Recommended Guidance for Review of Existing National Primary Drinking Water Regulations

Recommended by
The National Drinking Water Advisory Council (NDWAC)

November 2000

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ACRONYMS LIST

ANPRM	–	Advance Notice of Proposed Rule Making
ASTM	--	American Society for Testing and Materials
ATP	--	Alternate test procedure
ATSDR	--	Agency for Toxic Substances and Disease Registry
AWWARF	--	American Water Works Association Research Foundation
BAT	--	Best Available Technology
BEIR	--	Biological Effects of Ionizing Radiation
BMP	--	Best management practice
CCL	--	Contaminant Candidate List
D/DBP	--	Disinfection/Disinfection By-Product
EPA	--	Environmental Protection Agency
EPA-LV	--	Las Vegas, Nevada EPA Laboratory
EQIP	--	Environmental Quality Incentives Program
ESWTR	--	Enhanced Surface Water Treatment Rule
FIFRA	--	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	--	Food Quality Protection Act
FR	--	*Federal Register*
FRC	--	Federal Radiation Council
IARC	--	International Agency for Research on Cancer
ICR	--	Information Collection Rule
ICRP	--	International Commission on Radiological Protection
IOC	--	Inorganic chemical
IRIS	--	Integrated Risk Information System
ISO	--	International Standards Organization
LCR	--	Lead and Copper Rule
LT2ESWTR	--	Long-Term 2 Enhanced Surface Water Treatment Rule
MCL	--	Maximum contaminant level
MCLG	--	Maximum contaminant level goal
MDBP	--	Microbial contaminants and disinfection by-products
MDL	--	Method detection limit
ML	--	Minimum Level
MOE	--	Margin of Exposure
MRDL	--	Maximum residual disinfectant level
MRDLG	--	Maximum residual disinfectant level goal
MRL	--	Minimum reporting level
NAS	--	National Academy of Sciences
NAWQA	--	National Water Quality Assessment Program
NCOD	--	National Drinking Water Contaminant Occurrence Database
NCRP	--	National Council on Radiation Protection and Measurement
NDWAC	--	National Drinking Water Advisory Council
NERL	--	National Exposure Research Laboratory
NIST	--	National Institute of Standards and Technology

ACRONYMS (*continued*)

NOAEL	--	No-Observed-Adverse-Effect Level
NIPDWR	--	National Interim Primary Drinking Water Regulation
NPDWR	--	National Primary Drinking Water Regulation
NRCS	--	Natural Resource Conservation Service
NRPB	--	National Radiation Protection Board
NRWA	--	National Rural Water Association
NWIS	--	National Survey of Water Information System
OGWDW	--	Office of Ground Water and Drinking Water
ORIA	--	Office of Radiation and Indoor Air
OPP	--	Office of Pesticide Programs
OW	--	Office of Water
PAD	--	Population Adjusted Dose (aPAD -- acute; cPAD -- chronic)
PE	--	Performance evaluation
PQL	--	Practical quantitation level
PT	--	Proficiency Testing
PWS	--	Public water system
RfD	--	Reference dose (aRfD -- acute effects; cRfD -- chronic effects)
RSC	--	Relative source contribution
SDWA	--	Safe Drinking Water Act
SDWIS	--	Safe Drinking Water Information System
SM	--	Standard Method
SOC	--	Synthetic organic chemical
SWTR	--	Surface Water Treatment Rule
THMs	--	Trihalomethanes
TRI	--	Toxic Release Inventory
TT	--	Treatment technique
UNSCEAR	--	United Nations Scientific Committee on the Effects of Atomic Radiation
URCIS	--	Unregulated Contaminant Information System
USDA	--	United States Department of Agriculture
USDOI	--	United States Department of the Interior
USGS	--	United States Geological Survey
VOC	--	Volatile organic chemical
WG	--	Working group
WRAS	--	Watershed Restoration Action Strategies
WS	--	Water Supply

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EXECUTIVE SUMMARY

The Safe Drinking Water Act (SDWA), as amended in 1996, requires that the U.S. Environmental Protection Agency (EPA) review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them, no less often than every six years. This document describes the process and strategy for regulatory review that the National Drinking Water Advisory Council (NDWAC) proposes that EPA use to meet this statutory requirement. The guidelines presented here are the NDWAC recommendations, based on its review of the EPA May 2000 draft guidance. The EPA draft document had been developed through internal EPA deliberations and discussions with the diverse stakeholders involved in drinking water and its protection.

EPA plans to complete the first review of NPDWRs by August 2002. That review will include all NPDWRs promulgated prior to 1996. Those contaminants that are the subject of current rulemaking activities or are being reviewed on a separate schedule will not be included in the first six-year review cycle. Drinking water standards promulgated after 1996 will be reviewed at a later date.

For the first review cycle, EPA will propose and promulgate any revisions determined to be appropriate after the completion of the review cycle (i.e., after August 2002). These will be separate activities and will be completed consistent with EPA rulemaking policies and procedures. The actual details of the regulatory change (e.g., specific changes to the maximum contaminant level goal (MCLG)) will be determined as a part of this rulemaking process and not as a part of the review process. In subsequent six-year cycles, EPA should complete both the review and any appropriate NPDWR revisions within a six-year window (i.e., specific regulatory changes will be part of the review process).

