurttio *et al.,* 1999) were also considered in EPA's evaluation of the risk from arsenic. However, these studies were not sufficient to develop a dose-response relationship.

2. Dose-Response Relationship

Numerous comments were received about the quantitative estimation of potential cancer risks to U.S. populations from drinking water exposure to arsenic. Concerns were raised about the extrapolation of the dose (exposure)—response relationship observed in a study of cancer incidence in an arseniasis-endemic area of Taiwan with high levels of arsenic in water (Chen *et al.,* 1988; Wu *et al.,* 1989; Chen *et al.,* 1992) to estimate potential response in the U.S. to arsenic in water at lower levels.

Some commenters asked whether it is appropriate to assume a linear dose response for arsenic given that arsenic does not appear to be directly reactive with DNA. Other commenters urged strict adherence to the linear approach, and recommended choosing an MCL that is below the 1/10,000 level of estimated risk based on that approach.

Some commenters also noted that independent scientific panels (EPA, 2000q; NRC, 1999; EPA, 1997e; EPA, 1988) who have considered the Taiwan study have raised the caution that using the Taiwan study to estimate U.S. risk at lower levels may result in an overly conservative estimation of U.S. risk. The independent panels have each said that below the observed range of the high level of contamination in Taiwan the shape of the dose-response relationship is likely to be sublinear. Thus, an assumption that the effects seen per dose increment remain the same from high to low levels of dose may overstate the U.S. risk. Some commenters have urged that the Agency model the dose-response relationship as a sublinear one, rather than as a linear one as in the proposal and NODA for the rule. These commenters consider adherence to the linear model as a failure of the Agency to use the best available, peer-reviewed science as required by SDWA.

After consideration of the arguments made by the commenters, the Agency continues to believe that the best approach, given the uncertainties associated with the available data, is to use the linear approach to set the MCLG for arsenic. In the proposal and the NODA, EPA discussed the fact that the available data on arsenic's carcinogenic mode of action point to several potential modes of action, but which one is operative is unknown. For this reason, the data do not support use of an alternative to linearity. The Agency recognizes that the dose-response relationship may be sublinear. The Agency has considered both a linear extrapolation and a nonlinear approach in the selection of an MCL in this final rule. (see section III.D.1.g. and the comment response document for a thorough discussion of the Agency's position on the dose-response assessment for arsenic.)

3. Suggestions That EPA Await Further Health Effects Research

Several commenters expressed the opinion that EPA should delay setting a standard for arsenic until more research studies have been completed. These commenters focused on research areas such as health effects (especially at low doses), the mode of action, and the dose-response curve. Other commenters questioned EPA's support of new research and tracking of ongoing research.

Since developing the Arsenic Research Plan as required by the 1996 SDWA amendments, EPA and stakeholders have established a substantial research program. Significant research has been completed, and further research is underway. EPA is tracking the progress of ongoing research and will make research results available to the public. EPA is committed to issuing the arsenic regulation based on best available science and believes that the research currently available is sufficient to do so.

EPA believes that the research underway may provide important new data for future rulemakings on arsenic. However, EPA does not believe that a determination on the arsenic MCL must be delayed until this research is complete. Indeed, the U.S. Court of Appeals for the District of Columbia Circuit found that EPA:

> cannot reject the ''best available'' evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action—a possibility that will always be present'' and that ''[a]ll scientific conclusions are subject to some doubt; future hypothetical findings always have the potential to resolve the doubt. What is significant is Congress's requirement that the action be taken on the basis of the best available evidence at the time of rulemaking. The word ''available'' would be senseless if construed to mean ''expected to be available at some future date'' (*Chlorine Chemistry Council* v. *EPA,* 206 F.3d 1286, 1290–91 (D.C. Cir. 2000)).

In the future, as part of the 6-year review process, the Agency will evaluate new data to determine if the MCLG and/or MCL promulgated in today's regulation should be revised.

Research pertaining to arsenic in the drinking water is a priority for the EPA. In addition, EPA supports and encourages other organizations to sponsor new epidemiology and toxicology studies on arsenic. The nature of scientific research is that as each study attempts to address or resolve a particular issue, it also raises more questions for investigation. EPA recognizes that even when the ongoing set of studies are complete, more are likely to follow. Uncertainty is inherent in science; at no point will ''all'' research be finished and ''all'' questions be answered.

4. Sensitive Subpopulations

Some commenters encouraged EPA to set the arsenic standard as low as possible to protect vulnerable populations. These commenters felt that EPA should consider human development and reproduction and variously defined vulnerable populations as persons with immune, cardiovascular, and nervous system disorders, children, low-income people, Native Americans, diabetics, and geriatric populations.

The 1996 SDWA amendments include specific provisions in section 1412(b)(3)(C)(i)(V) that require EPA to assess the effects of a 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. The NRC subcommittee (NRC, 1999) noted that there is a marked variation in susceptibility to arsenic-induced toxic effects which may be influenced by factors such as genetic polymorphisms (especially in metabolism), life stage at which exposures occur, sex, nutritional status, and concurrent exposures to other agents or environmental factors. EPA shares the view of the NRC report which 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. The EPA agrees with NRC that there is not enough information to make risk conclusions regarding any specific subpopulations. However, EPA believes it is appropriate to consider effects on infants due to their greater consumption of water per body weight and is considering whether to issue a health advisory that will address this issue.

A study of a population in Chile exposed to about 800 µg/L in its drinking water for a period of years showed significant association with this exposure and fetal and infant mortality that declined to background when the water was treated to remove arsenic. This study was cited by a commenter as indicating more general sensitivity of fetuses and infants. The dose was one that had a range of significant arsenic toxicity effects on the adult population. It is logical that fetuses of mothers so exposed would be affected and infants would have received several times the adult exposure per kg body weight and, consequently, more toxicity. This study does not indicate disproportionate effects on fetuses or infants at low doses. Once the water was treated the effects declined to background (Hopenhayn-Rich *et al.,* 2000).

5. EPA's risk analysis

Several commenters felt that EPA did not follow the NRC recommendations that ''the final calculated risk should be supported by a range of analyses over a fairly broad feasible range of assumptions'', misinterpreted the NRC report, or relied solely on the NRC report and thus did not do an appropriate risk assessment for arsenic. Others viewed the NRC report as lacking peer review or as being politically motivated.

The SAB (EPA, 2000q, pgs. 2–3) discussed EPA's use of the NRC report. In the cover letter to the Administrator they stated:

> * * * The NRC also noted a number of factors that likely differ between the Taiwanese study population and the U.S. population and which might influence the validity of arsenic cancer risk estimates in the United States. Even though the Agency did its own risk characterization (*i.e.,* they combined the NRC risk factors with U.S. exposure information and arsenic occurrence distributions to obtain a range of risks for use in their benefits analysis), they chose not to quantitatively take any of these factors into account at this time.
>
> The Panel agrees with conclusions reached by the NRC in its 1999 report on arsenic, especially their conclusion that ''there is sufficient evidence from human epidemiological studies * * * that chronic ingestion of inorganic arsenic arsenic [sic] causes bladder and lung, as well as skin cancer.'' The NRC also stated that currently the Taiwanese data are the best available for quantifying risk * * *. We note, however, that this Panel does not believe that resolution of all these factors can nor must be accomplished before EPA promulgates a final arsenic rule in response to the current regulatory deadlines. However, resolution of the critical factors * * *. in time for the next evaluation cycle for the arsenic regulation should be considered as a goal.

In closing the cover letter to the Administrator, the SAB stated:

> Specifically, the majority of the Panel members felt that there is adequate basis for the Agency to consider use of its discretionary authority under the Safe Drinking Water Act of 1996 to consider MCLs other than the proposed 5 µg/L.
>
> * * * The ultimate risk number derived from the Taiwanese study has proven very sensitive to the decision about the appropriateness of the comparison population. This of course, has important implications for the use of the data to estimate risk in the U.S. Also a study in Utah suggests that some U.S. populations may be less susceptible to the development of cancer, than those in Taiwan * * *. Also, a recently published study suggests that the incremental increases in lung and bladder cancers observed in the Taiwan study are of roughly the same magnitude, rather than the NRC's inference of a potentially two- to five-fold greater rate of lung cancer relative to bladder cancer.
>
> As noted by the NRC, the mechanisms associated with arsenic-induced cancer most likely have a sublinear character, which implies that linear models, such as those used by the Agency, overestimate risk * * *. Nonetheless, the Panel agrees with the NRC that available data do not yet meet EPA's new criteria for departing from linear extrapolation of cancer risk.

The NRC Subcommittee on Arsenic in Drinking Water explored a number of model approaches using the Taiwan epidemiology data for bladder cancer. Although there are indications that the dose-response relationship for arsenic may be nonlinear at low doses, a convincing biological argument for selecting a nonlinear model is not yet available. Thus, according to EPA's draft 1996 guidelines and consistent with the 1986 guidelines, EPA determined that a point of departure approach was most appropriate to estimate low-dose risks. EPA agreed with NRC's choice of the Poisson model. In the NODA, based on the Morales et al. study (2000), EPA conducted a re-analysis of the bladder and lung cancer data using a Poisson model with no comparison population to estimate points of departure for each health endpoint. In addition to the re-analysis of bladder and lung cancer risk, EPA did a sensitivity analysis of the effect of exposure to arsenic through water used in preparing food in Taiwan. In response to comments received on the proposed rule and the NODA, EPA has also analyzed the effect of exposure to arsenic through food and considered the effect of village level exposure data. In summary, EPA's final risk calculation is supported by analyses of the effect of various assumptions and uncertainties on the risk estimate and reflects the best available science.

EPA believes that it has done a thorough risk analysis on arsenic. Arsenic health risks have remained a high priority at EPA for over 20 years, and EPA scientists have closely followed all scientific developments. EPA established four independent scientific panels to evaluate arsenic health risks (EPA, 2000q; NRC, 1999; EPA, 1997e; EPA, 1988) and provided a sense of the views of the broader scientific community. EPA participated in conducting one of the major cancer mortality studies available on arsenic (Lewis *et al.*, 1999). In the proposed rule and NODA, EPA used the 1999 NRC report's analysis of the Taiwan data as well as other published scientific papers to characterize the potential health hazards of ingested arsenic. The NRC report represents a thorough examination of the best available, peer reviewed science through the late 1990s. Other studies that were important in EPA's analysis were the Utah study (Lewis *et al.*, 1999) and the Morales *et al.* (2000) study. In selecting the proposed MCL, EPA considered the uncertainties of the quantitative dose-response assessment, particularly the possible nonlinearity of the dose-response. EPA also considered the unquantifiable risks from arsenic such as noncancer effects. In response to commenters, EPA expanded its analysis of the Utah study (U.S. EPA, 2000x) and delved further into the uncertainties in the Taiwan data. The Agency made an adjustment to the lower-bound risk estimates to take into consideration the effect of exposure to arsenic through water used in preparing food in Taiwan. In addition, an adjustment was made to the lower-bound risk estimates to take into consideration the relatively high arsenic concentration in the food consumed in Taiwan as compared to the U.S. EPA also investigated the effect of the ecological exposure data on its risk estimates. When villages with only one arsenic measurement were removed from the data set (on the theory that the exposure data was too uncertain), or when village means instead of medians were used for the exposure estimates, there was no statistically significant change in the estimated point of departure, using Model 1 of Morales *et al.* (2000). In summary, EPA believes that it has completed a thorough risk analysis on arsenic that used the best available, peer reviewed science.

The NRC subjected their draft report to a very rigorous external peer review using its own procedures that are well established and generally acknowledged as being independent and objective. The SAB also reviewed the NRC report and EPA's risk analysis, which was, in part, based on the NRC report. In addition, the public was provided an opportunity to comment on the EPA risk analysis as a part of the arsenic proposal and NODA.

EPA disagrees that the NRC report was politically motivated. The NRC Subcommittee on Arsenic in Drinking Water was composed of 16 highly respected scientific experts. EPA believes that this panel produced an impartial analysis of the data available on the toxicity of arsenic.

6. Setting the MCLG and the MCL

Some commenters were confused about the difference between MCLGs and MCLs, how EPA sets MCLGs and MCLs based on legal, scientific, and policy principles, and the relationship between the MCLG and costs and benefits. Other commenters were concerned about a perceived ''anti-backsliding'' provision for MCLGs and MCLs in SDWA.

In accordance with SDWA, standards set for contaminants consist of two components, a maximum contaminant level goal (MCLG) and a national primary drinking water regulation (NPDWR) (section 1412(b)(1)(A)), which specifies either ''a maximum contaminant level (MCL) for such contaminant which is generally set as close to the maximum contaminant level goal as is feasible'' (section 1412(b)(4)(B)) or a treatment technique if ''it is not economically or technologically feasible to ascertain the level of the contaminant'' (section 1412(b)(7)(A)).

SDWA defines an MCLG 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)(A)). MCLGs for all carcinogens are set at zero unless adequate scientific data support a higher MCLG. In accordance with the SDWA, the MCLG is based on the best available peer reviewed science. An MCLG is a goal, not a regulatory limit that the Agency expects to be attained by water systems.

The MCLG must be proposed simultaneously with a national primary drinking water regulation (section 1412(a)(3)), which specifies a maximum contaminant level (MCL) as close to the MCLG as technically feasible. The MCL is the enforceable standard. SDWA allows EPA to make an exception to setting the MCL as close to the MCLG as is feasible where the ''Administrator determines * * * that the benefits of a maximum contaminant level * * * would not justify the costs of complying with the level.'' In this case, 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)). This exception was used to set the MCL for arsenic. EPA found that at the feasible level of 3 µg/L, the benefits of compliance did not justify the costs. The Agency determined that an MCL of 10 µg/L maximizes the health risk reduction benefits at a cost that is justified by the benefits (see preamble discussion of the risk management decision that was made for arsenic in section III.F.)

Some commenters argued that EPA sets the MCL within a risk-range of 10^{-4} to 10^{-6} without proper regard to the statutory requirements discussed above. This is not the case. As noted in the proposal, EPA has historically considered this risk range as protective of public health, and accordingly has sought to ensure that drinking water standards are within this risk range. However, the risk-range represents a policy goal for EPA, and is not a statutory factor in setting an MCL. In the case of arsenic, EPA did the benefit-cost analysis required by the statute. Having found that the benefits of an MCL at the feasible level were not justified by the costs, EPA set the MCL at 10 µg/L. This MCL maximizes health risk reduction benefits at a cost that is justified by the benefits.

EPA is required to review and revise as appropriate, each national primary drinking water regulation, at least every 6 years. Revisions to current regulations ''shall maintain, or provide for greater protection of the health of persons'' (section 1412(b)(9)). When new scientific data become available, the Agency may reevaluate the MCLG and MCL.

C. Occurrence

The principal concerns raised by the commenters and our responses are as follows:

1. Occurrence data

Several commenters expressed concern that EPA estimated occurrence using data from only 25 States and that the national estimate was thus not as robust as it should have been. Many of these commenters suggested that EPA should request data from all States/more systems before issuing the final rule.

It is true that we based our occurrence estimate on data from only 25 States. However, we believe that we have compiled the most comprehensive and accurate occurrence estimate possible with currently available data, and that this estimate adequately supports our various analyses and final decisions.

For our occurrence analysis, we relied on data submitted voluntarily by State drinking water agencies. In doing so, we collected the largest available database on arsenic in drinking water, consisting of almost 77,000 observations from more than 26,600 public water systems in 25 States. We received but did not use data from six States (Florida, Idaho, Iowa, Louisiana, Pennsylvania, and South Dakota), because the data either could not be linked to PWSs; did not indicate if results were censored; were all zero; did not provide analytical or reporting limits; or were rounded to the nearest 10 µg/L.

In response to our request in the proposed rule for additional occurrence data, we received additional data from several States. However, in each case, the submitted data either corresponded closely to observations already in our data set (California, New Mexico, Utah), or were of the wrong kind or insufficient quantity to use in our estimation (Iowa, Maryland, Nebraska, Oklahoma, Vermont, West Virginia).

Of the States from whom we did not receive usable data, we believe that many do not have databases of the kind and quality that we would need for our occurrence analysis. We therefore could not have obtained such information from other States without requiring, in some instances, new monitoring to be undertaken and new data to be compiled.

In forming our occurrence estimate, we did not ignore States for which we have no suitable data. We accounted for these States by assigning regional occurrence distributions to them. Our resulting national estimates compare relatively closely with those developed by the utility industry and by the U.S. Geological Survey (EPA, 2000r).

Some commenters indicated EPA should not use data from the U.S. Geological Survey's National Ambient Water Quality Assessment (NAWQA) or EPA's NIRS, SDWIS, or Rural Water

Survey (RWS) to estimate occurrence. In forming our occurrence estimates, we used arsenic concentrations drawn only from our 25-State arsenic compliance monitoring database. We did not use observations from NAWQA, SDWIS, RWS, NAOS, NIRS, NOMS, Community Water System Survey (CWSS) or any other surveys or studies. As the preamble of the proposed rule (65 FR 38888 at 38903) states, we used National Organic Monitoring Survey (NOMS), RWS, and the 1978 CWSS in previous arsenic occurrence analyses, but did not use them for the present analysis because of their age and relatively high detection limits. The only information we used from SDWIS was the type and size of particular systems, and the numbers of systems and population served in different categories of systems. We used NAWQA, NAOS and NIRS only for comparison to our finished results.

2. Occurrence Methodology

Some commenters stated their belief that EPA had underestimated national occurrence because they believe that EPA did not have enough data with which to develop the estimate. Commenters also believed that, since the national occurrence is underestimated, noncompliance/co-occurrence are also underestimated.

We do not agree that we have underestimated arsenic occurrence. We have the largest existing database of arsenic in drinking water, with almost 77,000 observations from more than 26,600 public water systems in 25 States. We did not ignore States for which we have no data, but accounted for them by assigning regional occurrence distributions to them. Our data and methodology have been approved by an independent expert peer review panel. Our occurrence estimates are close to those of the NAOS and USGS.

Some commenters believe EPA's occurrence methodology is inconsistent with the way compliance is determined and that EPA should use a running annual average for estimating noncompliance.

We acknowledged in the proposed rule (65 FR 38888 at 38907) that our method of estimating occurrence is different from the method used for determining compliance with the MCL. Our method usually gives higher estimates, because we substitute non-zero values for non-detects, while under the regulatory definition of compliance, non-detects are assumed to equal zero. We believe our method is the best one despite the difference, for two reasons. First, our goal is to characterize arsenic occurrence as accurately as possible. Given a sound characterization of system-mean occurrence and of intra-system and intra-source variability, the numbers of systems and points of entry expected to fail the regulatory definition of compliance at some MCL option can be determined. The reverse calculation, on the other hand, is generally not possible. Second, as analytical methods improve and detection limits decrease, the difference between the two methods will decrease.

To the extent that our estimates disagree with those used for determining compliance, our estimates will be higher and thus will cause us to slightly overestimate the costs associated with any MCL option. Our estimates of benefits, on the other hand, should not be biased one way or the other by our occurrence estimate, since health risks are mainly determined by mean exposure over time, which we accurately characterize. The same would not be true if we used the regulatory definition of non-detects, which underestimates mean occurrence.

Commenters also pointed out that occurrence estimates in different parts of the rule and support documents are inconsistent. Although the analysis is internally consistent, apparent inconsistencies in the numbers arise from three sources: System versus site considerations, year of the SDWIS inventory, and use of best point or regressed estimates. With respect to the first point, because most large ground water systems have multiple entry points, some systems which have average concentrations below the MCL will still have impacted entry points. As a consequence, the number of impacted systems is much larger than the number of systems with mean concentrations above the MCL. In the proposal, this difference amounted to several hundred systems.

In connection with the second point, year of the SDWIS inventory, it is not unusual for there to be a change from year to year in the inventory of hundreds of water systems. This results from restructuring and consolidations, among other factors. In the final rule and supporting documents, we have tried to address this issue by consistently using a single set of baseline estimates, taken from EPA's Drinking Water Baseline Handbook (EPA, 2000b). Regardless, this factor is only responsible for a one or two percent variation in the impact estimate, and is not of sufficient significance to impact the decision making process.

The third issue relates to the representation of the mean system arsenic occurrence. In many tables, mean arsenic concentrations are presented which reflect our best point estimates. Nevertheless, the best estimate of national cost impacts derives from use of a best fit equation which incorporates all of the data. We have used these regressed fits in the development of the costs and benefits. The two sets of estimates are described in section III.C.4.

3. Co-Occurrence

Some commenters believe EPA has underestimated the co-occurrence of arsenic with radon.We agree that, based on the NWIS data, most systems with arsenic greater than 10 µg/L will also have radon greater than 300 pCi/L. However, only about 8% of all systems exceed both standards. Moreover, about 85% of such systems (again based on NWIS) have radon in the range of 300 to 1000 pCi/L, where incidental removal of radon will be most effective. We expect, for example, that systems with 300 to 1000 pCi/L of radon will be more likely to treat for arsenic by coagulation and microfiltration, which removes most radon incidentally by aeration. Therefore, we believe that the impact of co-occurrence of radon and arsenic will be small.

Some commenters believed that EPA did not evaluate the effect of different sulfate levels in its decision tree. We did evaluate several ranges of concentrations of sulfate and arsenic against each other (see 65 FR 38888 at 38938). The sulfate concentration ranges included 0 to 25, 25 to 120, 120 to 250, 250 to 500, and >500 mg/L. The arsenic concentration ranges included 0 to 2, 2 to 5, 5 to 10, 10 to 20, and >20 µg/L. For these ranges, there was no apparent change in co-occurrence of sulfate and arsenic as the concentrations increased. However, the Agency took the co-occurrence of arsenic and sulfate and the impact on anion exchange technology into consideration in the decision tree at sulfate levels of <20, 20 to 90, 90 to 120, and >120 mg/L. The revised decision tree for today's final rule only applies anion exchange when sulfate levels are less than 50 mg/L.

Some commenters expressed their belief that NWIS is inadequate to estimate national co-occurrence of arsenic and radon and that NWIS data should be verified as representative of PWS water use by requesting data from States. It is true that NWIS includes samples from non-drinking water supplies. NWIS is, however, the largest and best data base available for studying co-occurrence with over 40,000 ambient water samples. To the extent that non-drinking water samples affect our estimates, they should cause us to overestimate occurrence and therefore also co-occurrence. We realize that NWIS may not reflect conditions in any given State or water system; we use it only for deriving national estimates.

D. Analytical Methods

1. Analytical Interferences

Commenters expressed concern about the potential for matrix interferences in the analysis of arsenic at low levels. A potential for chloride interference when using ICP–MS with samples containing high levels of chloride was specifically noted by commenters. A commenter also stated that some investigators had reported arsenic results in drinking water samples that differed depending on the valence state of the arsenic in the sample (*i.e.*, As (III) or (V)) when using methods that used GHAA technology. The Agency agrees that interferences may be encountered when determining arsenic using the methods proposed in the June 2000 rule (including the GHAA technique). However, the Agency disagrees that the interferences are unexpected or impede compliance with the arsenic MCL of 0.01 mg/L. Four different measurement technologies are approved for the analysis of arsenic: AA furnace, AA-Platform, GHAA and ICP–MS with respective MDLs of 0.001 mg/L, 0.0005 mg/L, 0.001 mg/L, and 0.0014 mg/L. These technologies have been used for compliance determinations of arsenic for many years. The methods written around each of these technologies identify potential interferences and contain corrective procedures. In particular, the ICP–MS method warns of potential interferences from chloride and provides instructions to eliminate this problem.

2. Demonstration of PQL (Includes Acceptance Limits)

Several commenters agreed with the ±30% acceptance limit and the 0.003 mg/L PQL derived and proposed for arsenic. Other commenters expressed concerns that the PQL was not correctly derived or that the acceptance limits were too broad.

A commenter stated that the Agency should set the PQL at 5 to 10 times the method detection limits of 0.001mg/L which would result in a PQL range of 0.005 to 0.010 mg/L. As previously explained in section III.B.1 of this preamble, EPA only uses the MDL multiplier approach to derive a PQL when there is insufficient interlaboratory data to statistically derive a PQL. For arsenic, the Agency had ample WS data to derive a PQL using the interlaboratory approach.

Several commenters were concerned that the ‘‘PQL study is not realistic and does not account for matrix interference in real drinking water samples.’’ In addition, some commenters stated that the ‘‘PQL should be set at a level that is achievable by laboratories on a routine basis.’’ EPA disagrees that the PQL for arsenic is unrealistic, or that it has been set at a level that is unachievable on a routine basis. As explained in section III.B.1 of this preamble, EPA used the interlaboratory data from six recent WS studies to derive the arsenic PQL. The WS studies utilize reagent grade water (*i.e.*, blank water free of interferences) for the PE-samples that are analyzed in the WS study. Use of reagent water to prepare a test sample conforms with an accepted and longstanding practice in which a method developer validates an analytical method in blank water before looking for possible inaccuracies from matrix effects when the method is applied to a sample matrix (*e.g.*, a compliance drinking water sample). Reagent water is used as an initial benchmark for method development and testing, because it is interference-free and can be readily produced in any competent laboratory. A lab subsequently identifies and corrects for matrix effects by comparing its performance on reagent water to the results on the matrix (contaminated drinking water) or spiked matrix (clean drinking water spiked with arsenic) sample.

All of the methods approved for SDWA and Clean Water Act (CWA) compliance monitoring require that laboratories demonstrate acceptable performance in reagent grade water before drinking water samples are tested. A study conducted by Eaton (Eaton, 1994) found that the type of matrix and the analytical method used had no significant effect on the derivation of their PQL. This study included drinking waters with high total dissolved solids and total organic carbon, and arsenic concentrations that ranged from 0.001 to 0.010 mg/L. Thus, EPA disagrees with the comment that the PQL would be significantly different if derived in various drinking waters instead of in reagent water.

The Agency also believes that the derived PQL of 0.003 mg/L is realistic and is achievable on a routine basis. The derivation of the PQL for arsenic is consistent with the longstanding process used to determine PQLs for other metal contaminants regulated under SDWA. In deriving the PQL for arsenic, the Agency took into consideration the issue of laboratory capability, laboratory capacity, and the ability of laboratories to achieve a quantitation level on a routine basis. The PQL for arsenic was derived from data collected in WS studies in which PE-samples were prepared with reagent water spiked with low concentrations, <0.006 mg/L, of arsenic. These studies were conducted from 1992 to 1995. The number of EPA Regional and State laboratories that participated in each study ranged from 26 to 45 laboratories. Using acceptance limits of ±30% a linear regression analysis of this data yielded a PQL of 0.00258 mg/L. The Agency rounded up to derive the proposed PQL of 0.003 mg/L (3 µg/L) with a ±30% acceptance limit. Over 75% of the EPA Regional and State laboratories were able to report arsenic concentrations within ±30% of 3 µg/L. In addition, 62% of non-EPA laboratories that participated in these same WS studies were equally successful. The number of non-EPA laboratories in these WS studies ranged from 360 to 619 laboratories, which means that the number of laboratories that successfully analyzed the low concentration arsenic PE-samples ranged from 223 to 384. This data indicate that neither laboratory capacity nor capability will be a problem at a PQL of 3 µg/L ±30%. EPA, therefore, believes that competent laboratories are available, and with the use of the quality control instructions in the compliance methods will routinely achieve this level of performance.

Several commenters felt the acceptance limit of ±30% is too wide. The ±30% acceptance limit was based on a recommendation from the SAB. The SAB recommendation was to choose an acceptance limit similar to that set for other regulated metals (EPA, 1995). These limits range from ±15% for barium, beryllium, and chromium to ±30% for mercury and thallium (§ 141.23(k)(3)). EPA chose the upper (*i.e.*, wider) limit on this range to ensure that a sufficient number of laboratories could be certified for arsenic determinations (the number of laboratories that can achieve the accuracy acceptance limit increases as the limit is widened). Several commenters agreed with the proposed ±30% acceptance limit, because they shared EPA concerns about insufficient laboratory capacity if this limit was narrowed.

3. Acidification of samples

A commenter stated that the Agency needed to clarify that a sample can be collected in the field without acidification, and that acidification of the sample can be done later at the laboratory. The commenter believes that delaying acidification does not affect the compliance determination and that a laboratory is a better place in which to handle acids. The Agency agrees with this comment and had previously clarified in a final rule (64 FR 67450; December 1, 1999; see page 67452, item 11 and page 67456, item 3; EPA, 1999p), that acidification of samples may be conducted in the field or laboratory with acidification at the laboratory being the better and safer choice. In the 1999 rule, EPA noted that this change would be affected by amending footnote one to the table at § 141.23(k)(2) to read as follows:

> For cyanide determinations samples must be adjusted with sodium hydroxide to pH > 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4EC or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

Although the June 2000 proposal inadvertently omitted this footnote, today's final rule contains the correct footnote.

Another commenter believed that because the proposed sample preservation requirement for arsenic was new and supposedly untested, data collected under the previous requirements might not be comparable to data resulting from the new sample preservation requirement. These are not new analytical requirements. The commenter may have been misled by the statement in the preamble to the June 2000 arsenic proposal that EPA proposed to add a ''new'' requirement to the preservation and holding time table at § 141.23(k)(2). It is only new in the sense that EPA has codified the requirements in today's rule. Arsenic compliance data collected in the past and the arsenic data discussed in the June 2000 proposal were collected using these preservation and holding time conditions.

E. Monitoring and Reporting Requirements

1. Compliance Determinations

Most of the comments regarding compliance determinations requested the Agency to provide further clarification on this issue. Many commenters specifically asked EPA to specify whether samples collected quarterly as a result of an MCL violation are defined as compliance samples or confirmation samples. In today's final rule, the Agency has provided further clarification in the regulatory language to eliminate any misinterpretation.

The Agency defines quarterly samples as compliance samples that must be used to determine compliance. Confirmation samples are any samples that the State requires that go beyond the minimum Federally required samples defined in the following paragraph.

Systems will determine compliance based on the compliance samples obtained at each sampling point. If any sampling point is in violation of an MCL, the system has a MCL violation. For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. Systems monitoring annually or less frequently whose sample result exceeds the MCL for inorganic contaminants in § 141.23(c), or whose sample result exceeds the trigger level for organic contaminants listed in §§ 141.24(f) or 141.24(h) must revert to quarterly sampling in the next quarter. The system will not be considered in violation of the MCL until it has completed one year of quarterly compliance sampling. If any sample result will cause the running annual average to exceed the MCL at any sample point (*i.e.*, the analytical result is greater than four times the MCL), the system is out of compliance with the MCL immediately. Systems may not monitor more frequently than specified by the State to determine compliance unless it has applied to and obtained approval from the State. If a system does not collect all required samples when compliance is based on a running annual average of quarterly samples, compliance will be based on the running annual average of the samples collected. If a sample result is less than the detection limit, zero will be used to calculate the annual average. States have the discretion to delete results of obvious sampling or analytic errors.

States still have the flexibility to require confirmation samples for positive or negative results. States may require more than one confirmation sample to determine the average exposure over a 3-month period. Confirmation samples must be averaged with the original analytical result to calculate an average over the 3-month period. The 3-month average must be used as one of the quarterly concentrations for determining the running annual average. The running annual average must be used for compliance determinations.

Some commenters requested rule language that clearly specifies how to determine compliance and others requested approval of scientific methodologies that more accurately reflect the average annual contaminant exposure. Today's rule requires that monitoring be conducted at all entry points to the distribution system. However, the State has discretion to require monitoring and determine compliance based on a case-by-case analysis of individual drinking water systems.

The Agency cannot in this rule address all of the possible outcomes that may occur at a particular water system; therefore, EPA encourages drinking water systems to inform State regulators of their individual circumstances. Some systems have implemented elaborate plans including targeted, increased monitoring that is much more representative of the average annual mean contaminant concentration to which individuals are being exposed. (Some States determine compliance based on a time or flow weighted average.) In many cases, the State can demonstrate that compliance is being calculated based on scientific methods that are more representative of the true contaminant concentration that individuals are being exposed to over a year, but it substantially increases the sampling and analytical costs.

Some States require that systems collect samples from wells that only operate for 1 month out of the year regardless of whether they are operating during scheduled sampling times. The State may determine compliance based on several factors including, but not limited to, the quantity of water supplied by a source, the duration of service of the source, and contaminant concentration.

2. Monitoring of POU Devices

Several commenters indicated that there will be many implementation problems with POU devices. EPA agrees that some issues such as scheduling and access for routine maintenance of POU devices, liability, and monitoring may be difficult but believes they can be alleviated with sufficient planning. The Agency will be providing POU operation and maintenance guidance for small systems after publication of the final rule. In general, EPA believes that POU systems can be easily installed, maintained, and monitored for removal efficacy.

EPA believes that it is feasible for public water systems to own, control, and maintain POE/POU devices for arsenic MCL compliance either directly or through a contract with a qualified party. This approach, however, requires more recordkeeping to monitor individual devices than does centralized treatment. Both POU AA and RO can be obtained with mechanical warnings to ensure that customers are notified of operational problems. In the case of activated alumina, such warnings include shut-off valves that are triggered prior to the adsorptive capacity of the media being exhausted, based on the volume of water treated. Reverse osmosis POU devices come with total dissolved solids detectors that activate warning lights when membrane integrity is compromised.

Systems having high arsenic concentrations in the finished water that choose to achieve compliance using POU treatment would shift from monitoring at a central location to monitoring at the POU devices. As is the case with any system that installs treatment to lower contaminant concentrations to levels below the MCL, the monitoring frequency is part of the compliance agreement between the Primacy Agency and the system. The compliance agreement must require monitoring that is as protective as monitoring for systems using centralized treatment and may not be less frequent than the routine monitoring required in today's rule (i.e., annual samples for surface water systems and one sample every three years for ground water systems). The Primacy Agency will be responsible for negotiating the monitoring schedule with the system for POU devices and may amend the compliance agreement with the system to increase or reduce the monitoring frequency to an alternate schedule depending upon maintenance, public responses, the implementation of the service agreement, and the initial monitoring results. For purposes of forecasting national compliance costs, EPA assumed that all POU devices would be monitored for arsenic with one sample taken the first year following installation, samples taken annually in subsequent years, and replacement of the filter cartridge at each POU site every 6 months.

3. Monitoring and Reporting for NTNCWSs

Most commenters disagreed with EPA's approach of requiring NTNCWSs to monitor and provide public notification. Instead, the majority of commenters indicated that EPA should either require full coverage or not regulate NTNCWSs. In today's rule making, EPA is requiring NTNCWSs to comply with the arsenic regulation, including the monitoring and reporting requirements associated with arsenic in § 141.23, the MCL listed in § 141.62, and the public notification requirements (NTNCWSs are subject to the same requirements as those of CWSs). EPA acknowledges that there is uncertainty associated with its information about exposure patterns for consumers of water from NTNCWSs and the demographics of these facilities. Thus, our understanding of the health risks to consumers of water from NTNCWSs is uncertain. In the case of arsenic, however, EPA believes the additional uncertainty in the overall risk analysis supports the decision to treat these facilities the same as CWSs. EPA also believes the decision to cover these facilities is underscored by consideration of the risks to children who consume water at day care facilities or schools that are served by NTNCWSs.

4. CCR Health Language and Reporting Date

Comments received on EPA's proposed consumer confidence reporting (CCR) requirements were equally split. Some commenters supported EPA's proposal to include health effects language in CCRs if a system detects arsenic above the revised MCL prior to the effective date. Others disagreed with the proposal because they believed providing this information prior to the effective date would be confusing to consumers and would not allow sufficient time to inform consumers about the risks associated with arsenic. These dissenting commenters generally felt that it would be more useful for systems to provide notice to consumers that the MCL has been revised and systems will be required to comply by the effective date of the revision.

The Agency believes that it is important to provide customers with the most current understanding of the risk presented by arsenic as soon as possible after establishing the new standard. In today's rule, community water systems that detect arsenic between the revised and existing MCL must include health effects language in their consumer confidence reports prior to the effective date of the revised MCL. The Agency does not believe that inclusion of this information will be unnecessarily confusing to consumers because, under the CCR rule systems have the flexibility to place this information in context. EPA expects that affected systems will include not only the health effects language but also an explanation that the current MCL has been revised and the system is not in violation because the new standard has not yet taken effect.

EPA is finalizing an MCL somewhat higher than the technologically feasible MCL. Since some commenters expressed concern about the risk that a higher-than-feasible MCL might present to certain consumers, EPA is requiring systems that detect arsenic at concentrations greater than 5 μg/L and up to and including 10 μg/L to provide additional information to their customers. EPA believes that consumers should be aware of the uncertainties surrounding the risks presented by very low levels of arsenic. While EPA addressed many of the sources of uncertainty in its risk analysis of arsenic in support of the final rule, several sources of uncertainty remain and will be considered in the future in the context of the periodic review and revision, if appropriate, of drinking water regulations as required by section 1412(b)(9) of SDWA.

5. Implementation Guidance

EPA appreciates the fact that the final rule will place a new implementation burden on many water systems, particularly small systems. This is particularly true of small ground water systems that heretofore have not been obliged to install, operate, and maintain a treatment facility. EPA also understands that new or more sophisticated treatment technologies will have obvious implications in terms of operator capacity. EPA has addressed this issue in several ways, and does not believe that it is an impediment to promulgating this new MCL. In brief, some of the ways these implementation concerns have been addressed are as follows. EPA has identified a number of affordable small system treatment technologies that are based on consideration of the capabilities of small system operators. Systems will have the latitude to choose the type of treatment technology that is most cost effective and appropriate (from an operation and maintenance standpoint) for their particular situation. EPA also plans to publish implementation guidance for small systems within 60 days of publication of the final rule that will provide helpful information to aid small systems in both selecting and operating small treatment technologies. EPA has exercised its statutory authority under section 1412(b)(10) of SDWA to provide an additional 2 years for small systems to comply with this rule (for a total of 5 years). Individual small systems may apply for exemptions with extensions that can provide for a total of an additional 9 years to comply with the requirements of this rule. Finally, EPA notes that the final rule provides more ''buffer'' between the feasible level (3 μg/L) and the MCL of 10 μg/L as compared to the proposed level of 5 μg/L. Thus, treatment facilities that experience operation difficulties would have more latitude in terms of the timing and type of corrective measures that would need to be taken than would be the case with a more stringent final MCL. For all of the above reasons, EPA does not believe that there are any insurmountable implementation problems associated with the final MCL for arsenic.

6. Rounding Analytical Results

Today's rule requires that data be reported to the nearest 0.001 mg/L (3 significant figures). Some commenters felt that the rounding approach described in the proposed rule would significantly impact State programs. The proposed rule solicited comment on an approach requiring all values greater than or equal to 6 to be rounded up and all values less than or equal to 4 to be rounded down (*i.e.* a value of 0.0056 mg/L would be rounded to 0.006 mg/L). Results ending in 5 would round the third significant digit to the closest ''even'' number. Therefore, a result of 0.0155 mg/L would be rounded to 0.016 mg/L, and 0.0145 mg/L would be rounded to 0.014 mg/L. Some commenters supported EPA's rounding approach. Other commenters indicated that implementing this revision would affect State data management operations and would require staff training.

The Agency recognizes that implementing a revision to the existing rounding guidance may impact State database and computer programs. In today's final rule, the Agency is encouraging States to continue using the rounding scheme that EPA recommended in the ''Water Supply Guidance #72'', dated April 6, 1981. EPA stated in this guidance that:

> All MCLs contained in the National Interim Primary Drinking Water Regulations are expressed in the number of significant digits permitted by the precision and accuracy of the specified analytical procedures. Data reported to the State or EPA should be in a form containing the same number of significant digits as the MCL. In calculating data for compliance purposes, it is necessary to round-off by dropping the digits that are not significant. The last significant digit should be increased by one unit if the digit dropped is 5, 6, 7, 8, or 9. If the digit is 0, 1, 2, 3, or 4 do not alter the preceding number.

For example, analytical results for arsenic of 0.0105 mg/L would round off to 0.011 mg/L while a result of 0.0104 mg/L would round off to 0.010 mg/L.

F. Treatment Technologies

1. Demonstration of Technology Performance

Many comments on the proposed arsenic rule (EPA, 2000i) expressed the concern that the treatment options that EPA designated as BAT for compliance with the arsenic MCL have not been adequately demonstrated in full-scale operation for arsenic removal. Commenters noted that there are relatively few arsenic treatment facilities in the U.S., and these facilities are generally small and were designed for an arsenic MCL of 50 µg/L. Although many of the treatment options designated as BAT are widely used for other water treatment objectives, commenters stated that the limited application of these technologies to arsenic removal, especially in large plants, creates uncertainty as to their efficacy and feasibility for this purpose. Commenters alleged that this situation makes it difficult for water systems to determine appropriate compliance technology choices and raises questions regarding the validity of EPA's estimates of costs for compliance with the arsenic MCL.

> EPA notes that SDWA section 1412(b)(4)(E) states: [E]ach national primary drinking water regulation which establishes a maximum contaminant level shall list the technology, treatment technique, and other means which the Administrator finds to be feasible for purposes of meeting such maximum contaminant level.

SDWA defines feasible in section 1412(b)(4)(D) as follows:

> For the purposes of this subsection, the term ''feasible'' means feasible with the use of the best technology, treatment techniques, and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration).

Thus, SDWA requires EPA to list feasible compliance treatment options based on demonstration of efficacy under field conditions and taking cost into consideration.

For compliance with the arsenic MCL, EPA judged technologies to be a best available technology when the following criteria were satisfactorily met:

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

After reviewing a number of technologies, EPA identified the following as BAT for arsenic removal: ion exchange, activated alumina, reverse osmosis, modified coagulation/filtration, modified lime softening, electrodialysis reversal, and oxidation/filtration. EPA believes that all of these treatment options meet the SDWA criteria of demonstrated efficacy under field conditions and, further, meet the additional criteria listed above which EPA has historically used to identify BAT. Studies which support this assessment are described in ''Technologies and Costs for Removal of Arsenic from Drinking Water'' (EPA, 2000t). Consequently, identification of these technologies as BAT is appropriate.

EPA recognizes that application of the arsenic BAT treatment options to full-scale plants where they are optimized specifically for arsenic removal is limited. This is especially true in regard to large plants. Nevertheless, as stated previously, it is appropriate for EPA to identify these technologies as BAT because they have been demonstrated to be effective for arsenic removal under field conditions. Moreover, all of the technologies listed as BAT have an established history of successful application at full scale in water treatment plants for related treatment objectives, specifically including the removal of inorganic contaminants (EPA, 2000t). Ion exchange is applied in both municipal and POE/POU treatment for softening (i.e., removal of calcium and magnesium), as well as for removal of nitrate, arsenic, chromium, radium, uranium, and selenium. Activated alumina is used in water treatment plants to remove contaminants such as fluoride, arsenic, selenium, silica, and natural organic matter. Reverse osmosis has traditionally been employed to desalinate brackish water and sea water. Electrodialysis reversal systems are often used in treating brackish water to make it suitable for drinking, and have also been applied for wastewater recovery. Oxidation followed by filtration is utilized extensively in public water systems for removal of iron and manganese. Lime softening is widely applied for reducing calcium, magnesium, and other metals in large water treatment systems. Most surface water systems use coagulation/filtration processes for particulate removal, and a growing number of systems have modified these processes to increase removal of dissolved constituents, primarily TOC and certain metals.

EPA believes that the successful application of the arsenic BAT treatment options for the removal of contaminants other than arsenic is relevant to their ability to remove arsenic in full-scale plants. The physical and chemical mechanisms operative in these technologies for the removal of hardness, sodium, fluoride, TOC and other dissolved species are analogous to the mechanisms by which these technologies remove arsenic. In addition, none of these technologies have characteristics that would make them ineffective or infeasible at large scale or under long-term operation. The specific conditions under which optimized performance is achieved may differ somewhat between removal of arsenic and removal of other contaminants, just as they may differ from plant to plant based on water matrix and other treatment processes in use. However, because it has been shown that these technologies can remove arsenic under field conditions, and because these technologies have an established history of use for the removal of inorganic contaminants in full-scale systems, EPA believes it is appropriate and technically justified to conclude that they can be successfully used for arsenic removal in full-scale plants.

2. Barriers to Technology Application

EPA received many comments on the proposed arsenic rule (EPA, 2000i) that described challenges that systems would face in applying the technologies identified by EPA for compliance with the arsenic MCL. Among such challenges asserted by comments were the following: the cost and availability of adequately trained, certified operators, especially in small systems; hazards associated with the shipping, handling, and storage of chemicals, especially in regard to wells located in residential areas; and the infeasibility of water loss from treatment processes in arid regions. Note that comments dealing with residuals handling and disposal are addressed subsequently in section V.F.4 of this preamble.

In regard to water treatment plant operators, EPA believes that operator competency is critical for the protection of public health and the maintenance of safe, optimal, and reliable performance of water treatment and distribution facilities. Pursuant to SDWA section 1419(a), EPA has developed guidelines for the certification and recertification of the operators of community and nontransient noncommunity public water systems. These guidelines require that all operating personnel who make process control/system integrity decisions about water quality or quantity that affect public health must be properly certified by the State. EPA recognizes and has considered that the treatment technologies, which systems will install to comply with the arsenic MCL, may add complexity to existing treatment works or may be applied to previously untreated ground water. These situations will necessitate additional operator training to ensure that treatment processes are properly operated, and systems will incur additional costs associated with operator labor.

EPA believes there will be sufficient numbers of adequately trained and certified operators available to public water systems. Operator training programs are available throughout the U.S. through home study courses, classroom settings, and in-plant training. Current and new water treatment operators can obtain the training necessary to operate any of the treatment technologies considered for compliance with the arsenic MCL. EPA is developing a grants program pursuant to SDWA section 1419(d) to reimburse training and certification costs for operators employed by community water systems and nontransient, noncommunity water systems serving 3,300 or fewer people. This funding will reduce the compliance burden on these small systems, thereby increasing the likelihood that the systems will be able to reliably operate and maintain new treatment. Today's rule offers five years between promulgation and the time systems must be in compliance. An exemption can provide three additional years to achieve compliance, and this exemption may be renewed for up to six years for small systems. The Agency believes this amount of time will offer ample opportunity for States' operator training and certification programs to prepare operators.

EPA's Operator Certification Guidelines require that a certified operator be responsible, in charge, and available to all community and nontransient, noncommunity water systems. However, this does not mean a certified operator must be on site at every treatment facility 24 hours a day, 7 days a week. The treatment technologies do not necessarily require constant supervision of operators. Depending upon State requirements, regional certified operators could travel from facility to facility on a regular basis to oversee the efforts of the non-certified operators provided the certified operator was also available to the system on an on-call basis. Systems must consider their operational constraints in selecting treatment technologies and in establishing appropriate operational controls.

EPA has accounted for additional labor costs associated with the operation of treatment technologies for compliance with the arsenic MCL. The Agency's analyses of additional costs are described in ‘‘Technologies and Costs for Removal of Arsenic from Drinking Water’’ (EPA, 2000t). The labor rates used to develop operation and maintenance costs are conservative estimates based on loaded rates for certified operators in large and small systems.

Concerns expressed by commenters on the storage, handling, and application of chemicals used in arsenic treatment centered on hazards to the public health and safety if an accidental release occurred. These comments hinged on the fact that ground water systems may have wells located in residential and high population-density areas. Several commenters asserted that the risks from chemical application in these areas may outweigh the hazards associated with potentially elevated arsenic concentrations. Among the chemicals of concern are chlorine for pre-oxidation, and acids and bases for pH adjustment.

While EPA understands the nature of this concern, EPA does not believe that chemical usage for compliance with the arsenic MCL poses a significant risk. Systems using chemicals should employ established safety and emergency response procedures, along with effective operator training and certification. Measures that can be taken to alleviate potential problems with chemical handling and storage include: review chemical documentation to check quantity and quality; visually inspect chemicals and conduct appropriate verification tests; label and secure unloading points; verify adequate receiving tank capacity; inspect chemical containers for any damage or evidence of leaks; specify delivery at scheduled times; specify equipment necessary for safe handling and transfer of chemicals; and supervise unloading with trained personnel (Casale and LeChevallier, 2000).

Many community water systems currently disinfect with chlorine. This includes many small systems and ground water systems with wells in residential areas. Small systems and ground water systems typically apply chlorine as hypochlorite that carries relatively little risk. Liquified chlorine gas is generally cheaper and is used by many large systems. The use of chlorine gas involves certain risks associated with accidental leakage. However, these risks are well understood and are managed through high standards of equipment specification, operation and management procedures, and training of personnel (Porter *et al.,* 2000).

Systems using activated alumina may lower the pH of the feedwater in order to increase process efficiency, and subsequently raise the pH to stabilize the water. EPA believes that most large systems have a sufficient level of technical expertise to modify pH without difficulty. However, EPA recognizes that very small systems may lack the operator capacity to successfully rely on pH modification as a component of a treatment process. In estimating costs for compliance with the arsenic MCL, EPA assumed that most very small systems using activated alumina would not adjust the raw water pH. These plants would run under less-than-optimal conditions but would still meet the arsenic MCL. Furthermore, for small systems and for other systems that may lack the technical expertise to adjust pH, other treatment options are available. Because of the number and flexibility of treatment options available to systems, along with the training and certification of operators, EPA believes that hazards to the public as a result of arsenic treatment will be minimal.

In regard to concerns with water scarcity, EPA notes that of the technologies listed in the proposed rule as BAT, only reverse osmosis (RO) and electrodialysis reversal (EDR) produce reject water in a quantity likely to make them undesirable in arid regions. While EDR and RO were listed as BAT in the proposed rule, they were not used in the final national cost estimate because other options are more cost effective and do not reject a large volume of water like these two technologies. Thus, we did not assume that any systems would chose EDR and assumed that RO would only be used by a small fraction of small systems and only in POU devices. POU devices treat only a small fraction of the household water, so that any water loss is minimized. Consequently, EPA does not believe that commenters' concerns about water scarcity alter EPA's projections of systems' ability to comply with the arsenic MCL. Moreover, in today's rule EPA has established the MCL for arsenic at 10 ppb. At this level, it would be possible for many systems to use RO or EDR in a split-stream mode, treating a portion of the water, and blending treated and untreated water to achieve compliance. This option would enable systems to significantly reduce the amount of reject water produced were they to select these technologies.

In cases where the available water resources are limited, systems may select technologies like activated alumina, anion exchange, and coagulation assisted microfiltration where water loss is limited to a few percent or less. As discussed in ‘‘Technologies and Costs for Removal of Arsenic from Drinking Water’’ (EPA, 2000t), the principal water losses associated with anion exchange and activated alumina result from the rinsing of the beds after regeneration and, in some limited cases, backwashing for removal of solids. In normal operating conditions, EPA expects this waste water to amount to a small percentage of the total water produced.

3. Small System Technology Application

A number of commenters raised concerns over the small system compliance technologies described in the proposal. Many of these comments questioned the ability of small systems to apply these technologies. EPA has carefully considered these comments and responses to the significant issues are provided below (see section I.G. for a discussion of the affordable small system compliance technologies under today's final rule).

The most significant issues raised by comments addressed the application of Point-of-Use/Point-of-Entry (POU/POE) treatment in small systems. Comments cited requirements for preoxidation for activated alumina (AA) units as reasons why the POU/POE devices would not be desirable. EPA notes that many small systems have disinfection treatment systems in place that could act as preoxidation for POE/POU units. Comments also raised concerns regarding the brine or concentrate stream generated by reverse osmosis (RO) POU/POE units. Commenters questioned whether the systems would waste precious water in arid areas. EPA believes systems in arid areas are more likely to select activated alumina (AA) or another centralized treatment technology. Commenters also raised concern over the disposal of the concentrate from these units into sewer or septic systems. In response, EPA believes it would be highly unlikely for the concentrate stream to pose problems because only about 1% of the household water is treated, thereby minimally influencing the quality of the sewage discharged from the household. Finally, commenters questioned the ability of small systems to maintain POE/POU devices which are installed in private homes. EPA believes it is feasible for public water systems to own, control, and maintain POE/POU devices for arsenic MCL compliance either directly or through a contract with a qualified party. While EPA recognizes that access to homes for maintenance may be an issue for some systems, we believe that such access would be permitted in others, especially if significant cost savings could be achieved.

4. Waste Generation and Disposal

Many comments stated that EPA did not adequately consider problems with waste generation and disposal when evaluating which technologies would be most appropriately used for achieving compliance. Commenters expressed particular concern with anion exchange, activated alumina, and reverse osmosis because wastes generated from these processes, depending upon their operating and site specific conditions, could be hazardous or difficult to dispose of. Comments indicated that many utilities would have difficulty in achieving compliance with the proposed rule while also maintaining compliance with other environmental laws and regulations (e.g., RCRA and CWA). Commenters questioned EPA's analysis for the proposed rule that indicated that no RCRA hazardous wastes would need to be disposed in the decision tree.

Arsenic treatment technologies produce three different types of wastes: Brines, sludges and spent media. Depending upon arsenic concentration and the characteristics of the waste, each of these wastes can pose disposal challenges and has the potential for being classified as hazardous.

Arsenic wastes are defined as hazardous if their toxicity characteristic (TC) exceeds 5 mg/l of arsenic. The Toxicity Characteristic Leaching Procedure (TCLP) is a method by which waste is evaluated to determine if it exceeds the TC. If waste is $< 0.5\%$ dry-weight solids, then the liquid is defined as the TCLP extract and concentrations in it are compared against the TC level to determine if it is hazardous. If the waste is $\geq 0.5\ \%$ dry-weight solids, then a TCLP that conservatively simulates leaching from a landfill is used to determine if the TC level would be exceeded. EPA considered TC and TCLP results from residuals produced by the treatment technologies under consideration and selected only those technologies that would not produce a hazardous waste.

Upon the review of public comments and further analysis, EPA agrees with comments that some of the treatment train technologies in the decision tree of the proposed rule could have created hazardous wastes under certain operational circumstances. Thus, EPA has narrowed its selection of available technologies in the decision tree for the final rule as indicated in Table V.F–4.1. EPA believes that the treatment options included in Table V.F–4.1 can address all treatment challenges without creating hazardous wastes, while being able to achieve compliance with the final rule. EPA has revised its national costs upward to reflect the changes in the decision tree. These costs are described in more detail in this preamble and in support documents for this rule (EPA, 2000o and EPA, 2000t).

More specific rationale for the changes in the treatment train technologies considered in the decision tree are discussed in the following paragraphs and in the ‘‘Technology and Cost Document’’ (EPA, 2000t).

a. Anion exchange. When anion exchange resins are cleaned, they create a regeneration brine. Influent sulfate and arsenic concentrations, regeneration level, and rinse volume influence the resultant brine concentration levels of arsenic. EPA conducted modeling to determine the feasible operating conditions and source water arsenic and sulfate concentrations under which anion exchange could effectively remove arsenic without creating an arsenic brine that exceeded an arsenic concentration of 5 mg/L. Based on this analysis (EPA, 2000t), EPA determined brine arsenic concentrations could exceed 5 mg/L when: (a) Arsenic influent levels exceed 15 µg/L and sulfate concentrations exceed 25 mg/L, and (b) when arsenic influent levels exceed 25 µg/L and sulfate concentrations ranged between 25 and 90 mg/L. Based on this analysis, EPA eliminated landfills and evaporation ponds from the final decision tree for the conditions indicated in Table V.F–4.1.

As part of its proposed and final decision tree evaluation, EPA assumed that brine streams with < 0.5% solids could potentially be disposed of through domestic sewage or mixtures of domestic sewage to POTWs regardless of the TC, since this is excluded from regulation under RCRA. Piping the brine directly to the POTW without passing through the sewer system does not meet the exclusion, nor does trucking the brine to the POTW. Even though brine disposal via sewage to POTWs is not restricted by RCRA, EPA recognizes that brine disposal can be restricted by the POTW's pretreatment programs. POTWs may establish Technically Based Local Limits (TBLLs) for arsenic to control: arsenic concentrations in POTW biosolids, arsenic concentration in the POTW discharge, or total dissolved solids (TDS) in the POTW discharge.

Many comments indicated that significant increases in total dissolved solids would make brine disposal to a POTW unacceptable, especially in the Southwest where water resources are scarce. Even under the lowest regeneration level of 5.1 lb/ft^3 assumed in EPA's analysis, TDS increases would likely be prohibited by POTWs when influent sulfate concentrations exceed 90 mg/L, and limited to POTWs where brine volume is very small compared to total volume for sulfate concentrations between 25 and 90 mg/L. Therefore, as described in section I.F., EPA modified the compliance decision tree to assume systems with sulfate concentrations greater than 50 mg/L would not select anion exchange as a treatment technology. In its final decision tree, EPA assumed that drinking water plants with sulfate concentrations of less than 20 mg/l and with a regeneration frequency of 1500 bed volumes, or with sulfate concentrations between 20 and 50 mg/l and a regeneration frequency of 700 bed volumes, might use anion exchange with waste disposal via sewage to POTWs and be able to comply with local TBLLs. In the final decision tree less than 10% of the systems are assumed to use anion exchange versus over 50% of the systems being assumed to use this technology under the proposal.

b. Activated alumina. The proposed rule considered activated alumina with regeneration and listed discharge to a sanitary sewer as the disposal mechanism for the brines. Many comments on the proposed rule noted that TBLLs for arsenic or total dissolved solids might restrict discharge of brine streams to the sanitary sewer. Under today's final rule (see section I.F.), regeneration of activated alumina media is not recommended for a number of reasons, including the difficulty of disposing of the brines. In the final decision tree, EPA assumes disposal of spent AA media (either from central treatment or POU) to landfills as the waste disposal method for AA. EPA believes that spent AA media will be nonhazardous because the TCLP test is conducted using weak acid at a pH of 5 which is near the optimal pH for adsorption of arsenic onto AA (Kempic, 2000). Wang et al. (2000) evaluated AA spent media from two small systems having treating influent arsenic concentrations of > 50 µg/l and found TCLP with arsenic concentrations of 0.07 mg/L or less, well below the TCLP limit of 5 mg/L. Some public comments indicated concern that the TCLP test conditions at the pH of 5 may not reflect conditions at landfills which may have higher pHs. In response, EPA notes that the TCLP is the defining test specified in 40 CFR 261.24 for determining whether a waste is TC hazardous, and it applies regardless of the actual management of the waste unless some exemption applies.

In the final decision tree, EPA has revised the treatment train assumptions for AA to be operated in series (i.e., two treatment units in sequence rather than as singular units as was considered under the proposal) under various pH conditions (see Table V.F–4.2). Operation in series will allow longer-run times and more cost-efficient disposal of spent media. The range of pH conditions is assumed in consideration of public comments that some utilities will prefer to operate without pH adjustment, thereby minimizing oversight and the ‘‘footprint’’ of land needed for the treatment facilities (since no additional chemical feed or storage facilities are needed). While pH adjustment to low levels will optimize AA removal of arsenic, this may not be an option for certain facilities depending upon land availability. Therefore, EPA considers a wide range of pH conditions of AA in the series mode.

c. Reverse osmosis. Except for POU treatment, EPA did not use reverse osmosis in the decision tree of either the proposed or final rule (EPA, 2000h); EPA, 2000o). The concentrate stream from POU devices can be disposed of through discharge into domestic wastewater and thereby be exempt from RCRA regulation. It would also be highly unlikely for the concentrate stream to pose problems with TBLLs because only about 1% of the household water is treated, thereby minimally influencing the quality of the sewage reaching the POTW. Therefore, the decision tree to the final rule includes POU reverse osmosis.

TABLE V.F–4.1.—TREATMENT TRAINS IN FINAL VERSUS PROPOSED ARSENIC RULE DECISION TREE

Treatment train: treatment & residuals management combination	National cost estimate assumes will be selected by systems in		Reason for change
	Proposed rule	Final rule	
Regionalization	NO	NO	N/A
Alternate Source	NO	NO	N/A
Modify Lime Softening	YES	YES	N/A

TABLE V.F–4.1.—TREATMENT TRAINS IN FINAL VERSUS PROPOSED ARSENIC RULE DECISION TREE—Continued

Treatment train: treatment & residuals management combination	National cost estimate assumes will be selected by systems in		Reason For Change
	Proposed rule	Final rule	
Modify Coagulation/Filtration	YES	YES	N/A
Anion Exchange (25 mg/L sulfate) & POTW discharge.	YES	YES	Treatment name revised—Anion Exchange (<20 mg/L sulfate).
Anion Exchange (150 mg/L sulfate) & POTW discharge.	NO	NO	N/A
Anion Exchange (25 mg/L sulfate) & Evaporation Pond, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Anion Exchange (150 mg/L sulfate) & Evaporation Pond, Landfill.	NO	NO	N/A
Activated Alumina (16500 Bed Volumes) & Landfill	YES	REVISED	Revised approach uses multiple columns in series operation.
Activated Alumina (3000 Bed Volumes) & Landfill	NO	NO	N/A
Reverse Osmosis & direct discharge	NO	NO	N/A
Reverse Osmosis & POTW discharge	NO	NO	N/A
Reverse Osmosis & Chemical Precipitation, Landfill.	NO	NO	N/A
Coagulation Microfiltration & Mech. Dewatering, Landfill.	YES	YES	N/A
Coagulation Microfiltration & Non-Mech. Dewatering, Landfill.	YES	YES	N/A
Oxidation Filtration & POTW discharge	YES	YES	N/A
Anion Exchange (25 mg/L sulfate) & Chem Precipitation, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Anion Exchange (150 mg/L sulfate) & Chem Precipitation, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Activated Alumina (16500 BV) & POTW	NO	NO	N/A
Activated Alumina (3000 BV) & POTW	NO	NO	N/A
Anion Exchange (90 mg/L sulfate) & POTW	YES	REVISED	Lower sulfate concentration selected to minimize total dissolved solids increase. Commenter issue—EPA evaluation.
Anion Exchange (90 mg/L sulfate) & Evaporation Pond, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Point-of-Entry Activated Alumina	YES	NO	Run length only exceeds six months when finished water pH <7.5
Point-of-Use Reverse Osmosis	YES	YES	N/A
Point-of-Use Activated Alumina	YES	YES	N/A

TABLE V.F–4.2.—NEW OR REVISED TREATMENT TRAINS

Treatment Train	Revision
Activated Alumina (pH7-pH8) & Landfill.	Series Operation.
Activated Alumina (pH8–8.3) & Landfill.	Series Operation.
Activated Alumina (pH adjusted to pH6—23,100 Bed Volumes) & Landfill.	Series Operation.
Activated Alumina (pH adjusted to pH6—15,400 Bed Volumes) & Landfill.	Series Operation.
Anion Exchange (20–50 mg/L sulfate) & POTW.	Use 700 Bed Volumes as Run Length.

5. Emerging Technologies

A number of comments state that several of the emerging technologies discussed in the proposal (*e.g.,* granular ferric hydroxide, see section I.F) are likely to be the most cost effective treatment option for systems, particularly small systems. These comments state that systems may not select these emerging technologies because they have not been listed as BAT. In response, EPA must clarify that systems are not required to use BAT to achieve compliance with the MCL. A system may use any technology that is accepted by the State primacy agency provided the technology achieves compliance with the MCL. However, if a system is unable to meet the MCL with its chosen technology, the system will not be eligible for a variance unless the installed technology is listed as BAT. Other comments indicated that there will not be sufficient time for further testing of these emerging technologies prior to the effective date of the MCL. EPA notes that because of the capital improvements required for compliance with the MCL, the effective date of today's rule is 5 years from the date of promulgation for all system sizes. This should provide systems with adequate time for testing of the emerging technologies. Moreover, States may, as described in section I.H, provide small systems with up to an additional nine years to comply through exemptions.

G. Costs

1. Disparity of Costs

Many public comments stated that EPA substantially underestimated costs for implementing the proposed rule. Comments pertained to national cost or regional cost estimates and system level cost estimates. Commenters stated that EPA's national cost estimates were low because: (a) The decision tree led to an over selection of technologies with low associated costs, and (b) the system level costs associated with the selected technologies were low. Elaboration of public comment concerns and EPA's response in each of these categories follows. Also, since many public comments referred to the report ''Cost Implications of a Lower Arsenic MCL'' (Frey *et al.*, 2000) as a basis for their comments, EPA analyzed the report in detail. As noted below, the Agency disagrees with the approach Frey *et al.* (2000) used to produce the cost estimates in this report.

a. What is EPA's response to major comments on the decision tree for the proposed rule? Commenters indicated that EPA's decision tree did not adequately recognize constraints in technology selection including feasibility of waste disposal, concerns with compliance with other EPA regulations (*e.g.*, RCRA and CWA), land availability, complexity of operation and availability of skill level (particularly for small systems), and excess use of water in water scarce areas. Particular concern was raised by the extent to which EPA predicted that anion exchange would be used given concerns with sulfate and total dissolved solids, chromatographic peaking (possible rapid breakthrough of arsenic at above influent concentration levels due to competition from other ions), and handling of regeneration process streams and disposal of wastes (some of which may be hazardous). Commenters also suggested that EPA over predicted the use of greensand filtration since it only removes a limited amount of arsenic at low iron concentrations. Comments suggested that EPA should consider much greater use of activated alumina in the spent media replacement mode with disposal to landfills because of facility of operation and low costs. Comments also suggested use of reverse osmosis and nano-filtration in areas unlikely to have a water scarcity problem. Although central treatment with reverse osmosis was listed as one of the possible compliance technologies under the proposed rule, it was not used in the EPA's decision tree.

In preparing the cost estimate for the proposed rule, EPA predicted compliance outcomes by considering: (1) Technologies already in place, (2) feasibility of application of the technology, and (3) least cost of technology. Given all available information at the time of proposal, EPA developed its decision tree. EPA received many informative comments pertaining to the feasibility of various treatment technologies considered. EPA agrees with public comments that some of the waste disposal options considered with anion exchange under the proposed rule could create hazardous wastes (see V.F.4. of this preamble). To address this concern EPA has eliminated the following treatment trains from its final decision tree: Anion exchange with chemical precipitation and disposal of waste to landfills, and anion exchange with discharge to evaporation ponds and disposal of waste to landfills.

EPA agrees with public comments that activated alumina is likely to be used by many more systems than EPA predicted in the proposal. In response to comments, EPA revised the treatment train assumptions for AA to be operated in series under various pH conditions. Operation in series will allow longer run times and more cost-efficient disposal of spent media. The range of pH conditions is assumed in consideration of public comments that some utilities will prefer to operate without pH adjustment, thereby minimizing oversight and the ''footprint'' needed for the treatment facilities. While pH adjustment to pH 6.0 will optimize AA removal of arsenic, this may not be an option for certain facilities depending upon available land and expertise. Thus, EPA recognizes higher operational costs for AA for a substantial number of systems operating at less than optimal pH.

Research (Subramanian *et al.*, 1997) indicates that oxidation filtration (greensand filtration) achieved about 80% removal of arsenic when the iron to arsenic ratio was 20:1 but less than 50% removal when the iron to arsenic ratio was 7:1. In developing national cost estimates, EPA assumed that systems would opt for this type of technology only if more than 300 µg/L of iron was present in the source water and no more than 50% arsenic removal was needed to achieve the MCL. EPA believes that its applicability assumptions for greensand filtration are conservative and therefore continues to support its usage in the decision tree for the final rule. Greensand filtration is a relatively inexpensive technology that may be appropriate for those systems that do not require much arsenic removal and have high iron in their source water. However, in the decision tree for the final rule, EPA lowered the expected use of greensand filtration to systems serving less than 3,300 (versus in systems serving less than 10,000 under the proposed rule) and reduced its usage by about ⅓ (EPA, 2000h; EPA, 2000h). This drop is mainly attributed to the change in the MCL and fewer systems having arsenic at levels between 5 µg/L and 10 µg/L than between 10 and 20 µg/L. The ranges 5–10 µg/L and 10–20 µg/L reflect the arsenic concentration ranges that systems would have to fall within to be able to consider greensand, if only 50% removal efficiency is assumed.

EPA continues to believe that reverse osmosis, while a very effective technology for removing arsenic, is not likely to be used as a centralized treatment option (even in areas of ample water supply) because of higher costs relative to other treatment options. EPA did not consider nanofiltration a likely compliance technology because of high costs relative to other technologies and decreased removal efficiency when operated to constrain production of waste streams.

b. What is EPA's response to comments on system level costs? Under the proposed rule EPA only included activated alumina (AA) costs for small systems. A number of comments indicated that EPA should revise its decision tree to include AA and associated costs for all system sizes because AA is more economical than anion exchange. After considering the information provided by these comments, EPA expanded estimates of the use of AA in the decision tree for the final rule. EPA also revised its decision tree and developed costs for four different types of AA treatment for all system sizes—two for unadjusted pH and two where the pH has been adjusted to the optimal pH of 6. (The effects of these changes in the decision tree analysis are described in section V.G.1). The main change between the design used for the proposed rule versus the final rule is that smaller columns containing the activated alumina are operated in series rather than as a single column. This will provide greater utilization of the media before disposal and is more consistent with the designs used by commenters in evaluating disposable activated alumina. EPA's new AA costs specify different unit cost equations and flow boundary conditions for small versus large systems. Also, EPA has included new operating and maintenance (O&M) costs for waste disposal of spent AA media. The effect of all these changes is, in general, to decrease capital costs but to increase O&M costs and to increase overall AA system level costs within a particular size category. Despite these increases in costs for AA, AA is by far the most used technology among ground water systems in the final decision tree. The ''Arsenic Technologies and Costs'' (T&C) document (EPA, 2000t) for the final rule describes in detail the basis for the unit costs used for each of the new types of AA treatment.

Several comments indicated that EPA's cost estimates were calculated for flow rates outside of their boundary conditions and thus the accuracy of many of the unit costs are in error. EPA analyzed the data provided by these comments and revised the cost equations used to estimate unit costs for the final rule. We modified cost equations and flow boundary conditions for AA, modified coagulation filtration, modified lime softening, anion exchange, coagulation microfiltration, and POU treatment. Most of the unit costs increased relative to those used for the proposed rule. The T&C document (EPA, 2000t) describes the basis for the unit costs used for the final rule.

A number of comments stated that EPA's cost estimates should include pre-oxidation costs with AA in ground waters since many systems may not already be disinfecting. EPA must clarify that the cost estimates included prechlorination costs for any system that did not have existing disinfection treatment. For ground water systems, 13% to 54% (depending upon system size) of systems predicted to use AA were assumed to add pre-oxidation.

Several comments indicated that EPA's cost estimates for the proposal did not include corrosion control costs. However, the corrosion control costs were included as a component of the unit costs for the following technologies: modified lime softening, modified coagulation filtration, coagulation assisted microfiltration, and activated alumina options operating at the optimal pH. EPA believes that through appropriate use of corrosion control, systems will be able to comply with the lead and copper rule and meet the arsenic MCL.

c. What is EPA's response to comments that state the report ''Cost Implications of a Lower Arsenic MCL'' (Frey et al., 2000), be used as a basis for reflecting more realistic national costs than EPA's estimates? A number of comments noted that the report ''Cost Implications of a Lower Arsenic MCL'' (Frey *et al.*, 2000), ''the Cost Implications Report,'' or ''the report,'' provides best-case national estimated annualized costs of $1,460 million at the 5 μg/L arsenic MCL option and $605 million at the 10 μg/L MCL option. Many comments stated that EPA's national cost estimates were unrealistically low based upon the Cost Implications Report.

EPA appreciates the substantial level of information available from the Cost Implication Report in regard to evaluation of technological feasibility for arsenic removal. This report was one of several sources that influenced EPA to predict much less use of anion exchange and much greater use of activated alumina in the decision tree for the final rule. However, EPA believes that some parts of the report's analysis contributed to overestimating national cost estimates. These issues include differences in flow rate assumptions, unit costs, and national estimates for arsenic occurrence, summarized below. A more detailed analysis is available in EPA's Response to Comment Document for the final rule.

Flow rate assumptions. Flow rate assumptions are used with engineering cost models to estimate system level treatment costs for various technologies considered appropriate for achieving compliance. If flow rates are overestimated, system level treatment and national costs will be overestimated. EPA uses design flow rates to estimate capital costs and average flow rates to estimate operational and maintenance costs.

The Cost Implications Report (Frey *et al.*, 2000) uses significantly higher flow rates than EPA (EPA, 2000h; EPA, 2000o) for conducting national cost impact analysis for alternative arsenic MCLs. For most population categories of systems ranging between 3301 and 1 million people, AWWARF used flow rates that were 2–4 times higher than EPA's assumptions. Based on EPA's analysis of the Cost Implication Report it appears that the report used more system size categories than EPA and transferred flow rates for larger-system size categories into smaller-system size categories. EPA believes that differences in the flow rate assumptions would produce an estimate of at least $400 million per year higher than an estimate using EPA's flow rates for the proposed arsenic MCL option of 5 μg/L.

Since the release of the Cost Implications Report, the authors revised their analysis to include different flow rates (Frey *et al.*, October 2000), ''the Updated Cost Implications Report.'' The updated report based its new flow rates on the equations provided in the Proposed Arsenic in Drinking Water Rule Regulatory Impact Analysis (EPA, 2000h). The flow rates for ground water systems were based on the population/flow equations for publicly owned ground water systems and the authors selected the midpoint in each population category (e.g., using a flow of systems serving 550,000 persons to estimate costs for systems serving between 100,000 and 1 million people). In the Updated Cost Implications Report the authors state that:

> [T]he cost response to the difference in flow rates is mixed due to the large flow increases in the two largest population categories (100,0000 to 1 million and > 1 million) versus the decreases in the other flow categories (5,000 to 100,000).

EPA believes that the revised analysis with the new flow rates in the Updated Cost Implications Report still overestimates costs. First, the revised design and average flows are only larger for ground water systems with populations greater than 1 million people. Second, estimating flow rates for systems within a category using the population midpoint assumptions in the revised analysis continues to cause cost overestimates because many more systems in each population size category occur in the lower part of the range than the upper part of the range. For example, EPA's data indicate that, in the flow category of ground water systems serving 100,000 to 1 million people, one-half of the systems have populations under 173,000 people (EPA, December 1997 Freeze of Safe Drinking Water Information System) and that the mean population among systems is 248,000 people (EPA, 2000a). In its cost estimates, EPA considers the distribution of flow rates within each size category for estimating system level cost contributions to the national impact (EPA, 2000h; EPA, 2000o). Third, Table 4.6 of the Cost Implication Report (Frey *et al.*, 2000) provides a distribution of ground water systems nationally by system size and arsenic concentration, and indicates there are no ground water systems serving more than 1,000,000 projected to have arsenic concentrations that exceed 5 μg/L. Since no ground water systems serving more than 1,000,000 people need to treat for MCL options of 5 μg/L or higher, the national costs given in the revised report due to the revised flow rate assumptions in all categories should be lower for MCL options at or above 5 μg/L.

On a related issue, EPA believes that the operation and maintenance cost equations for anion exchange, activated alumina, coagulation/microfiltration, and nanofiltration in the Cost Implication Report (Frey *et al.*, 2000) were based on design flow rather than average flow. Using the operational and maintenance cost equations based on design flow rather than average flow significantly increases cost estimates, particularly for smaller systems (EPA's analysis indicates that for systems with a design flow of 1 M.D., the total annualized costs would increase by about 25% and for systems with a design flow of 10 M.D., the total annualized costs would increase by about 5%).

Unit Cost assumptions: The Cost Implication Report (Frey *et al.*, 2000) develops unit cost equations for a technology type based on a wide range of operating conditions, some of which may not be very cost effective (*e.g.,* anion exchange with sulfate concentrations ranging from 25 to 150 mg/l). Because of their recognized lack of cost effectiveness for particular situations, the technologies have limited application in the national compliance forecast, even in situations with sulfate concentrations less than 25 mg/L. This costing approach tends to overestimate costs for systems with favorable site specific conditions. On the other hand, EPA developed cost equations for technology types within an operating range for which the technology can most cost effectively operate (*e.g.*, anion exchange with sulfate concentrations of less than 25 mg/L) and used these equations for the limited number of systems that would meet the constraints. Utilities would not likely choose technologies unless they were favorable to use and thus only those conditions at which the technology is used should be costed, in our view.

EPA believes that the Cost Implication Report case study costs for activated alumina were significantly overestimated due to the vessel costs. The vendor quote used for vessel costs is for a complete activated alumina system, including the costs for vessels, media, pipes and valves, chemical feed and storage, start-up, shipping and contingencies. The vendor quote presents budget prices for three design flows and different size vessels are used for each design flow. The vessel sizes are listed with the budget price, along with many additional costs, which may have been a source of confusion. Since activated alumina is the most used technology in the compliance forecast in the Cost Implications Report, double counting full system costs for activated alumina will significantly affect national cost estimates, particularly for smaller systems.

Arsenic occurrence assumptions. The occurrence distributions based on the Frey and Edwards (1997) National Arsenic Occurrence Survey (NAOS) change throughout Chapter 4 of the Cost Implication Report. The national compliance costs are based on the occurrence distribution with the highest number of systems above the MCL options, but no basis is given for this selection. EPA believes that the arsenic occurrence distribution used in the report for the compliance forecast analysis significantly overestimates the distribution of arsenic occurrence above 20 µg/L and this significantly biases costs upward.

2. Affordability

Many commenters expressed concern that their system, or many households served by their system, would be unable to afford to comply with the proposed arsenic standard and that the DWSRF would be incapable of providing significant assistance. Concerns relating to costs and burden contributed to the Agency's decision to promulgate a standard of 10 µg/L rather than the proposed standard of 5 µg/L. The Agency's decision to promulgate a standard of 10 µg/L significantly reduces the impacts on small systems. At the proposed standard of 5 µg/L, about 6,500 community water systems would have needed to install treatment. At the promulgated standard of 10 µg/L, about 2,800 small community water systems (and 1100 NTNCWS) will need to install treatment. Total capital costs for the promulgated standard are 57% lower (for both community water systems and NTNCWS) than they would have been for the proposed standard. Although the number of systems needing to treat at the promulgated standard is well under one half of the number that would have needed to treat at the proposed standard, the household level impact for those systems needing to treat is about the same.

The Agency believes that affordability of drinking water at the household level is a function of two key variables: price of the water and the ability of the household to pay. Each of these two key variables is, in turn, a function of a number of other variables. A comprehensive and meaningful analysis of affordability for an individual system must include a complete assessment of all of the variables that influence both price and ability to pay. These variables are highly site specific. That is why the framework for addressing affordability concerns in SDWA consists of two distinct parts: (1) A national level affordability analysis focused on assessing what would be affordable (from a national perspective) for typical systems in a size class, and (2) State-level analysis, using State-developed criteria, to assess affordability for any specific system.

The price of drinking water (the actual charge imposed on the household for its water service) reflects the complex interplay of many variables. These variables include the water system's full cost of doing business, subsidies or other forms of financial assistance that offset some of the system's costs, and the allocation of costs by the water system to its users and the rate design employed by the water system. The system's cost of providing service is influenced by many different factors, *e.g.*, the quality of the source water available to the system, the type of treatment employed and the skill of its operation, and the basic organizational or institutional structure of the water system. Systems that effectively work together, perhaps by combining management, will realize lower overall costs compared to the same systems working independently. Section I.L discusses Federal financial assistance which is available to help systems comply with arsenic and other drinking water standards. Section III.E.4 further discusses issues considered by EPA in assessing the affordability of the arsenic rule.

One commenter submitted a study which concludes that establishing a new arsenic MCL at a level of 5 µg/L (or lower) will raise serious concerns about the affordability of water service for a majority of affected ground water systems. The Agency reviewed the study and notes a number of significant deficiencies in its assumptions and general methodology. The Agency disagrees with the commenter's selection of $50 per household per year as affordable on the basis of expenditures on lottery tickets and with the commenter's selection of $100 per household/year as posing ''serious affordability concerns'' on the basis of it representing some percentage of expenditures on health care or telephone service. The Agency notes that the Consumer Expenditure Survey, compiled by the Bureau of Labor Statistics, offers a broad overview of expenditure patterns across households of various incomes. The Consumer Expenditure Survey's data do not necessarily support the contention that an increase in water bills would force a low-income household to trade off health care or some other ''essential'' expenditure to pay the water bill. Clearly, however, individual household circumstances vary greatly and certain individual households may face difficult choices. Another important consideration is that assessing expenditure trade offs by low-income households must fully account for all the assistance such households can receive, including subsidized housing, medical care through Medicaid, food stamps, and so on. Simply looking at a low-income household on the basis of its cash income can overlook important assistance available. The commenter also assumes that if a regulation increases the cost of water by 0.5% of median household income in a community, it might raise an affordability concern. The commentor justifies this value by asserting that such an increase would be more than a 50% increase in the water bill for a typical household. The Agency finds this argument unconvincing. For a household with the median income, the water bill would represent about 0.9% of income. It is widely acknowledged that water has been historically underpriced. Thus, saying that no more than a 50% increase would be affordable is to accept the historic underpricing as appropriate. The commenter also assumes the cost estimates that EPA believes are significantly overestimated are correct. Thus, the commenter's conclusion that establishing a low arsenic standard will raise serious concerns about the affordability of water service for a majority of affected ground water systems is unsupported. The subsequent conclusion that existing variance and grant programs would not be adequate to alleviate affordability concerns is likewise unsupported. (See section I.H. of today's preamble for a discussion of variances and exemptions and section I.L. for a discussion of financial assistance available for complying with this rule.)

A number of commenters indicated that they did not agree with EPA's approach for assessing national level affordability. Affordability is a complex concept. Numerous different approaches have been developed for assessing affordability of drinking water and/or wastewater service. Many of these approaches are summarized in the Agency's publication ''Information for States on Developing Affordability Criteria for Drinking Water'' (EPA, 1998a). It is essential that the specific purpose for which any affordability criterion is developed be clearly understood. EPA's national affordability criteria are developed and applied for a very narrow and specific purpose.

Section 1412(b)(4)(E)(ii) of SDWA , as amended, requires EPA to list technology (considering source water quality) that achieves compliance with the MCL and is affordable for systems in three specific population size categories: 25–500, 501–3300, and 3301–10,000 when promulgating a national primary drinking water regulation which establishes an MCL. If, for any given size category/source water quality combination, an affordable compliance technology cannot be identified, section 1412(b)(15)(A) requires the Agency to list a variance technology. Variance technologies may not achieve full compliance with the MCL but they must achieve the maximum contaminant reduction that is affordable considering the size of the system and the quality of the source water. In order for the technology to be listed, EPA must determine that this level of contaminant reduction is protective of public health.

Thus, EPA developed national affordability criteria for the narrow and specific purpose of determining whether or not an affordable compliance technology exists, from a national perspective, for the specified size categories of systems, considering the quality of source waters available to them. The key point at issue here is what EPA should consider ''affordable'' from a national perspective. EPA does not define national level affordability in terms of what would be affordable to the least affluent water systems. Likewise, EPA does not define national level affordability in terms of what would be affordable to the most affluent water systems. Rather, a determination of national level affordability is concerned with identifying, for each of the given size categories, some central tendency or typical circumstance relating to their financial wherewithal.

The metric EPA selected for this purpose is the median household income for communities of the specified sizes. Some commenters expressed concern that EPA was using the national median household income (across all sizes of systems) in making judgments on national-level affordability. The Agency wishes to clarify that this was not the case. We used median household income for communities of the specified size categories, as documented in EPA's August 6, 1998 **Federal Register** notice (EPA, 1998h). The household is thus the focus of the national-level affordability analysis. EPA considers treatment technology costs affordable to the typical household if they represent a percentage of MHI that appears reasonable when compared to other household expenditures. This approach is based on the assumption that the affordability to the median household served by the CWS can serve as an adequate proxy for the affordability of technologies to the system itself. The national-level affordability criteria have two major components: current annual water bills (baseline) and the affordability threshold (total % of MHI directed to drinking water). Current annual water bills were derived directly from the 1995 Community Water System Survey. Based on 1995 conditions, 0.75–0.78% of MHI is being directed to water bills for systems serving fewer than 10,000 persons.

The fundamental, core question in establishing national-level affordability criteria is: what is the threshold beyond which drinking water would no longer be affordable for the typical household in each system size category? Based upon careful analysis, EPA believes this threshold to be 2.5% of MHI. In establishing this threshold, the Agency considered baseline household expenditures (as documented in the 1995 Consumer Expenditure Survey, Bureau of Labor Statistics) for piped water relative to expenditure benchmarks for other household goods, including those perceived as substitutes for higher quality piped water such as bottled water and POU/POE devices. Based on these considerations, EPA concluded that current household water expenditures are low enough, relative to other expenditures, to support the cost of additional risk reductions. The detailed rationale for the selection of 2.5% MHI as the affordability threshold is provided in the guidance document entitled ''Variance Technology Findings for Contaminants Regulated Before 1996'' (EPA, 1998l). The difference between the affordability threshold and current water bills is the available expenditure margin. This represents the dollar amount by which the water bill of the typical (median) household could increase before exceeding the affordability threshold of 2.5% of MHI.

The Agency recognizes that baseline costs change over time as water systems comply with new regulations and otherwise update and improve their systems. MHI also changes from year to year, generally increasing in constant dollar terms. For example, since 1995 MHI has increased (in 1999$) by 9.6%. Thus, to determine the available expenditure margin (the difference between the affordability threshold and the baseline) for each successive rule, adjustments would need to be made in both the baseline and the MHI. The Agency believes that, for purposes of assessing national-level affordability of the arsenic rule, the unadjusted baseline and unadjusted MHI are appropriate. Making adjustments to these two factors would not materially alter the outcome of the analysis, since both the baseline and the MHI would increase, and not by dramatically differing percentages. Thus the difference between the two would not significantly change.

By definition, the MHI is the income value exactly in the middle of the income distribution. The median is a measure of central tendency; its purpose is to help characterize the nature of a distribution of values. The Agency recognizes that there will be half the households in each size category with incomes above the median, and half the households with incomes below the median. The objective of a national-level affordability analysis is not to determine what is affordable to the poorest household in the U.S. Nor is it to determine what the richest household in the U.S. could afford. Rather, it is to look across all the households in a given size category of systems and determine what is affordable to the typical, or ''middle of the road'' household.

The distinction between national-level affordability criteria and affordability assessments for individual systems cannot be over-emphasized. The national-level affordability criteria serve only to guide EPA on the listing of an affordable compliance technology versus a variance technology for a given system size/source water combination for a given contaminant. In the case of arsenic, EPA determined that nationally affordable technologies exist for all system size categories and has therefore not identified a variance technology for any system size/source water combination. This means that EPA believes that the typical household in each system size category can afford the costs associated with the listed compliance technologies. EPA recognizes that individual water systems may serve a preponderance of households with incomes well below the median, or may face unusually high treatment costs due to some unusual local circumstance. As discussed more fully in sections I.H, I.L, and III.F.4, there are a number of tools available to address affordability concerns for these individual water systems. The major tools are financial assistance (low-interest loans and grants); extended compliance time-frames under a State-issued exemption; life-line and other types of rate structures that systems may use; and, restructuring of system management and operations through partnerships among systems.

3. Combined Cost of New Regulations

A number of commenters expressed concern about the cumulative cost to water systems of new drinking water regulations. The Agency recognizes this concern and acknowledges that there is a small percentage of systems faced with co-occurrence and for whom there will be multiple treatment requirements. However, for such systems, the Agency notes that installation of treatment for one contaminant (such as arsenic, in this case) may often reduce the amount of treatment needed to remove many types of subsequently regulated contaminants, since the initial treatment will likely remove at least some of the subsequently regulated contaminant; particularly, certain types of inorganic contaminants.

The most common cumulative impact will be that associated with initial monitoring. Most systems will need to conduct at least some limited initial monitoring for most regulated contaminants. However, for the vast majority of systems that will not detect the contaminant at levels of concern, subsequent monitoring will be limited and infrequent, with monitoring variances available for up to once every nine years.

4. Projected Effects of the New Standard on Other Regulatory Programs

Several commenters felt that EPA has underestimated the costs of the proposed rule by failing to fully consider the possible costs of a new, lower drinking water standard on other regulatory programs, particularly hazardous waste. EPA disagrees and does not believe that certain ancillary costs identified by commenters should be considered in the cost of compliance analysis nor should they be a factor considered in establishing the MCL. For instance, the prospective costs of future CERCLA site clean-up actions are not among the factors that SDWA requires EPA to consider in establishing an MCL. Moreover, there are a host of site-specific factors taken in account in any CERCLA site clean-up situation beyond the clean-up standard itself (which may be an MCL under the CERCLA requirement to consider ''applicable or relevant and appropriate requirements'' (ARARs)). In the case of RCRA, EPA notes that the arsenic in drinking water final rulemaking does not necessarily trigger a revision of the Toxicity Characteristic standard under RCRA. Thus, there are not necessarily any new costs to entities affected by RCRA requirements as a result of this rulemaking. In any case, SDWA section 1412(b)(3)(C)(i)(III) specifically excludes consideration of such costs from other regulatory programs in the development of drinking water standards.

H. Benefits of Arsenic Reduction

Significant comments on the benefits analysis for the proposed arsenic rule addressed the topics of the timing of health benefits accrual (latency); the use of the Value of Statistical Life (VSL) as a measure of health benefits; the use of alternative methodologies for benefits estimation; the Agency's consideration of non-quantifiable benefits in its regulatory decision-making process; the Agency's analysis of incremental costs and benefits of the proposed arsenic rule; and, the Agency's assumption that health risk reduction benefits will begin to accrue at the same time costs begin to accrue.

1. Timing of Benefits Accrual (Latency)

Some commenters argued that EPA should have discounted its health benefits for the arsenic rule over a cancer latency period. As noted in the proposed rule, EPA committed to taking this issue before the Science Advisory Board (SAB) for its advice and recommendations.

EPA brought this issue before the SAB in a meeting held on February 25, 2000 in Washington, DC (65 FR 5638, February 4, 2000; EPA, 2000a). The SAB submitted a final report on their findings and recommendations to us on July 27, 2000 (EPA, 2000j). This final report was made available on the EPA website at *www.epa.gov/sab/eeacf013.pdf.*

The SAB Panel noted that benefit-cost analysis, as described in the Agency's Guidelines [for economic analysis], is not the only analytical tool nor is efficiency the only appropriate criterion for social decision making, but notes that it is important to carry out such analyses in an unbiased manner with as much precision as possible. In its report, the SAB recommended that the Agency continue to use a wage-risk based VSL as its primary estimate; any appropriate adjustments that are made for timing and income growth should be part of the Agency's main analysis while any other proposed adjustments should be accounted for in sensitivity analyses to show how results would change if the VSL were adjusted for some of the major differences in the characteristics of the risk and of the affected populations.

Specifically, the SAB report recommended that: (1) Health benefits brought about by current policy initiatives (i.e., after a latency period) should be discounted to present value using the same rate that is used to discount other future benefits and costs in the primary analysis; (2) adjustments to the VSL for a ''cancer premium'' should be made as part of a sensitivity analysis; (3) adjustments to the VSL for voluntariness and controllability should be made as part of a sensitivity analysis; (4) altruism should be addressed in a sensitivity analysis and separately from estimation of the value of a statistical cancer fatality and the circumstances under which altruism can be included in a benefit-cost analysis are restrictive; (5) estimates of VSLs accruing in future years should be adjusted in the primary analysis to reflect anticipated income growth, using a range of income elasticities; (6) adjustments to the VSL for risk aversion should be made in a sensitivity analysis; (7) it is theoretically appropriate to calculate WTP for individuals whose ages correspond to those of the affected population, but that more research should be conducted in this area; and (8) no adjustment should be made to the VSL to reflect health status of persons whose cancer risks are reduced.

Consistent with the recommendations of the SAB, EPA developed a sensitivity analysis of the latency structure and associated benefits for arsenic, a summary of which is shown in Section III.E of the final preamble. This analysis consists of health-risk reduction benefits which reflect adjustments for discounting, incorporation of a range of latency period assumptions, adjustments for growth in income, and incorporation of other factors such as a voluntariness and controllability. Although the SAB recommended accounting for latency in a primary benefits analysis, the Agency believes that, in the absence of any sound scientific evidence of latency periods for arsenic related cancers, discounted benefits estimates for arsenic are more appropriately accounted for in a sensitivity analysis. Sensitivity analyses are generally reserved for examining the effects of accounting for highly uncertain factors, such as latency periods, on health risk reduction benefits estimates.

2. Use of the Value of Statistical Life (VSL)

Some commenters felt that the Value of Statistical Life (VSL) used by EPA in its analysis of benefits for the arsenic rule was incorrect. EPA disagrees with these commenters for several reasons. First, the VSL used by the Agency in its benefits analysis is based on the most current data available. The VSL, as recommended by Agency guidance and EPA's SAB, is derived from a statistical distribution of the values found in 26 wage-risk studies, which were chosen as the best such studies available from a larger body of studies. This examination of studies was undertaken by EPA's Office on Air and Radiation in the course of its Clean Air Act retrospective analysis. EPA believes the VSL estimate ($6.1 million, 1999 dollars) to be the best estimate at this time and is recommending that this value be used by the various program offices within the Agency. This estimate may, however, be updated in the future as additional information becomes available to assist the Agency in refining its VSL estimate. The VSL estimate is consistent with current Agency economic analysis guidance, which was reviewed by EPA's SAB.

Also, the use of the VSL for benefits valuation is consistent with recommendations from EPA's SAB, which discussed this issue in their meeting on February 25, 2000 in Washington, DC. The SAB's report on their findings and recommendations from the February meeting stated that:

> despite limitations of the VSL estimates, these seem to offer the best available basis at present for considering the value of fatal cancer risk reduction. We therefore recommend that the Agency continue to use a wage-risk-based VSL as its primary estimate, including appropriate sensitivity analyses to reflect the uncertainty of these estimates (EPA, 2000j).

In addition, some commenters disagreed with EPA's valuation of a human life. EPA disagrees with these commenters because the VSL does not represent the value of an actual human life. Rather, the VSL represents the value of people's willingness to pay for small changes in the risk of a fatality.

3. Use of Alternative Methodologies for Benefits Estimation

Several commenters suggested that the Agency use a Quality Adjusted Life Years (QALYs) or a Life Years approach in its valuation of health benefits for the arsenic rule. EPA disagrees with these commenters because the current economic literature does not support these methodologies and EPA believes these approaches are not sufficient for use in economic analyses.

The use of alternative methodologies, such as Quality Adjusted Life Years (QALYs) and a Life-Years approach, has been extensively discussed both within EPA and also before the Environmental Economics Advisory Committee (EEAC) of EPA's SAB. The QALY method allows information on life expectancy and quality of life to be combined into a single number for benefits valuation purposes. QALYs involve rating each year of life on a scale from zero to one, where one represents perfect health and zero represents the worst possible health state. Because patients themselves, or sometimes citizens of the community, are responsible for ''rating'' each year, these quality-of-life tradeoffs are highly subjective and may not be very meaningful. Regarding the use of QALYs, the SAB committee stated that ''there are no published studies that show that persons with physical limitations or chronic illnesses are willing to pay less to increase their longevity than persons without these limitations. People with physical limitations appear to adjust to their conditions, and their WTP to reduce fatal risks is therefore not affected. The EEAC suggests that no adjustments be made to the VSL to reflect the health status of persons whose cancer risks are reduced, unless additional research documents such effects'' (EPA, 2000j).

A Life-Years approach involves use of a Value of Statistical Life Year (VSLY) measure. The VSLY measure values life-years that would be lost if an individual were to die prematurely. The relationship between the value of risk reductions and expected life years remaining is complex; current research does not provide a definitive way of developing estimates of VSLY that are sensitive to such factors as current age, latency of effect, life years remaining, and social valuation of risk reduction. While age adjustments may be desirable from a theoretical standpoint, in the absence of such information, the mainstream economics literature does not support developing VSLY estimates.

The SAB's Environmental Economics Advisory Committee (EEAC), in its report, confirmed this finding. The use of VSLY for valuing life-years lost was found by the EEAC to not have a sufficient theoretical and empirical basis for making any adjustments at this time. While the EEAC agreed that the theoretically appropriate method is to calculate WTP for individuals whose ages correspond to those of the affected population, the Committee recommended that more research be conducted on this topic before the Agency makes any adjustments for age in its estimates of health risk reduction benefits.

Therefore, because of the limitations enumerated above, EPA disagrees with the use of the VSLY as a measure of benefits. This position has also been incorporated in the Agency's Guidelines for Preparing Economic Analyses (EPA, 2000n). The Agency's economic analysis guidelines were reviewed and approved by the Regulatory Policy Council and are considered when the Agency makes economic policy determinations.

At this time, current Agency policy is to use VSL estimates for the monetization of health risk reduction benefits. As noted already, this policy is also consistent with recommendations from the EPA's SAB, which discussed this issue in a meeting held on February 25, 2000 in Washington, DC.

4. Comments on EPA's Consideration of Nonquantifiable Benefits

Some commenters felt that EPA did not fully consider nonquantifiable benefits in their decision-making process. EPA respectfully disagrees with these commenters. SDWA requires that the Agency take into consideration any potential quantifiable and nonquantifiable benefits associated with regulating arsenic in drinking water. To this end, the Agency displayed quantifiable costs and benefits and nonquantifiable benefits in the same table in the proposal (see Table XI–1 of the proposed rule), so that quantifiable and nonquantifiable benefits were given equal consideration in the determination of a regulatory level. In selecting a proposed MCL of 5 μg/L, the Agency based its risk management decision on both the quantifiable bladder and lung cancer benefits and also on the significant amount of nonquantifiable benefits associated with regulating arsenic in drinking water. In addition, EPA has provided analysis and considered the nonquantified benefits in the same manner for the final rule.

By definition, nonquantifiable benefits cannot be measured and were not measured in the benefit-cost analysis for the arsenic rule. EPA attempted to consider these potential benefits in both the proposed and final rule since the Agency believes they might occur. Such nonquantifiable benefits may include skin cancer, kidney cancer, cancer of the nasal passages, liver cancer, prostate cancer, cardiovascular effects, pulmonary effects, immunological effects, neurological effects, endocrine effects, and customer peace-of-mind benefits from knowing their drinking water has been treated for arsenic.

As stated in section 1412(b)(4)(C) of the SDWA, ''* * * the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C).'' Paragraph (3)(C) contains the description of the seven Health Risk Reduction and Cost Analysis elements that the Agency must consider. These seven elements include quantifiable and nonquantifiable heath risk reduction benefits, quantifiable and nonquantifiable health risk reduction benefits from reducing co-occurring contaminants, quantifiable and nonquantifiable costs, incremental costs and benefits, effects of the contaminant on the general population as well as on any sensitive sub-populations, possible increased health risks, and uncertainties in the analysis of any of these elements.

5. Comments on EPA's Assumption of Benefits Accrual Prior to Rule Implementation

As noted by some commenters, EPA does not make a benefits adjustment for the period prior to rule compliance. EPA does not make this adjustment for two reasons. First, EPA assumes that costs accrue during the same period and does not adjust these costs to account for a phasing in of the rule. Therefore, the analysis treats benefits and costs in exactly the same manner. Second, the Agency anticipates that many systems will begin installing treatment prior to the compliance date. This will ensure they are in compliance on the date that the rule takes effect. As treatment is installed to meet the compliance date, benefits will begin to accrue to those served by these systems.

I. Risk Management Decision

1. Role of Uncertainty in Decision Making

Several commenters questioned the proposed MCL on the basis of the uncertainties associated with aspects of the technical analyses supporting this rulemaking. Most of these comments dealt with the Agency's analysis of the health effects of arsenic. Section V.B. of today's preamble responds to these comments in more detail, and thus, only a relatively brief response to these comments, as they affect the risk management decision, is offered here. The uncertainties pointed out by commenters, together with the considerable costs of compliance with a new, lower standard, led several commenters to suggest that the Agency promulgate a significantly higher MCL than was proposed.

In response, EPA believes that several considerations are important. First, we note that humans are more sensitive to arsenic than laboratory animals. Thus, assessments of the health effects of arsenic necessarily rely, in part, on studies in which human populations have been exposed to relatively high levels (where demonstrable effects can be clearly seen and distinguished) and in which extrapolations to safe levels can be performed, and very low probabilities of adverse effects are projected. Uncertainties are inherent in any such analysis and would attach to similar kinds of contaminants (for which humans are more sensitive than animals and where no animal model exists). Second, EPA has more fully considered the various uncertainties to which many commenters refer and has striven to account for them either qualitatively and quantitatively. Third, the Agency requested and has carefully considered the advice of the National Research Council of the National Academy of Sciences and the Drinking Water Committee of the Science Advisory Board on these issues as a part of our deliberations leading to a final MCL. In summary, we believe that our analysis of the health risks of arsenic in drinking water is fully supportive of the final MCL and is based upon the best available science. While we acknowledge that uncertainties in our understanding of the health effects of arsenic remain, we believe there is sufficient information to support today's promulgated standard.

2. Agency's Interpretation of Benefits Justify Costs Provision

Many commenters offered a variety of points of view on EPA's cost-benefit analysis and on its interpretation of the provision of SDWA allowing the Administrator to set a level higher than the feasible level if the benefits of a standard do not justify the costs (section 1412(b)(6) of SDWA). EPA appreciates the many comments on its cost-benefit analysis, but respectfully disagrees with those comments that suggest its analysis is fundamentally flawed and does not support the proposed or final rule. Assessment of cost and benefits in cases where not all information can be precisely known, as is the case here, is a challenging exercise. Sections V.G. and V.H. of this preamble to the final rule provide a more detailed response to the various cost and benefit estimation comments received. In summary, we believe these costs and benefits have been correctly calculated, within the limits of available data and information, and that they adequately support both the proposed and final rule. Consistent with our statutory requirements, we have carefully considered costs and benefits analysis in proposing and promulgating a final rule that includes an MCL higher than the feasible level. Based on our further analysis of a variety of factors, including the costs and benefits, and after consideration of the various comments, we have decided to establish the final MCL at a higher level than proposed. As discussed in detail in section III.F. of this preamble, the Agency believes that, at an MCL of 10 μg/L, the benefits justify the costs. In our deliberations, we examined total national costs and benefits, incremental costs and benefits across various optional regulatory levels, and household costs for various system size categories. However, it is important to recognize that the Agency is also required to comply with the statutory requirement to ''maximize health risk reduction.'' Thus, while evaluation of costs and benefits is a key consideration in the exercise of the discretionary authorities under section 1412(b)(6) of the SDWA, the decision criteria used in developing a final MCL also has an important risk reduction component.

Some commenters also stated their belief that the benefits must exceed the costs in order for a particular standard to be ''justified'' in accordance with section 1412(b)(6) of SDWA. EPA disagrees and believes, for several reasons, that the benefits of the final standard do justify the costs. First, in connection with this rulemaking, EPA notes that there are a number of non-monetizable benefits that limit the value of a strict numeric comparison of costs and benefits. Second, EPA has calculated a range of monetizable benefits and believes that a portion of the range of benefits do, in fact, ''overlap'' the costs. Finally, EPA notes that Congressional report language clarifies the intent of section 1412(b)(6) and indicates that benefits do not need to strictly equal or exceed costs in order for a particular regulatory standard associated with those costs to be justified. (see S. Rep. 104–169, 104th Cong., 1st Sess. at 33.)

3. Alternative Regulatory Approaches

A number of commenters suggested that EPA tailor the arsenic drinking water standard in light of local or regional considerations. Market-based and seasonal standards were suggested in this regard. EPA understands these comments and the desire of these commenters to exercise flexibility in local or Regional decision-making in order to reflect information about local arsenic occurrence patterns, local public health priorities, available resources, or other pertinent factors. EPA notes that SDWA does provide for local and Regional flexibility in the implementation of new standard in a variety of ways. State decisions on use of State Revolving Loan Funds and Public Water System Supervision grant funds should be based upon local needs, local priorities, and available local funds. In addition, States may provide variances to qualifying systems under section 1415(a) of SDWA. States may also grant exemptions to qualifying water systems to provide additional time to comply with a new standard (with an opportunity for extensions) to help address the kinds of situations that many commenters are concerned about. However, SDWA does not provide a basis for establishing regional, local, or further-tailored drinking water standards as these commenters suggest. Rather, SDWA is designed to ensure uniform levels of public health protection across the country (except as specifically provided for in variances from the standard). In addition, certain Executive Orders such as Executive Order Number 12898 (Environmental Justice) reinforce this SDWA requirement and are specifically designed to ensure that disadvantaged communities are not protected at levels that are less than those afforded nationally. Thus, EPA disagrees with the suggestion that the level of the final standard be altered to address local or regional considerations, or otherwise tailored, except as specifically provided for by SDWA.

4. Standard for Total Arsenic vs. Species-Specific Standards

Several commenters expressed concern that an arsenic in drinking water standard based on total arsenic may unfairly penalize many drinking water systems, since these commenters felt that only inorganic forms of arsenic are considered to be toxic. Thus, the argument goes: the portion of a compliance sample that is comprised of organic arsenic would unfairly ''count against'' the utility when determining whether or not the concentration of arsenic in the sample exceeds the MCL. EPA believes, based on our understanding of occurrence patterns of arsenic, that source waters overwhelmingly contain inorganic arsenic. However, EPA also believes that there is a recent body of scientific evidence that indicates organic arsenic may also be toxic. Thus, it is important to know the total amount of arsenic present—both inorganic and organic.

Allowing for only the relative concentration of inorganic arsenic to be measured in compliance samples would impose an additional expense and would only account for a portion of the potentially toxic arsenic present. EPA does not believe such an approach is appropriate for the reasons discussed and instead believes the final MCL should be expressed as total arsenic.

J. Health Risk Reduction and Cost Analysis (HRRCA)

1. Notice and Comment Requirement

Several commenters stated that EPA was required to publish the HRRCA for public comment prior to proposing the arsenic regulation. EPA respectfully disagrees with these commenters. SDWA section 1412(b)(3)(C) states that ''when proposing any national primary drinking water regulation that includes a maximum contaminant level, the Administrator shall, with respect to a maximum contaminant level that is being considered in accordance with paragraph (4) and each alternative maximum contaminant level that is being considered pursuant to paragraph (5) or (6)(A), publish, and seek comment on, and use for purposes of paragraphs (4), (5), and (6) an analysis of * * *'' the quantifiable and nonquantifiable health risk reduction benefits, the quantifiable and nonquantifiable health risk reduction benefits from reducing co-occurring contaminants, the quantifiable and nonquantifiable costs, the incremental costs and benefits, the effects of the contaminant on the general population as well as on any sensitive subpopulations, any possible increased health risks, and uncertainties in the analysis of any of the above factors.

The above section of the statute provides for the publication of the HRRCA for any contaminant, except radon in drinking water, concurrently with the proposed regulation. Had Congress intended for the arsenic HRRCA to be published in advance of the proposal, the statute would have specifically provided for that, as it did in the case of radon. Section 1412(b)(13)(C) refers to the specific requirements for radon in drinking water. In this section of the statute, Congress required the Agency to publish the HRRCA for radon in drinking water six months in advance of the proposal.

In the proposed arsenic rule, the Agency provided an analysis of the costs, benefits, and other HRRCA requirements, which was shown in Section XIII of the preamble to the proposed rule. The public was provided a 90-day comment period in which to submit comments on all aspects of the proposed rule, including costs, benefits, and HRRCA requirements.

2. Conformance With SDWA Requirements

Some commenters felt that EPA did not meet the statutory requirements for conducting a HRRCA in section 1412(b)(3)(C)(i) and did not analyze the incremental costs and benefits associated with each alternative maximum contaminant level considered in conformance with SDWA requirements. EPA has met these requirements by conducting a HRRCA and an incremental analysis which are described in section XIII.D. of the preamble for the proposed rule. The HRRCA requirements, incremental costs, and incremental benefits are also discussed in the Economic Analysis of the proposed rule.

Some commenters also noted that EPA's incremental cost-benefit analysis lacked significant detail. The Agency addressed these concerns by adding more text to the incremental analysis section in the preamble for the final rule.

Several other commenters stated that the proper interpretation of SDWA is to use only an incremental analysis to determine if the benefits justify the costs. EPA respectfully disagrees with this interpretation because section 1412(b)(4)(C) of SDWA states ''* * * the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C).'' Paragraph (3)(C) contains the description of the seven Health Risk Reduction and Cost Analysis elements that the Agency must consider. These seven elements include quantifiable and nonquantifiable health risk reduction benefits, quantifiable and nonquantifiable health risk reduction benefits from reducing co-occurring contaminants, quantifiable and nonquantifiable costs, incremental costs and benefits, effects of the contaminant on the general population as well as on any sensitive subpopulations, possible increased health risks, and uncertainties in the analysis of any of these elements. The Agency must consider all seven elements, not just incremental benefits and costs, when making a determination as to whether the benefits of the proposed rule justify the costs.

VI. Administrative and Other Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735, October 4, 1993) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

- 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;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, or;
- 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'' because it will have annual costs of more than $100 million. As such, this action was reviewed by OMB. Changes made in response to OMB suggestions or recommendations are documented in the public record. EPA prepared an Economic Analysis (EA) pursuant to Executive Order 12866 and a revised version of the EA is in the docket for this rule (EPA, 2000o).

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.

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.

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 the Small Business Administration's (SBA) Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be PWSs serving fewer than 10,000 persons. In accordance with the RFA requirements, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested comment, consulted with the SBA, and finalized the alternative definition in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition would be applied to this regulation as well.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the regulated small entities in accordance with section 609(b) of the RFA. A detailed discussion of the Panel's advice and recommendations is found in the Panel Report (EPA 1999e). A summary of the Panel's recommendations is presented at (65 FR 38963, June 22, 2000). All Panel's recommendations directly applicable to this rulemaking are included in this final rule.

As required by section 604 of the RFA, EPA also prepared a final regulatory flexibility analysis (FRFA) for today's final rule. The FRFA in combination with today's preamble, addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA is available for review in the docket, (EPA 2000w) and is summarized below.

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

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

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

(3) A description of the reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the rule and the type of professional skills needed to prepare the report or record;

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

(5) a description of the steps taken to minimize the significant impact on small entities consistent with the stated objectives of the applicable statutes, including a statement of the factual, policy, and legal reasons why EPA selected the alternative the final rule and why the other significant alternatives to the rule that were considered which affect the impact on small entities were rejected.

The following is a summary of the FRFA. The first requirement is discussed in section II. and III.D.1 of this preamble. The second, third, fourth and fifth requirements are summarized as follows.

a. *Comments on the IRFA.* Commenters on the IRFA raised a number of issues, largely concerned with the potential cost of the rule. In the proposed arsenic rule and the RIA supporting the proposal (EPA 2000h), EPA estimated the costs for small systems for the four arsenic MCL regulatory options and requested comment on the IRFA. Some commenters felt that EPA had underestimated the costs for small systems to comply with the arsenic proposal. In response to the comments, the Agency re-evaluated the economic effects on small entities after publication of the proposal (as discussed in greater detail in Section III.). EPA updated its assessment for the FRFA based on comments and the final regulatory decisions, *i.e.*, the final MCL level, full coverage of NTNCWS, and updated costs of compliance, including waste disposal costs.

b. Reporting, Recordkeeping and Other Requirements for Small Systems. The 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. NTNCWSs are added to the systems that must meet the MCL for arsenic by this rulemaking. Small systems are also required to provide arsenic information in the Consumer Confidence Report or other public notification if the system exceeds specific arsenic finished water concentrations including 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 and a reporting requirement when one half of the MCL is exceeded (see section V.E.). 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.

c. Number of Small Entities Affected. The number of small entities subject to today's rule is shown in Table VI.B–1 below.

TABLE VI.B–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.

EPA's FRFA estimates that the economic impact of the final rule will not be significant for the vast majority of small systems. Of the 71,011 small entities potentially affected by the Arsenic Rule, 94% are expected to incur average annualized costs of less than $40. This average reflects total costs for systems that will not need to modify or install treatment to meet the MCL and mostly reflects monitoring costs. This equates to approximately 0.001% of average annual revenue. The remaining 6%, 3,907 systems, estimated to need additional or modified treatment to meet the MCL are expected to incur average annualized costs of approximately $20,816, or 0.70% of average annual revenue. Although EPA has worked with small communities to minimize the burden of compliance with this rule, the Agency anticipates that several hundred systems may nevertheless experience costs in excess of 3% of annual revenues. As noted below, financial assistance and exemptions (providing additional time) are available for small systems for compliance.

d. Minimizing small system impact and the final MCL. As discussed in more detail in section I.L. of this preamble, EPA notes that $1.7 billion is available each year through the SRF and RUS program to support necessary capital improvements to ensure compliance. SDWA also provides small systems additional time to comply through a provision for exemptions. Systems serving fewer than 3,300 persons can apply for an exemption from the State (SDWA section 1416(b)(3)) that can provide up to an additional nine years to comply (for a total of 14 years from the effective date of the rule). EPA discusses in section III.F. of this preamble the decisions to select the final MCL. EPA is preparing a small entity compliance guide to help small entities comply with this rule as required by Section 212 of SBREFA. This guide will be available for small systems within a few months of the promulgation date of this rule. Small systems may obtain a copy of the guide from EPA's web site, www.epa.gov/safewater.

C. Unfunded Mandates Reform Act (UMRA) of 1995

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, Tribal, and local governments and the private sector. Under UMRA section 202, EPA generally must prepare a written statement, including a benefit-cost analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, Tribal, and local 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 why that alternative was not adopted.

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

EPA has determined that this rule contains a Federal mandate that may result in expenditures of $100 million or more for State, Tribal, and local governments, in the aggregate, or the private sector in any one year. A detailed description of this analysis is presented in EPA's Economic Analysis of the arsenic rule (EPA, 2000o) which is included in the Office of Water docket for this rule. Accordingly, EPA has prepared under section 202 of the UMRA a written statement which is summarized below.

a. Authorizing legislation. Today's rule is issued pursuant to section 1412(b)(13) of the 1996 amendments to SDWA that 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, (and subsequently amended to June 22, 2001) to promulgate this rule.

b. Cost-benefit analysis. Section III. of this preamble, describing the Economic Analysis (EA) (EPA, 2000o), health risk analysis and the cost and benefit analysis for arsenic, contains a detailed analysis in support of the arsenic rule. Today's final rule is expected to have a total annualized cost of approximately $181 million (Exhibit 6–9, EPA, 2000o). This total annualized cost includes the total annual administrative costs of State, Tribal, and local governments, in aggregate, less than 1% of the cost, and total annual treatment, monitoring, reporting, and record keeping impacts on public water systems, in aggregate, of approximately $1.3 million. EPA estimates the total annual costs of administrative activities for compliance with the MCL to be approximately $2.7 million.

The EA includes both qualitative and monetized benefits for improvements in health and safety. EPA estimates the final arsenic rule will have total annual monetized benefits for bladder and lung cancer of approximately $140 to 198 million for the MCL of 10 μg/L. The monetized health benefits of reducing arsenic exposures in drinking water are attributable to the reduced incidence of fatal and non-fatal bladder and lung cancers. At an arsenic level of 10 μg/L, an estimated 21 to 30 fatal bladder and lung cancers and 12 to 26 non-fatal bladder and lung cancers per year are prevented.

In addition to quantifiable benefits, EPA has identified several potential non-quantifiable benefits associated with reducing arsenic exposures in drinking water. These potential benefits include health effects that are difficult to quantify because of the uncertainty surrounding their estimation. Non-quantifiable benefits may also 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.

c. Financial Assistance. Section III of this preamble describes the various Federal programs available to provide financial assistance to State, Tribal, and local 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) Grant 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. Also, the Rural Utilities Service (RUS) of the United States Department of Agriculture (USDA) operates a Water and Waste Disposal Loan and Grant Program. This program provides low-interest loans and grants to public entities and not-for-profit corporations serving populations of 10,000 or fewer persons.

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 an arsenic MCL of 10 μg/L to the extent reasonably feasible. The Agency believes that the cost estimates, indicated previously and discussed in more detail in section III of today's rule, accurately characterize future compliance costs of the 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. While the percentage of systems impacted varies from region to region, no area has impacts substantial enough to create a disproportionate burden. For the proposal, EPA did identify (Table V–2, p. 38908) that there are a larger percentage of systems in the Western and New England regions, whose drinking water quality currently would exceed the MCL for arsenic. For such regions, total compliance, therefore, may be incrementally costlier than for systems in regions where a smaller percentage currently exceed the arsenic MCL. However, even this difference is not considered by EPA to represent a disproportionate impact.

To estimate the potential disproportionate impacts on social segments of this rule, this analysis also developed three other measures:

(1) Reviewing the impacts on small versus large CWSs;

(2) Reviewing the costs to public versus private CWSs; and

(3) reviewing the household costs for the rule.

Table 6–11 of the EA (EPA, 2000o) shows that the total treatment costs for small CWSs (serving fewer than 10,000 persons) is less than the total treatment for large CWSs; therefore, there is no disproportionate impact on small systems versus large systems. Table 8–29 of the EA shows that there is not a disproportionate impact when comparing costs for public CWSs to costs for private CWSs of the same size. Public systems have slightly higher costs than public CWSs. Table 8–30 of the EA show household costs by system size. Cost per household increases as system size decreases. Cost per household is higher for households served by smaller systems than larger systems. These values are expected 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.

Moreover, even if there were a disproportionate impact associated with the final MCL, EPA does not have any authority to tailor the regulation to provide regional or ownership relief. Finally, as previously noted, EPA adopted a 10 μg/L arsenic MCL rather than the proposed (5 μ/L) or feasible level (3 μg/L) of arsenic MCL in part because of the benefit cost issues raised by commenters. This should serve to mitigate the costs of the rule to some degree. EPA also provided delayed compliance deadlines for all systems which should also reduce the economic effect on systems with higher ground water arsenic levels.

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.

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. Macro-economic effects tend to be measurable in nationwide econometric models only if the economic impact of the regulation reaches 0.25% to 0.5% 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% compliance, the total annual costs are approximately $181 million, 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, Tribal, and local governments. In developing the proposed rule, EPA consulted with small governments pursuant to its plan established under section 203 of the UMRA to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. Consistent with the intergovernmental consultation provisions of section 204 of UMRA, EPA held, prior to proposal, consultations with the governmental entities affected by this rule. EPA held four public meetings for stakeholders prior to proposal and an additional meeting after proposal. The Agency convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns, including small local governments. EPA consulted with small entity representatives prior to convening the Panel to get their input on the arsenic rule. Two of the small entities represented small governments. A detailed description of the SBREFA process can be found in the docket of this rulemaking (EPA, 1999e). EPA also made presentations at Tribal meetings in Nevada, Alaska, and California. In addition, EPA made 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.

g. Nature of State, Tribal, and local government concerns and how EPA addressed these concerns. In general, comments on the proposed UMRA discussion continued to cite costs and funding for compliance as concerns. EPA has further revised the costs for this final rule based on comments and continues to believe that there are affordable technologies (see section III.E.). Cost was one of the issues EPA considered in deciding to exercise its discretionary authority under section 1412(b)(6) of SDWA to propose that the MCL be set a level higher than the feasible level in the proposed rule of 5 µg/L and to set the final level of 10 µg/L. Commenters asked that funding be increased to the Drinking Water State Revolving Fund (DWSRF) or somehow fully fund compliance with the proposed requirements. While the DWSRF program is proving to be a significant source of funding, it cannot be viewed as the only source of funding. There are strategies other than Federal funding (such as system bundling) for meeting the arsenic rule. Federal, State and local governments, private business and utilities will need to work in partnership to help address the significant infrastructure needs for complying with today's rule.

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 (EPA, 2000h) and Health Risk Reduction and Cost Analysis (HRRCA) for the proposed arsenic rule (EPA, 2000i, see section XIII.) evaluated arsenic levels of 3 µg/L, 5 µg/L, 10 µg/L, and 20 µg/L. (see section III. of the proposed rule for more discussion of the regulatory alternatives considered.)

i. Selection of the regulatory alternative. As explained in section III.F. of today's preamble, the Agency selected an MCL of 10 µg/L which is the most cost-effective alternative since it maximizes benefits.

D. Paperwork Reduction Act (PRA)

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*, and has assigned OMB control number 2040–0231.

Under this rule, respondents to the monitoring, reporting, and recordkeeping requirements include the owners and operators of community water systems and State officials that must report data to the Agency. Monitoring for arsenic is required at each entry point to the distribution system. States will have discretion in grandfathering existing data for determining initial monitoring baselines for the currently regulated contaminants.

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

For PWSs, the number of hours required to perform each activity may vary by system size. This rule applies to community water systems and non-transient non-community water systems. There are approximately 74,607 PWSs and 56 States and territories considered in this ICR. During the first three years after promulgation of this rule, the average burden hours per respondent per year is estimated to be 8 hours for PWSs and 915 hours for States. During this period, the total burden hour per year for the approximately 74,663 respondents covered by this rule is estimated to be 667,179 hours to prepare to comply with this final arsenic rule. The average number of responses per year by PWSs is 49,738. The average number of responses for the States is expected to be 75 per year during the first three-year period. The average burden hours per response for PWSs is 4. The average burden hours per response for States is 229. Total annual labor costs during this first 3-year period are expected to be about $9.9 million per year for PWSs. The information collected is not confidential.

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 ways to comply with any previously applicable instructions and requirements; train personnel to collect information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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

E. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (Pub. L. No. 104–113, section12(d), 15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, material specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide to Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

Today's rule does not establish any technical standards; thus, NTTAA does not apply to this rule. However, it should be noted that systems complying with this rule need to use previously approved technical standards already included in § 141.23. As discussed in the proposed rule for arsenic (65 FR 38888) and in today's final rule (section I.F.1.), one consensus method (SM 3120B) and one EPA method (EPA 200.7), are withdrawn by this rule because the method detection limits for these methods are inadequate to reliably determine the presence of arsenic at the MCL of 10 μg/L. After the removal of these methods, the four remaining analytical methods currently approved for compliance monitoring of arsenic in drinking water are published by consensus organizations. The four methods published by these consensus organizations include SM 3113B, SM 3114B, ASTM 2972–93B and ASTM 2972–93C. These methods 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).

F. Executive Order 12898: Environmental Justice

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agencies' 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 consulted with minority and low-income stakeholders.

On March 12, 1998, the Agency held a stakeholder meeting to address various 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 meetings by video conference call between 11 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 March 12, 1998 meeting were:

- Solicit ideas from stakeholders on known issues concerning current drinking water regulatory efforts;
- Identify key issues of concern to stakeholders, and;
- Receive suggestions from stakeholders concerning ways to increase representation of communities in EPA 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 regulation.

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 final 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.

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, imposes substantial direct compliance costs, and 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 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 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 the docket for this proposed rulemaking. EPA consulted extensively with State, Tribal, and local governments. For example, EPA held four public stakeholder meetings in Washington, D.C. (two meetings); San Antonio, Texas; and Monterey, California. An additional public stakeholder meeting was held after the proposal was published in Reno, Nevada. A summary of this meeting is included in the docket of this rulemaking. 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). EPA officials presented a summary of the rule to the National Governor's Association in a meeting on May 24, 2000. In addition, EPA 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.

Several issues were raised by stakeholders (including elected officials) regarding the arsenic rule provisions, most of which were related to reducing burden and maintaining flexibility. The Office of Water was able to reduce burden and increase flexibility for the proposal in a number of areas in response to these comments (see section XIV.G. of the proposed rule).

Commenters on the proposed rule continued to request a reduction of burden and increased flexibility as well as to question the need for the rule. Section V. of this preamble and the Comment Response Document (EPA, 2000u) discuss the comments and EPA's response in detail. The Agency exercised its discretionary authority under section 1412(b)(6) of SDWA to propose that the MCL be set at a level higher than the feasible level in the proposed rule and, in the final rule, to move from the proposed level of 5 µg/L to 10 µg/L.

I. Executive Orders 13084 and 13175: Consultation and Coordination With Indian Tribal Governments

On November 6, 2000, the President issued Executive Order 13175 (65 FR 67249) entitled, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 took effect on January 6, 2001, and revokes Executive Order 13084 (Tribal Consultation) as of that date. EPA developed this final rule, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13984.

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, significantly or uniquely affects the communities of Indian Tribal governments, and imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments, or 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 or uniquely affect communities of Indian tribal governments. It may 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 this rule. In developing the rule, EPA consulted with Tribal governments to permit them to have meaningful and timely input into its development.

In order to inform and involve Tribal governments prior to proposing the arsenic rule, EPA staff attended the 16th Annual Consumer Conference of the National Indian Health Board on October 6–8, 1998, convened a Tribal consultation meeting on February 24–25, 1999, and conducted a series of workshops at the Annual Conference of the National Tribal Environmental Council on May 18–20, 1999. Tribal representatives were generally supportive of an arsenic standard that ensures a high level of water quality, but raised concerns over funding for regulations. With regard to the 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. Comments submitted on the proposed arsenic rule repeated the concern that Tribes might not be able to afford to meet the arsenic requirements.

The Agency believes that the requirements of this final rulemaking are affordable nationally, including Tribal PWSs. As discussed in section I.G. of this preamble, EPA has developed and applied a national affordability criterion to the projected costs of compliance of this rule for small systems (those serving less than 10,000 persons). Using this approach, EPA has identified affordable compliance technologies that small systems (including Tribal PWSs) may use to comply with today's final rule.

J. Plain Language

Executive Order 12866 and the President's memorandum of June 1, 1998 require each agency to write its rules in plain language. Readable regulations help the public find requirements quickly and understand them easily. They increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. Of the several techniques typically utilized for writing readably, using a question and answer format, and using the word, ''you'' for whoever must comply, do the most to improve the look and sound of a regulation. The preamble for today's final rule uses the first principle and was developed using a plain language question and answer format. Today's final rule language does not use these principles since the rule only modifies or adds to existing regulatory language that is in the previous regulatory language format. EPA received comments on the use of plain language. Commenters suggested that the Agency had not clearly explained certain terms for example, ''dose-response'' and ''parts per billion.'' The comments were centered around technical and scientific issues and terms that are often difficult to discuss in a plain language format. EPA considered these comments in writing the section of this final rule to which those comment apply. EPA made every effort to write this preamble to the final rule in as clear, concise, and unambiguous manner as possible.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 23, 2001.

L. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with section 1412 (d) and (e) of SDWA, the Agency discussed or submitted possible arsenic rule requirements to the Science Advisory Board (SAB), National Drinking Water Advisory Council (NDWAC), and to the Secretary of Health and Human Services and requested comment from the Science Advisory Board (SAB) on the arsenic rule.

On March 13th and 14th, 2000 in Washington DC, the Agency met with the Science Advisory Board during meetings open to the public where several of the Agency's Drinking Water Rules were discussed. A copy of the SAB's comments may be found in the docket. SAB provided substantive comments on the proposed arsenic rule which are discussed in sections V.B. and V.F. of this preamble.

In addition, the National Drinking Water Advisory Council was consulted on this rulemaking on several occasions throughout the rule's development (*e.g.,* November 1999 in Baltimore, Maryland; April 2000 in San Francisco, CA; November 2000 in Arlington, VA). The summary of the deliberations and recommendations of the Council may be found in the docket for this rule.

The Agency coordinated with the Department of Health and Human Services in several ways. Representatives of the Centers for Disease Control and Prevention (CDC), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Food and Drug Administration (FDA) were invited to the Agency's stakeholder meetings on the arsenic rulemaking and on the mailing list for updates. We provided FDA staff with summaries of the meetings, meeting materials, and a briefing paper. In addition, the Agency maintained contact with CDC representatives on the status of CDC-funded research on skin adsorption that could have a bearing on the Agency's deliberations. EPA commented on and monitored the progress of the updated ''Toxicological Profile for Arsenic'' issued by ATSDR. Finally, we provided ongoing progress reports on the Agency's arsenic in drinking water rulemaking activities to representatives of FDA relative to the timing of bottled water regulations that need to follow the promulgation of the Agency's final rule.

M. Likely Effect of Compliance With the Arsenic Rule on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA as amended requires that, in promulgating a NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. The following summarizes the analysis performed to fulfill this statutory obligation. (EPA, 2000v)

Overall water system capacity is defined in guidance (EPA, 1998g) as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity has three components: technical, managerial, and financial. Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. Technical capacity refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. Managerial capacity is the ability of a water system to conduct its affairs in a manner enabling the system to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities. Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements.

The arsenic rule establishes five requirements that may impact the TMF capacity of PWSs:

(1) Compliance with MCL revised to 10 μg/L from 50 μg/L (40 CFR 141.62);

(2) Revised arsenic monitoring schedule [(modified to join the standard monitoring framework (SMF) used for other inorganic contaminants (IOCs)] (§ 141.23(c))—includes requirement for public notification of MCL exceedance, but not Consumer Confidence Report (CCR) requirements (§ 141.154);

(3) New source monitoring (§ 141.24);

(4) Removal of EPA Method 200.7 and SM 3120 from list of approved analytical methods to demonstrate compliance (§ 141.23); and

(5) Inclusion of arsenic health effects language in CCRs (§ 141.154).

The arsenic rule applies to all CWSs (54,370 systems) and NTNCWSs (20,255 systems)—74,625 systems in all (EPA, 2000b). However, many systems will not be affected by the new arsenic requirements. Table VI.M–1 provides a complete listing of the requirements and a description of the type and number of systems affected by each requirement.

TABLE VI.M–1.—REQUIREMENTS OF THE ARSENIC RULE AND NUMBER OF SYSTEMS AFFECTED

Requirement	Affected systems [1]			
	Description	Number		
		CWSs	NTNCWSs	Total
Compliance with revised MCL (10 µg/L)	Systems with As ≥ 10 µg/L	3,024	1,080	4,104
Revised monitoring schedule	CWSs with As between 3 µg/L (PQL) and 50 µg/L and all NTNCWSs.	10,590	20,255	30,845
New source monitoring	Systems that develop a new source to meet the revised MCL.	~0	~ 0	<100
Removal of specified analytical methods	All CWSs that currently use banned methods.	<100	N/A	<100
Inclusion of health effects language in CCR	CWSs with As ≥5–25 µg/L	~4,000	N/A	~4,000

[1] Estimates derive from actual system impacts projected in cost benefit analysis. Will differ from system-level figures discussed earlier in preamble. Reflect all systems having impacts, including those partially impacted.

Those systems whose current source(s) will not meet the revised MCL must either develop a new source, install new treatment processes, or enhance their existing treatment processes. (The impact of developing a new source are included in the analysis of the new source requirement.) The installation, operation, and maintenance of new treatment technologies will require a substantial enhancement of these systems' technical capacity. Specifically, source water adequacy will be reduced (marginal sources may no longer be viable), the system will be required to greatly enhance its infrastructure (particularly its treatment processes) to meet the technical challenge posed by the revised MCL, and system operators will require correspondingly greater technical expertise to successfully operate new and more advanced treatment processes.

The impacts to the managerial capacity of systems affected by the revised arsenic MCL are not anticipated to be as great as the technical and financial challenges. Nonetheless, many system managers will need to review the implications of the revised MCL and may need to hire a more highly certified operator or provide additional training for the existing operator.

In addition, systems will need to rely upon and improve their interactions with the service community and technical/financial assistance providers. System management will need to explain the following issues: (1) The reason why the arsenic standard was revised, (2) the safety of the water that the system provides, and (3) the reason for new or higher fees. These activities are in addition to the inclusion of the health effects language in the CCR and therefore will impact the managerial capacity of a system.

The impacts of the arsenic rule requirements to the technical capacity of systems are closely tied to financial impacts. Systems that must install additional treatment processes or upgrade their current treatment processes may face significant costs. These costs may be especially difficult for many of the affected systems to absorb since many of them are relatively small (i.e., serving less than 3,300 customers), and therefore typically have a smaller revenue base and fewer households over which they may distribute the additional costs. The rule specifically allows the use of centrally managed POU-treatment devices to achieve compliance with the revised arsenic MCL. However, the installation, operation, maintenance, and management of these devices still represents a substantial expense for small systems.

To obtain funding from either public or private sources, systems will need to demonstrate sound financial accounting and budgeting practices, and the ability to repay their debts. As a result, many of the smallest systems that do not currently charge explicitly for water service (e.g., mobile home parks, camp grounds, etc.) may need to begin to bill their customers. Those systems that already charge for water service will likely need to increase their rates (sometimes requiring approval of the local public utilities commission (PUC)), and improve their recordkeeping procedures.

EPA anticipates that the revised monitoring and reporting framework will have a relatively limited impact on system capacity even though some CWSs will no longer be eligible for reduced monitoring and others will no longer be able to composite. NTNCWSs will be required to monitor for arsenic for the first time. To comply with this requirement system management will need to ensure that staff understand the new requirements, that monitoring records are properly maintained, and that the appropriate reports are provided to the State primacy agency and EPA. In addition, systems will face a slight increase in monitoring costs that may require systems to adjust their budgeting practices and fee structures. Nonetheless, since most systems are already familiar with the SMF for IOCs, the impact to capacity is minimal.

There will be a substantial impact on capacity for those systems that must develop a new source to meet the revised MCL. In addition to the monitoring requirements specified in the arsenic proposal, these systems will expend substantial effort and money to ensure that their new source(s) will consistently provide reliable production of high quality water.

Removing two currently approved analytical methods should not have a large impact on system capacity. Since similarly priced alternative methods are available, it was estimated that there would be little to no impact to the managerial and financial capacity of systems that currently rely on this method (or whose laboratory relies on this method). A system may need to ensure that the systems' laboratory uses an approved method and may need to ensure that the operator is aware of the change in approved analytical methods.

The requirement for affected systems (those with arsenic levels above half the revised MCL) to immediately begin incorporating health affects language into their CCRs will principally impact the managerial capacity of systems. Specifically, systems will need to: (1) incorporate information about arsenic into their CCRs; (2) explain to the service community the reason why they are including such information; (3)

explain the health implications of current arsenic levels; and potentially, (4) explain how the system anticipates meeting the revised MCL. Moreover, affected systems will also need to prepare to respond to customer queries regarding the new arsenic information and the system's compliance status.

The arsenic rule will have a substantial impact on the capacity of the 4,100 CWSs and NTNCWSs that must reduce arsenic levels or develop new sources to meet the revised MCL. However, while the impact to these systems is significant, only five percent of all systems regulated under the Arsenic Rule (4,104 of 74,625) will be affected by this requirement. The new monitoring and reporting requirements, removal of approved analytical methods, and inclusion of health effects language in the CCR are expected to impact the capacity of approximately an additional 26,000 systems to a small degree. About 31,000 systems (i.e., 40% of regulated systems) are expected to experience minimal impact on their capacity as a result of the arsenic rule.

VI. References

Agency for Toxic Substances and Disease Registry. 1998. Draft Toxicological Profile for Arsenic. Prepared for the US Department of Health and Human Services by the Research Triangle Institute.

Albores, A., M.E. Cebrian, I. Tellez and B. Valdez. 1979. Comparative Study of Chronic Hydroarsenicism in Two Rural Communities in the Region Lagunra of Mexico. [in Spanish]. Bol. Oficina Sanit. Panam. 86:196–205.

American Public Health Association (APHA). 1992 and 1995. Standard Methods for the Examination of Water and Wastewater. 18th Edition, American Public Health Association,1015 Fifteenth Street N.W., Washington, DC 20005.

American Society for Testing and Materials (ASTM). 1994 and 1996. Annual Book of ASTM Standards. Vol. 11.01 and 11.02, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

Aposhian, H.V., E.S. Gurzau, X.C. Le, A. Gurzau, S.H. Healy, X. Lu, M. Ma, R.A. Zakharyan, R.M. Maiorino, R.C. Dart, M.G. Tircus, D. Gonzalez-Remariz, D.L. Morgan, D. Avram, D. and M.M. Aposhian. 2000. Occurrence of monomethylarsonous acid in urine of humans exposed to inorganic arsenic. Chemical Research Toxicology 13:693–697.

Borgono, J.M, P. Vincent, H. Venturino, and A. Infante. 1977. Arsenic in the Drinking Water of the City of Antofagasta: Epidemiological and Clinical Study before and after the Installation of a Treatment Plant. Environmental Health Perspectives 19:103–105. August, 1997.

Borzsonyi, M., A. Berecsky, P. Rudnai, M. Csanady and A. Horvath. 1992. Epidemiological Studies on Human Subjects Exposed to Arsenic in Drinking Water in Southeast Hungary. Archives of Toxicology. 66:77–78.

Buchanan, W.D. 1962. Toxicity of Arsenic Compounds. Amsterdam, Elsevier Scientific Publishers. pp v–viii.

Buchet, J.P. and D. Lison. 1998. Mortality by cancer in groups of the Belgium population with a moderately increases intake of arsenic. International Archives Occupational Environmental Health 71:125–130.

Carmignani, M., P. Boscolo and A. Iannaccone. 1983. Effects of chronic exposure to arsenate on the cardiovascular function of rats. British Journal Industrial Medicine 40:280–284.

Casale, R. and M. LeChevallier. 2000. Contaminants in Drinking Water Treatment Chemicals: A Survey of the American Water Works System. Proceedings American Water Works Association Water Quality Technology Conference. Salt Lake City, UT. November 5–9.

Cebrian, M. 1987. Some Potential Problems in Assessing the Effects of Chronic Arsenic Exposure in North Mexico [preprint extended abstract]. New Orleans, LA, American Chemical Society.

Cebrian, M. E., A. Albores, M. Aguilar and E. Blakely. 1983. Chronic Arsenic Poisoning in the North of Mexico. Human Toxicology. 2:121–133.

Chen, C.J., Y.C. Chuang, T.M. Lin, and H.Y. Wu. 1985. Malignant neoplasms among residents of a blackfoot disease-endemic area in Taiwan: high arsenic artesian well water and cancers. Cancer Research. 45:5895–5899.

Chen, C.J., M., Wu, S.S. Lee, J.D. Wang, S.H. Cheng, and H.Y. Wu. 1988. Atherogenicity and carcinogenicity of high-arsenic artesian well water. Multiple risk factors and related malignant neoplasms of blackfoot disease. Arteriosclerosis. 8:452–460.

Chen, C.J. and C.J. Wang. 1990. Ecological correlation between arsenic level in well water and age-adjusted mortality from malignant neoplasms. Cancer Research 50:5470–5474.

Chen, C.J., C.W. Chen, M.M. Wu, and T.L. Kuo. 1992. Cancer potential in liver, lung, bladder and kidney due to ingested inorganic arsenic in drinking water. British Journal of Cancer 66:888–892.

Chen, C.J., R.M. Hsueh, M.S. Lai, M.P. Shu, S.Y. Chen, M.M. Wu, T.L. Kuo, and T.Y. Tai. 1995. Increased prevalence of hypertension and long-term arsenic exposure. Hypertension 25:53–60.

Chen, G.-Q, J. Zhu, X-G. Shi, J.H. Ni, H.-J. Zhong, G-Y. Si, X.-L. Jin, W. Tang, X.-S. Li, S.-M. Xong, Z.-X. She, G.-L. Sun, J. Ma, P. Zhang, T.-D. Zhang, C. Gazin, T. Naoe, S.-J. Chen, and Z. Chen. 1996. In vitro studies on cellular and molecular mechanisms of arsenic trioxide (As_2O_3) in the treatment of acute promyleocytic leukemia: As_2O_3 induces NB43 cell apoptosis with downregulation of Bcl-2 expression and modulation of PQL–RARα/PML proteins. Blood 83:1053–1061.

Chen, C.J., H.Y. Chiou, M.H. Chiang, L.J. Lin and T.Y. Tai. 1996. Dose-Response Relationship Between Ischemic Heart Disease Mortality and Long-Term Arsenic Exposure. Arteriosclerosis, Thrombosis, and Vascular Biology. 16(4):504–510.

Chen. Personal correspondence to Herman Gibb, January 3, 2000.

Clifford, D. and Z. Zhang. 1994. Arsenic Chemistry and Speciation. American Water Works Association Annual Conference. New York, NY. June 19–23.

Clifford, D., G. Ghurye, A. Tripp, J. Tong. 1997. Final Report: Phases 1 and 2, City of Albuquerque Arsenic Study. Field Studies on Arsenic Removal in Albuquerque, New Mexico Using the University of Houston/EPA Mobile Drinking Water Treatment Research Facility. Prepared for John Stromp, IIII, Water Resources Manager, City of Albuquerque. December 1997.

Clifford, D., G. Ghurye, A. Tripp, T. Jian. 1998. Final Report: Phase 3 City of Albuquerque Arsenic Study. Field Studies on Arsenic Removal in Albuquerque, New Mexico using the University of Houston/EPA Mobile Drinking Water Treatment Research Facility. Prepared for John Stomp, Water Resources Manager, City of Albuquerque. August, 1998.

Cogliano, V.J., E.D. Kroese, G.A. Zapponi, L. Attias and I. Marcello. 1999. Chapter 1. Introduction. In: Cogliano, V.J., E.G. Luebeck and G.A. Zapponi eds., 1999. Perspectives on Biologically Based Cancer Risk Assessment. NATO: Challenges of Modern Society, Plenum Press. pp. 1–20.

Cox, D.R. and D. Oakes. 1984. Analysis of Survival Data. London: Chapman and Hall.

Cropper, M.L and U. Subramanian. 1999. Public Choices Between Lifesaving Programs: How Important Are Lives Saved? Valuing Environmental Benefits: Selected Essays of Maureen Cropper. Cheltenham, United Kindom. Edward Elgar.

Cuzick, J., S. Evans, M. Gillman, and D. A. Price Evans. 1982. Medicinal

Arsenic and Internal Malignancies. British Journal of Cancer. 45:904–911.

Cuzick, J., P. Sasieni, and S. Evans. 1992. Ingested arsenic, keratoses, and bladder cancer. American Journal of Epidemiology. 136(4):417–421.

Desi, I. 1992. Arsenic Contamination of Drinking Water in South-East Hungary. Geographia Medica. 22:45–53.

Eaton, A.D. 1994 Determining the practical quantitation level for arsenic. Journal AWWA. Pgs. 100–114. February 1994.

Engel, R.R., and H.H. Smith. 1994. Arsenic in drinking water and mortality from vascular disease: An ecological analysis in 30 countries in the United States. Arch. Environmental Health. 49:418–427.

Frey, M., J. Chwirka, S. Kommineni, and Z. Chowdhury. ''Cost Implications of A Lower Arsenic MCL''. May 5, 2000. American Water Works Association Research Foundation, Denver Co. (included as an attachment to comment I–G1.466)

Frey, M., J. Chwirka, S. Kommineni, and Z. Chowdhury. ''Update Cost Implications Of A Lower Arsenic MCL''. October 10, 2000.

Frey, M.M. and M.A. Edwards. 1997. Surveying Arsenic Occurrence. Journal of the American Water Works Association. 89(3):105–117.

Guha Mazumder, D.N., J. Das Gupta, A. Santra, A. Pal, A. Ghose, S. Sarkar, N. Chattopadhaya and D. Chakraborty. 1997. Non-Cancer Effects of Chronic Arsenicosis with Special Reference to Liver Damage. In Arsenic: Exposure and Health Effects. Abernathy, C.O., Calderon, R.L. and Chappell, W., Eds. London, Chapman and Hall: pp. 112–123.

Guha Mazumder, D.N., B.K. De, A. Santra, J. Dasgupta, N. Ghosh, B.K. Roy, U.C. Ghoshal, J. Saha, A. Chatterjee, S. Dutta, R. Haque, A.H. Smith, D. Chakraborty, C.R. Angle and J.A. Centeno. 1999. Chronic arsenic toxicity: Epidemiology, natural history and treatment. In Chappell, W.R., C.O. Abernathy and R.L. Calderon, eds. Arsenic Exposure and Health Effects. Elsevier. Amsterdam. pp. 335–347.

Hindmarsh, J.T., O.R. McLetchie, L. P. M. Heffernan, O.A. Hayne, H.A. Ellenberger, R.F. McCurdy and H.J. Thiebaux. 1977. Electromyographic Abnormalities in Chronic Environmental Arsenicalism. Analytical Toxicology. 1:270–276.

Hopenhayn-Rich, C., M.L. Biggs, A. Fuchs, R. Bergoglio, E.E. Tello, H. Nicolli and A.H. Smith. 1996. Bladder Cancer Mortality Associated With Arsenic in Drinking Water in Argentina. Epidemiology. 7(2):117–124.

Hopenhayn-Rich, C., M.L. Biggs and A.H. Smith. 1998. Lung and Kidney Cancer Mortality Associated with Arsenic in Drinking Water in Cordoba, Argentina. Epidemiology. 27:561–569.

Hopenhayn-Rich, C., S.R. Browning, I. Hertz-Picciotto, C. Ferreccio, C. Peralta, and H. Gibb. 2000. Chronic Arsenic Exposure and Risk of Infant Mortality in Two Areas of Chile. Environmental Health Perspectives 108:667–673. July 2000.

Kempic, J.B. 2000. Centrally managed POU/POE Option for Compliance with the Arsenic Regulation. AWWA Inorganic Contaminants Workshop, Albuquerque, NM, February 27–29, 2000.

Kurttio, P., E. Pukkala, H. Kahelin, A. Auvinen, and J. Pekkanen. 1999. Arsenic Concentrations in Well Water and Risk of Bladder and Kidney Cancer in Finland. Environmental Health Perspectives 107(9):705–710

Lai, M.S., Y.M. Hsueh, C.J. Chien, M.P. Shyu, S.Y. Chen, T.L. Kuo, M.M. Wu, and T.Y. Tai. 1994. Ingested Inorganic Arsenic and Prevalence of Diabetes Mellitus. American Journal of Epidemiology. 139(5):484–492.

Le, X.C., M. Ma, X. Lu, W.R. Cullen, H.V. Aposhian and B. Zheng. 2000. Determination of monomethylarsonous acid, a key arsenic methylation intermediate, in human urine. Environmental Health Perspectives. 108(11):1015–1018.

Lewis, D.R., J.W. Southwick, R. Ouellet-Hellstrom, J. Rench and R.L. Calderon. 1999. Drinking Water Arsenic in Utah: A Cohort Mortality Study. Environmental Health Perspectives. 107(5):359–365.

McCullagh, P. and J.A. Nelder. 1989. Generalized Linear Models (2nd ed.). London: Chapman and Hall.

Morales, K.H., L. Ryan, T.L. Kuo, M.M. Wu and C.J. Chen. 2000. Risk of internal cancers from arsenic in drinking water. Environmental Health Perspectives 108:655–661.

Morris, J.S., M. Schmid, S. Newman, P.J. Scheuer and S. Sherlock. 1974. Arsenic and Noncirrhotic Portal Hypertension. Gastroenterology. 66:86–94.

Morton, W., G. Starr, D. Pohl, J. Stoner, S. Wagner and P. Weswig. 1976. Skin cancer and water arsenic in Lane County, Oregon. Cancer 37:2523–2532.

NAS (National Academy of Sciences. 1977. Arsenic. National Academy Press, Washington, DC, 332 pp.

National Cancer Institute (NCI). 1999. Ries, L.A.G., C.L. Kosary, B.A. Miller, L. Clegg and B.K. Edwards. SEER Cancer Statistics Review, 1973–1996, Bethesda, MD.

National Research Council (NRC). 1989. Recommended Dietary Allowances, 10th Edition. National Academy Press. Washington, DC, pp. 283.

National Research Council. 1999. Arsenic in Drinking Water. Washington, DC. National Academy Press.

Nevens, F., J. Fevery, W. Van Steenbergen, R. Sciot, V. Desmet and J. De Groote. 1990. Arsenic and Noncirrhotic Portal Hypertension: A Report of Eight Cases. Hepatology. 11:80–85.

Ng, J.C., A.A. Seawright, L. Qi, C.M. Garnett, B. Chiswell and M.M. Moore. 1999. Tumours in mice induced by exposure to sodium arsenate in drinking water. In Chappell, W.R., C.O. Abernathy and R.L. Calderon, eds. Arsenic Exposure and Health Effects. Elsevier. Amsterdam. pp. 217–223.

Petrick, J.S., A. Ayala-Fierro, W.R. Cullen, D.E. Carter and H.V. Aposhian. 2000. Monomethylarsonous acid (MMA^{iii}) is more toxic than arsenite in Chang liver human hepatocytes. Toxicol. Appl. Pharmacol. 163:203–207.

Porter, M., I. Elliot, S. Marshall, J. Routh and R. Matousek. 2000. Large Scale Gas Generator Eliminates On-Site Chlorine Storage. Proceedings American Water Works Association Annual Conference. Denver, CO. June 11–15.

Portier, C. 1987. Statistical properties of a two stage model of carcinogenesis. Environmental Health Perspectives 76:125–131.

Rahman, M. and J.O. Axelson. 1995. Diabetes Mellitus and Arsenic Exposure: a Second Look at Case-Control Data from a Swedish Copper Smelter. Occupational Environmental Medicine. 52:773–774.

Rahman, M., M. Tondel, S.A. Ahmad, and C. Axels. 1998. Diabetes Mellitus Associated with Arsenic Exposure in Bangladesh. American Journal of Epidemiology. 148(2):198–203.

Resevz, R.L. 1999. Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives. Columbia Law Review. 99:941–1017.

Roth, F. 1956. Concerning Chronic Arsenic Poisoning of the Moselle Wine Growers with Special Emphasis on Arsenic Carcinomas. Krebsforschung. 61:287–319.

Sabbioni, E., M. Fischbach, G. Pozzi, R. Pietra, M. Gallorini and J. L. Piette. 1991. Cellular Retention, Toxicity and Carcinogenic Potential of Seafood Arsenic. I. Lack of Cytotoxicity and Transforming Activity of Arsenobetaine in the BALB/3T3 Cell Line. Carcinogenesis. 12:1287–1291.

Schoof, R.A., L.J. Yost, E. Crecelius, K. Irgolic, W. Goessler, H.R. Guo, and H. Green. 1998. Dietary arsenic intake in

Taiwanese districts with elevated arsenic in drinking water. Human and Ecological Risk Assessment. 4 (1): 117–135.

Schoof, R.A., L.J. Yost, J. Eickhoff, E.A. Crecelius, D.W. Cragin, D. M. Meacher, and D.B. Menzel. 1999. A market basket survey of inorganic arsenic in food. Food and Chemical Toxicology. 37: 839–846.

Simms, J. and F. Azizian. 1997. Pilot Plant Trials on the Removal of Arsenic from Potable Water Using Activated Alumina. Proceedings AWWA Water Quality Technology Conference, November 9–12, 1997.

Simms, J., J. Upton, and J. Barnes. 2000. Arsenic Removal Studies and the Design of a 20,000 m^3 per Day Plant in the UK. AWWA Inorganic Contaminants Workshop, Albuquerque, NM, February 27–29, 2000.

Smith, A.H., M. Goycolea, R. Haque and M. L. Biggs. 1998. Marked Increase in Bladder and Lung Cancer Mortality in a Region of Northern Chile Due to Arsenic in Drinking Water. American Journal of Epidemiology. 147(7):660–669.

Southwick, J.W., A.E. Western, M.M. Beck, T. Whitley, R. Isaacs, J. Petajan and C. D. Hansen. 1983. An Epidemiological Study of Arsenic in Drinking Water in Millard County, Utah. In Arsenic: Industrial, Biomedical, Environmental Perspectives. Lederer, W.H. and Fensterheim, R.J., Eds. New York, Van Nostrand Reinhold: pp. 210–225.

Styblo, M., L.M. Del Razo, L. Vega, D.R. Germolic, E.L. LeChuyse, G.A. Hamilton, W. Reed, C. Wang, W.R. Cullen and D.J. Thomas. 2000. Comparative toxicity of trivalent and pentavalent inorganic and methylated arsenicals in rat and human cells. Archives Toxicology 74:289–299.

Szinicz, L. and Forth, W. 1988. Effect of As_2O_3 on gluconeogenesis. Archives Toxicology 61:444–449.

Subramanian, K.S., T. Viraraghavan, T. Phommavong, and S. Tanjore. 1997. Manganese Greensand for Removal of Arsenic in Drinking Water. Water Quality Research Journal Canada. 32:3:551–561.

Tabacova, S., D.D. Baird, L. Balabaeve, D. Lolova and I. Petrov. 1994. Placental Arsenic and Cadmium in Relation to Lipid Peroxides and Glutathione Levels in Maternal-Infant Pairs From a Copper Smelter Area. Placenta. 15:873–881.

Talar-Williams, C., R.M. Hijazi, M.M. Walther, W.M. Linehan, C.W. Hallahan, I. Lubensky, G.S. Kerr, G.S. Hoffman, A.S. Fauci and M.C. Sneller. 1996. Cyclophosphamide-induced cystitis and bladder cancer in patients with Wegener Granulomatosis.. Annals of Internal Medicine, 124:477–484.

Tay, C.H. and C.S. Seah. 1975. Arsenic Poisoning From Anti-Asthmatic Herbal Preparations. Medical Journal, Australia. 2:424–428.

Tsai, S.M., T.N. Wang, and Y.C. Ko. 1998. Cancer mortality trends in a blackfoot disease endemic community of Taiwan following water source replacement. Journal of Toxicology and Environmental Health Part A 55:389–404.

Tsai, S.M., T.N. Wang and Y.C. Ko. 1999. Mortality for Certain Diseases in Areas with High Levels of Arsenic in Drinking Water. Archives of Environmental Health. 54(3):186–193.

Tseng, W.P., H.M. Chu, S.W. How, J.M. Fong, C.S. Lin, and S. Yeh. 1968. Prevalence of skin cancer in an endemic area of chronic arsenicism in Taiwan. Journal of the National Cancer Institute. 40:453–463.

Tseng, W.P. 1977. Effects and Dose-Response Relationships of Skin Cancer and Blackfoot Disease with Arsenic. Environmental Health Perspectives. 19:109–119.

Tsuda T., Babazono A., Yamamoto, E., Krumatani, N., Mino,Y., Ogawa, T., Kishi, Y., Aoyama, H. 1995. Ingested arsenic and internal cancer: a historical cohort study followed for 33 years. Am. J. Epidemiol. 141:198–209.

US Census. 2000. (www.census.gov. Population Characteristics—Issued September, 2000).

US EPA. 1975. Water Programs: National Interim Primary Drinking Water Regulations. **Federal Register**. Vol. 40, No. 248, p. 59566. December 24, 1975.

US EPA. 1976. National Interim Primary Drinking Water Regulations. Office of Water Supply. EPA 570/9–76–003.

US EPA. 1980. Water Quality Criteria Documents; Availability. **Federal Register**. Vol. 45, No. 291, p. 79318. November 28, 1980.

US EPA. 1983. National Revised Primary Drinking Water Regulations; Advance Notice of Proposed Rulemaking. **Federal Register**. Vol. 48, No. 194, p. 45502. October 5, 1983.

US EPA. 1984. Health Assessment Document for Inorganic Arsenic. Office of Health and Environmental Assessment, Office of Research and Development. EPA–600/8–83–021F. March, 1984.

US EPA. 1985a. National Revised Primary Drinking Water Regulations; Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms; Proposed Rule. **Federal Register**. Vol. 50, No. 219, p. 46936. November 13, 1985.

US EPA. 1985b. National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals; Proposed Rule. **Federal Register**. Vol. 50, No. 219, p. 46906. November 13, 1985.

US EPA. 1988. Special Report on Ingested Inorganic Arsenic: Skin Cancer; Nutritional Essentiality. Risk Assessment Forum. EPA/625/3–87/013. July 1988.

US EPA. 1989a. Cover letter dated August 14, 1989, from SAB to EPA. Ad Hoc Work Group, Drinking Water Subcommittee, Environmental Health Advisory Committee, Science Advisory Board Report: A Critical Examination of the Evidence for a Threshold For Cancer Risk in Humans from Inorganic Arsenic. Washington, DC. June 1989 report.

US EPA. 1989b. Cover letter dated September 28, 1989 from SAB to EPA. Science Advisory Board's Review of the Arsenic Issues Relating to the Phase II Proposed Regulations From the Office of Drinking Water. Science Advisory Board Committee: Drinking Water Subcommittee of the Environmental Health Committee.

US EPA. 1991a. National Primary Drinking Water Regulations—Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations. **Federal Register**. Vol. 56, No. 20, p. 3526. January 30, 1991.

US EPA. 1991b. Arsenic IRIS File; Arsenic, Inorganic. February 1991. Used for 1992 National Toxics Rule, December 22, 1992, 57 FR 60848.

US EPA. 1991c. Arsenic Research Recommendations memorandum dated April 12, 1991 from John R. Fowle III, Chair of the Arsenic Research Recommendation Workgroup, Health Effects Research Laboratory.

US EPA. 1992a. Science Advisory Board Report: Review of the Office of Research and Development's Arsenic Research Recommendations. Washington, DC. Science Advisory Board. EPA–SAB–DWC–92–018. May 1992.

US EPA. 1992b. National Primary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals; Final Rule. **Federal Register**. Vol. 57, No. 138, p. 31776. July 17, 1992.

US EPA. 1992c. Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance; Final Rule. **Federal Register**. Vol. 57, No. 246, p. 60848. December 22, 1992.

US EPA, 1992d. Bartley, C.B., P.M. Colucci, and T. Stevens. The Inorganic

Chemical Characterization of Water Treatment Plant Residuals. EPA/600/SR–92–117, Cincinnati.

US EPA. 1992e. Occurrence Assessment for Arsenic in Public Drinking Water Sources. Prepared by Wade Miller Associates under contract to EPA. September 10, 1992.

US EPA 1993a. Small Water System Byproducts Treatment and Disposal Cost Document Washington, DC Office of Ground Water and Drinking Water. April 1993.

US EPA 1993b. Water System Byproducts Treatment and Disposal Cost Document; Draft Final. Washington, DC. Office of Ground Water and Drinking Water. April 1993.

US EPA. 1993c. Science Advisory Board Report: Review of the Draft Drinking Water Criteria Document on Inorganic Arsenic. Washington, DC. Science Advisory Board. EPA–SAB–DWC–94–004. November 8, 1993.

US EPA. 1993d. Inorganic Arsenicals; Conclusion of Special Review. **Federal Register**. Vol. 58, No. 234, p. 64579. December 8, 1993.

US EPA. 1994a. EPA Method 200.15, Determination of Metals and Trace Elements in Water By Ultrasonic Nebulization Inductively Coupled Plasma-Atomic Emission Spectrometry. Methods for the Determination of Metals in Environmental Samples—Supplement I, Rev 1.2. EPA/600/R–94–111. May 1994.

US EPA. 1994b. Methods for the Determination of Metals in Environmental Samples—Supplement I. EPA/600/R–94–111, NTIS PB 94–184942.

US EPA. 1994c. SW–846 Method 6020, Inductively Coupled Plasma-Mass Spectrometry. Test Methods for Evaluating Solid Waste: Physical/Chemical Methods. Third Edition, September 1994 Update II.

US EPA. 1994d. SW–846 Method 7060A, Arsenic (Atomic Absorption, Furnace Technique). Test Methods for Evaluating Solid Waste: Physical/Chemical Methods. Third Edition, September 1994 Update II.

US EPA. 1994e. SW–846 Method 7062, Antimony and Arsenic (Atomic Absorption, Borohydride Reduction). Test Methods for Evaluating Solid Waste, Physical/Chemical Methods. Third Edition, September 1994 Update II.

US EPA. 1994f. National Primary and Secondary Drinking Water Regulations: Analytical Methods for Regulated Drinking Water Contaminants; Final Rule. **Federal Register**. Vol. 59, No. 232, p. 62456. December 5, 1994.

US EPA. 1995. Science Advisory Board Report: Review of Issues Related to the Regulation of Arsenic in Drinking Water. Washington, DC. Science Advisory Board. EPA–SAB–DWC–95–015. July 19, 1995.

US EPA. 1996a. Proposed Guidelines for Carcinogenic Risk Assessment; Notice. **Federal Register**. Vol 61, No. 79, p. 17960. April 23, 1996.

US EPA. 1996b. EPA Method 1632, Inorganic Arsenic In Water by Hydride Generation Quartz Furnace Atomic Absorption. EPA/821/R–96–013. July 1996.

US EPA. 1996c. Performance Evaluation Studies Supporting Administration of the Clean Water Act and the Safe Drinking Water Act. **Federal Register**. Vol. 61, No. 139, p. 37464. July 18, 1996.

US EPA. 1996d. Investigator-Initiated Grants on Health Effects of Arsenic. **Federal Register**. Vol 61, No. 236, p. 64739. December 6, 1996.

US EPA. 1996e. SW–846 Method 7063, Arsenic in Aqueous Samples and Extracts by Anodic Stripping Voltammetry (ASV). Test Methods for Evaluating Solid Wastes, Physical/Chemical Methods. Third Edition, December 1996, Update III.

US EPA. 1997a. Drinking Water Infrastructure Needs Survey. First Report to Congress. EPA 812–R–97–001. January, 1997.

US EPA. 1997b. Manual for the Certification of Laboratories Analyzing Drinking Water. EPA 815/B–97/001.

US EPA. 1997c. March 1994 Workshop on Developing an Epidemiology Research Strategy for Arsenic in Drinking Water. Prepared for EPA's National Health and Environmental Effects Research Laboratory by SRA Technologies. April 14, 1997.

US EPA 1997d. Performance Evaluation Studies Supporting Administration of the Clean Water Act and the Safe Drinking Water Act. **Federal Register**. Vol. 62, No. 113, p. 32112. June 12, 1997.

US EPA. 1997e. National Center for Environmental Assessment. Report on the Expert Panel on Arsenic Carcinogenicity: Review and Workshop. Lexington, MA. Prepared by the Eastern Research Group under contract to US EPA. August 1997.

US EPA 1997f. SAB Report by the Environmental Health Committee: Guidelines for Cancer Risk Assessment. EPA–SAB–EHC–97–010 September 30, 1997.

US EPA. 1997g. Performance Based Measurement System. **Federal Register**. Vol. 62, No. 193, p. 52098. October 6, 1997.

US EPA. 1997h. Benefits and Costs of the Clean Air Act. 1970–1990. Clean Air Act § 812. Report Prepared for U.S. Congress by US EPA Office of Air and Radiation. Chapter 6. October. EPA 410–R–97–002.

US EPA. 1998a. Information for States on Developing Affordability Criteria for Drinking Water. EPA 816–R–98–002. February 1998.

US EPA. 1998b. Research Plan for Arsenic in Drinking Water. Office of Research and Development, National Center for Environmental Assessment. EPA/600/R–98/042. *www.epa.gov/ORD/WebPubs/final/arsenic.pdf* February 1998.

US EPA. 1998c. National Primary Drinking Water Regulations: Consumer Confidence Reports. Proposed Rule. **Federal Register**. Vol. 63, No. p. 7605. February 13, 1998.

US EPA. 1998d. Environmental Justice Stakeholders Meeting March 12, 1998 Meeting Summary.

US EPA. 1998e. Locating and Estimating Air Emissions From Sources of Arsenic and Arsenic Compounds. Research Triangle Park, NC. Office of Air Quality Planning and Standards. EPA–454–R–98–013. June 1998.

US EPA. 1998f. Removal of the Prohibition on the Use of Point of Use Devices for Compliance with National Primary Drinking Water Regulations. **Federal Register** (63 FR 31934). June 11, 1998.

US EPA. 1998g. Guidance on Implementing the Capacity Development Provisions of the Safe Drinking Water Act Amendments of 1996. EPA 816–R–98–006. July 1998.

US EPA. 1998h. Announcement of Small System Compliance Technology Lists for Existing National Primary Drinking Water Regulations and Findings Concerning Variance Technologies. Notice of Lists of Technologies and Upcoming Release of Guidance and Supporting Documents. **Federal Register**. Vol. 63, No. 153, p. 42032 at 43045. August 6, 1998.

US EPA. 1998i. National Primary Drinking Water Regulations: Consumer Confidence Reports. Final Rule. **Federal Register**. Vol. 63, No. 160, p. 44512. August 19, 1998.

US EPA, 1998j. National-Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking Water Act (Final Draft Report). Prepared by International Consultants, Inc., Hagler Bailly Services, Inc., & Janice A. Beecher, PhD under contract 68–C6–0039. August 19, 1998.

US EPA 1998k. National Primary Drinking Water Regulations: Analytical Methods for Regulated Drinking Water Contaminants; Final and Proposed Rule. **Federal Register**. Vol. 63, No. 171, p. 47097. September 3, 1998.

US EPA. 1998l. Variance Technology Findings for Contaminants Regulated Before 1996. Office of Water. EPA 815–R–98–003. September 1998.

US EPA. 1998m. Information for Small Entity Representatives Regarding the Arsenic in Drinking Water Rule. December 3, 1998.

US EPA. 1998n. Cost of Illness Handbook. Office of Pollution Prevention and Toxics. Chapter V Cost of Lung Cancer. September, 1998.

US EPA. 1999a. Drinking Water Baseline Handbook. Prepared by International Consultants, Inc. under contract with EPA OGWDW, Standards and Risk Management Division. February 24, 1999.

US EPA. 1999b. Technologies and Costs for the Removal of Arsenic From Drinking Water. Prepared by International Consultants, Inc. and Malcolm Pirnie, Inc. under contract 68–C–C6–0039 with EPA OGWDW. April 1999.

US EPA 1999c. A Guidebook of Financial Tools: Paying for Sustainable Environmental Systems. April 1999.

US EPA. 1999d. National Primary Drinking Water Regulations: Public Notification Rule, Proposed Rule. **Federal Register**. Vol. 64, No. 92, p. 25964. May 13, 1999.

US EPA. 1999e. Report of the Small Business Advocacy Review Panel on EPA's Planned Proposal of the National Primary Drinking Water Regulation for Arsenic. Cover memo to the Administrator and the report. June 4, 1999.

US EPA. 1999f. Decision Tree for the Arsenic Rulemaking Process. Washington, DC. Office of Ground Water and Drinking Water. July 1999.

US EPA 1999g. SAB Report by the Executive Committee: Review of Revised Sections of the Proposed Guidelines for Carcinogen Risk Assessment. EPA–SAB–EC–99–015. July 29, 1999.

US EPA. 1999h. Radon and Arsenic Regulatory Compliance Costs for the 25 Largest Public Water Systems (With Treatment Plant Configurations) Prepared for U.S. EPA by Science Applications International Corporation. August 10, 1999.

US EPA. 1999i. Geometries and Characteristics of Public Water Systems. Draft prepared by Science Applications International Corporation under contract with EPA OGWDW. August 15, 1999.

US EPA. 1999j. Cost of Illness Handbook. Office of Pollution Prevention and Toxics. Chapter 1 II.8. Cost of Bladder Cancer. September, 1999.

US EPA. 1999k. Cost of Illness Handbook. Office of Pollution Prevention and Toxics. Chapter V Cost of Lung Cancer. September, 1998.

US EPA. 1999l. Co-Occurrence of Drinking Water Contaminants. Prepared by Science Applications International Corporation under contract 68–C6–0059 for EPA OGWDW. EPA 815–R–00–025. September 30, 1999.

US EPA. 1999m. National Primary Drinking Water Regulations: Radon-222, Proposed Rule. **Federal Register**. Vol. 64, No. 211, p. 59246. EPA 815-z-99–006. November 2, 1999.

US EPA. 1999n. Small Systems Compliance Technology List for the Arsenic Rule. Washington, DC. Office of Ground Water and Drinking Water. November, 1999. EPA–815–R–00–011.

US EPA. 1999o. Technologies and Costs for the Removal of Arsenic from Drinking Water. Washington, DC. Office of Ground Water and Drinking Water. November, 1999. EPA–815–R–00–012.

US EPA. 1999p. National Primary Drinking Water Regulations: Analytical Methods for Chemical and Microbiological Contaminants and Revisions to Laboratory Certification Requirements; Final Rule. **Federal Register**. Vol. 64, No. 230, p. 67450. December 1, 1999.

US EPA. 1999q. Analytical Methods Support Document for Arsenic in Drinking Water. Prepared by Science Applications International Corporation under contract with EPA OGWDW, Standards and Risk Management Division. December, 1999. EPA–815–R–00–010.

US EPA. 1999r. Arsenic Risk Characterization, Part 1. Prepared by ISSI Consulting Group, Inc. for EPA Office of Water, Office of Standards and Technology. December 22, 1999.

US EPA 2000a. Meeting Notice of the Environmental Economics Advisory Committee (EEAC) of the Science Advisory Board (SAB) on February 25, 2000. **Federal Register**. Volume 65, Number 24. February 4, 2000. Page 5638.

US EPA. 2000b. Drinking Water Baseline Handbook, Second Edition. 4th quarter 1998 SDWIS freeze. Prepared by International Consultants, Inc. under contract with EPA OGWDW, Standards and Risk Management Division. March 17, 2000.

US EPA. 2000c. Estimated Per Capita Water Ingestion in the United States: Based on Data Collected by the United States Department of Agriculture's (USDA) 1994–1996 Continuing Survey of Food Intakes by Individuals. Office of Water, Office of Standards and Technology. EPA–822–00–008. April 2000.

US EPA 2000d. Review of the EPA's Draft Chloroform Risk Assessment by the Science Advisory Board Chloroform Risk Assessment Review Subcommittee. EPA–SAB–EC–00–009. April 28, 2000.

US EPA. 2000e. National Primary Drinking Water Regulations: Public Notification Rule; Final Rule. **Federal Register**. Vol. 65, No. 87, p. 25982. May 4, 2000.

US EPA. 2000f. National Primary Drinking Water Regulations: Ground Water Rule; Proposed Rule. **Federal Register**. Vol. 65, No. 91, p. 30193. May 10, 2000.

US EPA. 2000g. Arsenic Occurrence in Public Drinking Water Supplies. Public Comment Draft. Office of Water, Washington, D.C. EPA 815–D–00–001. May 2000.

US EPA. 2000h. Regulatory Impact Analysis (RIA) of the Arsenic Rule. May 2000. EPA 815–R–00–013. Available online www.epa.gov/ogwdw.

US EPA. 2000i. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Proposed Rule. **Federal Register**. Vol. 65, No. 121, p. 38888. June 22, 2000.

US EPA 2000j. SAB Report from the Environmental Economics Advisory Committee (EEAC) on EPA's White Paper "Valuing the Benefits of Fatal Cancer Risk Reduction. EPA–SAB–EEAC–00–013. July 27, 2000.

US EPA 2000k. Guidelines for Preparing Economic Analyses. EPA 240–R–00–003, September 2000.

US EPA 2000l. Internal Memorandum dated September 30, 2000 from Industrial Economics, Inc. to EPA. Update to Recommended Approach to Adjusting WTP Estimates to Reflect Changes in Real Income.

US EPA 2000m. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice of Data Availability. **Federal Register**. Volume 65, Number 204. October 20, 2000. Page 63027–63035.

US EPA 2000n. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring. Correction. **Federal Register**. Volume 65, Number 209. October 27, 2000.

US EPA 2000o. Arsenic Economic Analysis. Prepared by Abt Associate. EPA 815–R–00–026 December 2000.

US EPA 2000p National Primary Drinking Water Regulations; Radionuclides; Final Rule. **Federal Register**. Volume 65, Number 236. December 7, 2000.

US EPA 2000n. Arsenic Proposed Drinking Water Regulation: A Science Advisory Board Review of Certain

Elements of the Proposal. EPA–SAB–DWC–1–001. December 12, 2000. *www.epa.gov/sab.*

US EPA 2000r. Arsenic Occurrence in Public Drinking Water Supplies. Prepared by ISSI for Office of Ground Water and Drinking Water. EPA 815–R–00–023. December 2000.

US EPA 2000s. Impact of the Arsenic Rule on the Technical, Managerial, and Financial Capacity of Public Water Systems. December 29, 2000.

US EPA 2000t. Arsenic Technologies and Costs for the Removal of Arsenic from Drinking Water. December 2000.

US EPA 2000u. Arsenic Response to Comments Document. December 2000.

US EPA. 2000v. Radon and Arsenic Regulatory Compliance Costs for the 25 Largest Public Water Systems (With Treatment Plant Configurations) Prepared for U.S. EPA by Science Applications International Corporation. December 2000.

US EPA. 2000w. Final Regulatory Flexibility Analysis (FRFA) for the Final Arsenic Rule. December 29, 2000.

US EPA. 2000x. A Re-Analysis of Arsenic-Related Bladder and Lung Cancer Mortality in Millard County, Utah. Office of Ground Water and Drinking Water, Washington, DC. EPA 815–R–00–027. December 2000.

US EPA. 2000y. Geometries and Characteristics of Public Water Systems. Final Report. Prepared by Science Applications International Corporation under contract with EPA OGWDW. EPA 815–R–00–024. December 2000.

US GS. 1998. Reese, R.G., Jr., Arsenic. In United States Geological Survey Minerals Yearbook, Fairfax, VA, US Geological Survey.

US GS. 1999. Reese, R.G., Jr., Arsenic. In Mineral Commodity Summaries. Fairfax, VA, pgs. 26–27. US Geological Survey. January 1999.

US GS. 2000. Focazio, M., A. Welch, S. Watkins, D. Helsel & M. Horn. A retrospective analysis of the occurrence of arsenic in ground water resources of the United States and limitations in drinking water supply characterizations. Water Resources Investigations Report:99–4279. May 2000.

US Public Health Service. 1943. Public Health Service Drinking Water Standards. Approved Revisions to the 1925 Drinking Water Standards on December 3, 1942. Public Health Reports. 58(3):69–82. January 15, 1943.

US Public Health Service. 1946. Public Health Service Drinking Water Standards. Approved Revisions to the 1942 Drinking Water Standards by the American Water Works Association. Public Health Reports. 61(11):371–384. March 15, 1946.

US Public Health Service. 1962. Chapter 1—Public Health Service, Department of Health Education and Welfare. Title 42 Public Health, Part 72 Interstate Quarantine, Subpart J Drinking Water Standards. **Federal Register**. p. 2152. March 6, 1962.

Vahter, M. and E. Marafante. 1983. Intracellular interaction and metabolic fate of arsenite and arsenate in mice and rabbits. Chem.-Biol. Interact. 47:29–4.

Vahter, M. 1994. Species differences in the metabolism of arsenic. In: W.R. Chappell, C.O. Abernathy and C.R. Cothern, eds., Arsenic Exposure and Health, Science Technology Letters, Northwood, England. pp. 171–180.

Vahter, M. 1994. Species differences in the metabolism of arsenic compounds. Applied Organometallic Chemistry. 8:175–182.

Valentine, J.L., S.H. He, L.S. Reisbord, and P. L. Lachenbruch. 1992. Health response by questionnaire in arsenic-exposed populations. Journal of Clinical Epidemiology 45:487–494.

Vallee, B. L., D.D. Ulmer and W.E.C. Wacker. 1960. Arsenic Toxicology and Biochemistry. AMA Arch. Ind. Med. 21:56–75.

Wester, R.C., H.I. Maibach, L. Sedik, J. Melendres and M. Wade. 1993. In vivo and in vitro percutaneous absorption and skin decontamination of arsenic from water and soil. Fundamental Applied Toxicology 20:336–340.

WHO (World Health Organization). 1981. Environmental Health Criteria 18 Arsenic. United Nations Environment Programme, International Labour Organisation, and the World Health Organization.

WHO (World Health Organization). 1993. Guidelines for Drinking-Water Quality. Volume 1. Recommendations. World Health Organization. Geneva.

WHO (World Health Organization). 1998. International Agency for Research on Cancer, World Health Organization, ‘‘Cancer Survival in Developing Countries,’’ Publication No. 145, 1998.

Winship, K.A. 1984. Toxicity of Inorganic Arsenic Salts. Adverse Drug Reactions and Acute Poisoning Reviews. 3:129–160.

Wong, O., M.D. Whorton, D.E. Foliart and R. Lowengart. 1992. An ecologic study of skin cancer and environmental arsenic exposure. International Archives Occupational Environmental Health 64:235–241.

Woods, J.S. and B.A. Fowler. 1977. Environmental Health Perspectives 19:209–213.

Wu, M.M., T.L. Kuo, Y.H. Hwang and C.J. Chen. 1989. Dose-Response Relation Between Arsenic Concentration in Well Water and Mortality From Cancers and Vascular Diseases. American Journal of Epidemiology. 130(6):1123–1132.

Yost, L.J., R.A. School, and R. Aucoin. 1998. Intake of inorganic arsenic in the north American diet. Human and Ecological Risk Assessment: 4(1):137–152.

Yeh, S. 1973. Skin Cancer in Chronic Arsenicism. Human Pathology. 4(4):469–485.

Zaldivar, R. 1974. Arsenic Contamination of Drinking Water and Food-Stuffs Causing Endemic Chronic Poisoning. Beitr. Pathology. 151:384–400.

Zaldivar, R., L. Prunes and G. Ghai. 1981. Arsenic Dose in Patients with Cutaneous Carcinoma and Hepatic Hemangio-Endothelioma After Environmental and Occupational Exposure. Archives of Toxicology. 47:145–154.

List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 141

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

40 CFR Part 142

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

Dated: January 16, 2001.

Carol M. Browner,
Administrator.

For reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR parts 9, 141 and 142 as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

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

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

2. Amend the table in § 9.1 by removing the entry for 141.23–141.24 and adding new entries for 141.23(a)–(b), 141.23 (c), and 141.23(d)–141.24 to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * *	* *
National Prmary Drinking Water Regulations	
* * *	* *
141.23A(a)–(b)	2040–0090
141.23(c)	2040–0231
141.23(d)–141.24	2040–0090
* * *	* *

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

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

Subpart A—[Amended]

§ 141.2 [Amended]

2. In 40 CFR 141.2 revise the definition heading for ‘‘*Point-of-entry treatment device*’’ to read ‘‘*Point-of-entry treatment device (POE)*’’, and revise the definition heading for ‘‘*Point-of-use treatment device*’’ to read ‘‘*Point-of-use treatment device (POU)*’’.

3. Amend § 141.6 by revising paragraphs (a) and (c), and adding paragraphs (j) and (k) to read as follows:

§ 141.6 Effective dates.

(a) Except as provided in paragraphs (b) through (k) of this section, and in § 141.80(a)(2), the regulations set forth in this part shall take effect on June 24, 1977.

* * * * *

(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 maximum contaminant levels (MCL) listed in § 141.62 is effective for the purpose of compliance on January 23, 2006.

Requirements relating to arsenic set forth in §§ 141.23(i)(4), 141.23(k)(3) introductory text, 141.23(k)(3)(ii), 141.51(b), 141.62(b), 141.62(b)(16), 141.62(c), 141.62(d), and 142.62(b) revisions in Appendix A of subpart O for the consumer confidence rule, and Appendices A and B of subpart Q for the public notification rule are effective for the purpose of compliance on January 23, 2006. However, the consumer confidence rule reporting requirements relating to arsenic listed in § 141.154(b) and (f) are effective for the purpose of compliance on March 23, 2001.

(k) Regulations set forth in §§ 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) are effective for the purpose of compliance on January 22, 2004.

Subpart B—[Amended]

4. Amend § 141.11 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.

(b) The maximum contaminant level for arsenic is 0.05 milligrams per liter for community water systems until January 23, 2006.

* * * * *

Subpart C—[Amended]

5. Amend § 141.23 by:

a. Adding a new entry for ‘‘Arsenic’’ in alphabetical order to the table in paragraph (a)(4)(i) and adding endnotes 6, 7 and 8,

b. Revising paragraphs (a)(5) and (c) introductory text,

c. Adding paragraph (c)(9),

d. Revising paragraphs (f)(1), (i)(1), and (i)(2),

e.–h. Adding paragraph (i)(4),

i. Revising the entries for arsenic in the table in paragraph (k)(1),

j. Revising paragraph (k)(2) introductory text,

k. Adding a new entry for ‘‘Arsenic’’ in alphabetical order to the table to paragraph (k)(2) and revising footnote 1,

l. Revising the last sentence in paragraph (k)(3) introductory text, and

m. Adding a new entry for ‘‘Arsenic’’ in alphabetical order 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 INFORGANIC CONTAMINANTS

Contaminant	MCL (mg/l)	Methodology	Detection Limit (mg/l)
*	*	* * * *	*
Arsenic	[6] 0.01	Atomic Absorption; Furnace	0.001
		Atomic Absorption; Platform—Stabilized Temperature	[7] 0.0005
		Atomic Absorption; Gaseous Hydride	0.001
		ICP-Mass Spectrometry	[8] 0.0014
*	*	* * * *	*

* * * * *

[6] The value for arsenic is effective January 23, 2006. Unit then, the MCL is 0.05 mg/L.

[7] The MDL reported for EPA method 200.9 (Atomic Absorption; Platform—Stablized Temperature) was determined using a 2x concentration step during sample digestion. The MDL determined for samples analyzed using direct analyses (i.e., no sample digestion) will be higher. Using multiple depositions, EPA 200.9 is capable of obtaining MDL of 0.0001 mg/L.

[8] Using selective ion monitoring, EPA Method 200.8 (ICP–MS) is capable of obtaining a MDL of 0.0001 mg/L.

* * * * *

(5) The frequency of monitoring for asbestos shall be in accordance with paragraph (b) of this section: the frequency of monitoring for antimony, arsenic, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium and thallium shall be in accordance with paragraph (c) of this section; the frequency of monitoring for nitrate shall be in accordance with paragraph (d) of this section; and the

frequency of monitoring for nitrite shall be in accordance with paragraph (e) of this section.

* * * * *

(c) The frequency of monitoring conducted to determine compliance with the maximum contaminant levels in § 141.62 for antimony, arsenic, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium and thallium shall be as follows:

* * * * *

(9) All new systems or systems that use a new source of water that begin operation after January 22, 2004 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.

* * * * *

(f) * * *

(1) Where the results of sampling for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium indicate an exceedance of the maximum contaminant level, the State may require that one additional sample be collected as soon as possible after the initial sample was taken (but not to exceed two weeks) at the same sampling point.

* * * * *

(i) * * *

(1) For systems which are conducting monitoring at a frequency greater than annual, compliance with the maximum contaminant levels for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium is determined by a running annual average at any sampling point. If the average at any sampling point is greater than the MCL, then the system is out of compliance. If any one sample would cause the annual average to be exceeded, then the system is out of compliance immediately. Any sample below the method detection limit shall be calculated at zero for the purpose of determining the annual average. 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.

* * * * *

(4) Arsenic sampling results will be reported to the nearest 0.001 mg/L.

* * * * *

(k) * * *

(1) * * *

Contaminant and methodology [13]	EPA	ASTM [3]	SM [4]	Other
* * *	*	*	*	*
Arsenic [14]:				
Inductively Coupled Plasma [15]	[2] 200.7		[15] 3120B	
ICP-Mass Spectrometry	[2] 200.8			
Atomic Absorption; Platform	[2] 200.9			
Atomic Absorption; Furnace		D–2972–93C	3113B	
Hydride Atomic Absorption		D–2972–93B	3114B	
* * *	*	*	*	*

* * * * *

[2] "Methods for the Determination of Metals in Environmental Samples-Supplement I", EPA–600/R–94–111, May 1994. Available at NTIS, PB 95–125472.

[3] 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.

[4] 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.

* * * * *

[13] 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.

[14] 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.

[15] After January 23, 2006 analytical methods using the ICP–AES technology, may not be used because the detection limits for these methods are 0.008 mg/L or higher. This restriction means that the two ICP–AES methods (EPA Method 200.7 and SM 3120 B) approved for use for the MCL of 0.05 mg/L may not be used for compliance determinations for the revised MCL of 0.01 mg/L. However, prior to 2005 systems may have compliance samples analyzed with these less sensitive methods.

* * * * *

(2) Sample collection for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium, and thallium under this section shall be conducted using the sample preservation, container, and maximum holding time procedures specified in the table below:

Contaminant	Preservative[1]	Container[2]	Time[3]
*	*	*	* *
Arsenic	Conc HNO_3 to pH <2.	P or G	6 months
*	*	*	* *

[1] For cyanide determinations samples must be adjusted with sodium hydroxide to pH 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4°C or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

[2] P = plastic, hard or soft; G = glass, hard or soft.

[3] 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) * * * To receive certification to conduct analyses for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite and selenium and thallium, the laboratory must:

* * * * *

(ii) * * *

Contaminant	Acceptance limit
* *	* * *
Arsenic	±30 at ≥0.003 mg/L
* *	* * *

* * * * *

6. Amend § 141.24 by:

a. Adding a new sentence to the end of paragraph (f)(15) introductory text,

b. Revising paragraphs (f)(15)(i) and (f)(15)(ii) and adding new paragraphs (f)(15)(iii) through (f)(15)(v),

c. Adding paragraph (f)(22),

d. Adding a new sentence to the end of paragraph (h)(11) introductory text,

e. Revising paragraphs (h)(11)(i) and (h)(11)(ii) and adding new paragraphs (h)(11)(iii) through (h)(11)(v), and

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) * * * If one sampling point is in violation of an MCL, the system is in violation of the MCL.

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

(ii) Systems monitoring annually or less frequently whose sample result exceeds the MCL must begin quarterly sampling. The system will not be considered in violation of the MCL until it has completed one year of quarterly sampling.

(iii) If any sample result will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately.

(iv) If a system fails to collect the required number of samples, compliance will be based on the total number of samples collected.

(v) If a sample result is less than the detection limit, zero will be used to calculate the annual average.

* * * * *

(22) All new systems or systems that use a new source of water that begin operation after January 22, 2004 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)* * * If one sampling point is in violation of an MCL, the system is in violation of the MCL.

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

(ii) Systems monitoring annually or less frequently whose sample result exceeds the regulatory detection level as defined by paragraph (h)(18) of this section must begin quarterly sampling. The system will not be considered in violation of the MCL until it has completed one year of quarterly sampling.

(iii) If any sample result will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately.

(iv) If a system fails to collect the required number of samples, compliance will be based on the total number of samples collected.

(v) If a sample result is less than the detection limit, zero will be used to calculate the annual average.

* * * * *

(20) All new systems or systems that use a new source of water that begin operation after January 22, 2004 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. Amend the table in § 141.51(b) by adding a new entry for ‘‘Arsenic’’ in alphabetical order and adding a new endnote to read as follows:

§ 141.51 Maximum contaminant level goals for inorganic contaminants.

* * * * *

(b) * * *

Contaminant	MCLG (mg/L)
* * *	* *
Arsenic	zero[1]
* * *	* *

[1] This value for arsenic is effective January 23, 2006. Until then, there is no MCLG.

Subpart G—[Amended]

8. Amend § 141.60 by adding paragraph (b)(4) to read as follows:

§ 141.60 Effective dates.

* * * * *

(b) * * *

(4) The effective date for § 141.62(b)(16) is January 23, 2006.

9. Amend § 141.62 by:

a. Revising the first sentence of paragraph (b) introductory text,

b. Adding a new entry ‘‘(16)’’ for arsenic to the table in paragraph (b),

c. Adding a new entry for ‘‘Arsenic’’ in alphabetical order, adding new endnotes 4 and 5, adding a new item 12 and revising items 2 and 6 to list of ‘‘Key to BATs in Table’’ and revising the heading to the table in paragraph (c),

d. Adding paragraph (d).

The revisions and additions read as follows:

§ 141.62 Maximum Contaminant Levels for inorganic contaminants.

* * * * *

(b) The maximum contaminant levels for inorganic contaminants specified in paragraphs (b) (2)–(6), (b)(10), and (b) (11)–(16) of this section apply to community water systems and non-transient, non-community water systems. * * *

* * * * *

Contaminant	MCL (mg/L)
* * *	* *
(16) Arsenic	0.01

(c) * * *

BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(B)

Chemical Name	BAT(s)
* * *	* *
Arsenic[4]	1, 2, 5, 6, 7, 9, 12[5]
* * *	* *

* * * * *

[4] BATs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

[5] To obtain high removals, iron to arsenic ratio must be at least 20:1.

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

* * * * *

12 = Oxidation/Filtration

* * * * *

(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)[1] FOR ARSENIC[2]

Small system compliance technology	Affordable for listed small system categories[3]
Activated Alumina (centralized)	All size categories.
Activated Alumina (Point-of-Use)[4]	All size categories.
Coagulation/Filtration[5]	501–3,300, 3,301–10,000.
Coagulation-assisted Microfiltration	501–3,300, 3,301–10,000.
Electrodialysis reversal[6]	501–3,300, 3,301–10,000.
Enhanced coagulation/filtration	All size categories
Enhanced lime softening (pH> 10.5)	All size categories.
Ion Exchange	All size categories.
Lime Softening[5]	501–3,300, 3,301–10,000.
Oxidation/Filtration[7]	All size categories.
Reverse Osmosis (centralized)[6]	501–3,300, 3,301–10,000.
Reverse Osmosis (Point-of-Use)[4]	All size categories.

[1] Section 1412(b)(4)(E)(ii) of SDWA specifies that SSCTs must be affordable and technically feasible for small systems.

[2] SSCTs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

[3] 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.

[4] 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.

[5] Unlikely to be installed solely for arsenic removal. May require pH adjustment to optimal range if high removals are needed.

[6] Technologies reject a large volume of water—may not be appropriate for areas where water quantity may be an issue.

[7] To obtain high removals, iron to arsenic ratio must be at least 20:1.

Subpart O—[Amended]

10. Amend § 141.154 by revising paragraph (b) and adding paragraph (f) to read as follows:

§ 141.154 Required additional health information.

* * * * *

(b) Ending in the report due by July 1, 2001, a system which detects arsenic at levels above 0.025 mg/L, but below the 0.05 mg/L, and beginning in the report due by July 1, 2002, a system that detects arsenic above 0.005 mg/L and up to and including 0.01 mg/L:

(1) Must include in its report a short informational statement about arsenic, using language such as: While your drinking water meets EPA's standard for arsenic, it does contain low levels of arsenic. EPA's standard balances the current understanding of arsenic's possible health effects against the costs of removing arsenic from drinking water. EPA continues to research the health effects of low levels of arsenic, which is a mineral known to cause cancer in humans at high concentrations and is linked to other health effects such as skin damage and circulatory problems.

(2) May write its own educational statement, but only in consultation with the Primacy Agency.

* * * * *

(f) Beginning in the report due by July 1, 2002 and ending January 22, 2006, a community water system that detects arsenic above 0.01 mg/L and up to and including 0.05 mg/L must include the arsenic health effects language prescribed by Appendix A to Subpart O.

11. Amend Appendix A to Subpart O by revising the entry for arsenic under ''Inorganic contaminants:'' and adding an endnote 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)	[1]0.01	1000	[1]10	[1]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.
*	*	*	*	*	*	*

* * * * *

1. These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 mg/L and there is no MCLG.

Subpart Q—[Amended]

12. Amend Appendix A to Subpart Q by:

a. Revising the entry for "2. Arsenic" under "B. Inorganic Chemicals (IOCs)",

b. Redesignating endnotes 8 through 17 as endnotes 10 through 19 in the table and at the end of the table, and

c. Adding endnotes 8 and 9.

The revisions and additions read as follows:

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

Contaminant	MCL/MRDL/TT violations [2]		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
* * * *	*		*	*
B. Inorganic Chemicals (IOCs).				
* * * *	*		*	*
2. Arsenic	2	[8]141.62(b)	3	[9]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.

* * * * *

8. The arsenic MCL citations are effective January 23, 2006. Until then, the citations are § 141.11(b) and § 141.23(n).

9. The arsenic Tier 3 violation MCL citations are effective January 23, 2006. Until then, the citations are § 141.23(a), (l).

* * * * *

13. Amend Appendix B to Subpart Q by:

a. Revising entry "9. Arsenic" under "C. Inorganic chemicals (IOCs)",

b. Redesignating endnotes 11 through 21 as endnotes 12 through 22 in the table and at the end of the table, and

c. Adding endnote 11.

The revisions and additions read as follows:

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

Contaminant	MCLG [1] mg/L	MCL [2] mg/L	Standard health effects language for public notification
* *	*	*	* * *
9. Arsenic [11]	0	0.01	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.

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
* *	*	* *	* *

Appendix B—Endnotes

1. MCLG–Maximum contaminant level goal.

2. MCL–Maximum contaminant level.

* * * * *

11. These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 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—[Amended]

2. Amend § 142.16 by revising paragraph (e) introductory text, reserving paragraph (i), and adding 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, 141.32, 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):

* * * * *

(i) [reserved]

(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 paragraph (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 16(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 ensure all systems complete the required monitoring by 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 16(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 comply with MCL's and monitoring requirements. States must also specify the time frame in which new systems will demonstrate compliance with the MCLs.

3. Amend the table in § 142.62(b) by adding a new entry for ''Arsenic'' in alphabetical order, adding new endnotes 4 and 5, adding a new item 12 to list of ''Keys to BATs in Table'' and revising the heading to the table in paragraph (b) 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)

Chemical name	BAT(s)
* * *	* *
Arsenic[4]	[5]1, 2, 5, 6, 7, 9, 12
* * *	* *

* * * * *

[4] BATs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

[5] To obtain high removals, iron to arsenic ratio must be at least 20:1.

* * * * *

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

* * * * *

12 = Oxidation/Filtration

* * * * *

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