As long as NPDWR revisions maintain or provide for greater protection of the health of persons, the SDWA 1996 amendments give the Administrator discretion to determine if it is appropriate to revise an existing NPDWR. In order to determine that a revision is appropriate, EPA believes the revision must continue to meet the basic statutory requirements of the SDWA (e.g., set the maximum contaminant level (MCL) as close to the MCLG as is feasible) and present significant opportunities to: improve the level of public health protection; and/or to achieve cost savings while maintaining, or improving, the level of public health protection.

To define the scope of the six-year review process, this guidance identifies key assumptions that the NDWAC recommends that EPA use in its approach to regulatory review. Under the defined scope of review, EPA should:

- During the first six-year cycle, revisit data on which previous regulatory decisions were made, effectively identifying data gaps that need to be filled;
- In future six-year review cycles, assume that existing regulations are adequate, except where more current, reliable data are available;
- For the second and subsequent review cycles, group regulated contaminants for review, in order to achieve some efficiencies in the review process;
- Rely on data available to the Agency in a timeframe that allows the Agency sufficient time for the review process;
- Identify areas where significant data gaps exist and initiate activities to fill those gaps for subsequent review rounds; and
- Require defensible, scientific methods to carry out a review leading to a revision.

In addition, EPA should apply the basic principles of risk management in order to make the most protective and cost-effective decisions possible.

The types of regulatory revisions that EPA plans to consider are based on the various components of each primary drinking water regulation, and include possible changes to: MCLGs/MRDLGs; MCLs/MRDLs[1]; treatment techniques; other technologies (e.g., Best Available Technology, or Compliance and Variance Technology); monitoring requirements; other regulatory provisions; or, in rare instances, EPA may consider dropping a contaminant from regulation.

To most efficiently utilize limited resources, EPA plans to perform a series of analyses at the beginning of each review cycle, intended to target those NPDWRs that are the most appropriate candidates for revision. The Agency plans to use available, scientifically-sound data to make decisions regarding whether or not to revise a regulation. EPA proposes to review the following key information to make decisions regarding regulatory changes: health effects studies; technology assessments; and, occurrence and exposure analyses. EPA may consider other regulatory revisions not related to MCLG, MCL, or treatment technique requirements, such as monitoring, or reporting requirements. The Agency should also consider options that may lead to non-regulatory revisions, such as source water protection, to further enhance drinking water quality. In addition, EPA plans to conduct rough analyses of costs and benefits as part of the review process. Section III, *Key Elements of the Review Process*, provides a detailed discussion of the information review process.

[1] MRDLG -- Maximum residual disinfectant level goal. MRDL -- Maximum residual disinfectant level.

I. INTRODUCTION

A. Background

Under the Safe Drinking Water Act (SDWA), the U.S. Environmental Protection Agency (EPA) must periodically review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them. This requirement is contained in Section 1412(b)(9) of SDWA, as amended in 1996, which reads:

> *The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.*

Prior to the 1996 amendments, the SDWA required EPA to review NPDWRs at least every three years to determine whether any changes in technology, treatment techniques (TT) or other means might provide better health protection. EPA was required to publish its findings in the *Federal Register* (FR) and provide an explanation, after opportunity for public comment, of any finding that such new technology, treatment technique, or other means would not be feasible. Although the Agency did revise existing NPDWRs on occasion when new data became available, EPA did not have a systematic process for reviewing NPDWRs on a regular basis. One of the goals of the current effort is to establish a process for conducting regular reviews.

B. About this Guidance Document

This document describes the process and strategy for reviewing existing NPDWRs that the National Drinking Water Advisory Council (NDWAC) recommends that EPA use to meet this statutory requirement during each six-year cycle. It provides the guidelines and tools needed to conduct standardized, systematic reviews of NPDWRs during this and subsequent six-year cycles. It takes into account the most critical aspects of health protection and the setting of standards, as we know them under the SDWA. In addition, this guidance allows for the fact that numerous types of regulatory changes may be considered during a specific review cycle. Therefore the guidance contains an element of flexibility to allow EPA reviewers the opportunity to consider a range of possible issues. Further, revisions to the guidance may be appropriate from time to time to address changes such as: the availability of new appropriate data sources (or the loss of availability of an existing data source); revised policy guidelines; and significant fluctuations in Agency resources available to conduct the reviews. For this reason, EPA should review this guidance document periodically, modify it, when appropriate and with stakeholder involvement, to reflect changing circumstances.

Because of the advisory nature of the document, the term “should” denotes a recommendation of the NDWAC. The terms “proposes” or “plans to” denote EPA’s planned commitments. These planned commitments form the basis for the NDWAC to develop its recommendations. Note that in addition, this document also describes current EPA procedures that are related to the regulatory review process, as well as general description of activities that

are required of EPA, in order to fulfill its mandate under Section 1412 of the SDWA, as amended in 1996.

The review process described in this document will culminate with decisions of whether or not to revise each of the reviewed NPDWRs. This strategy has been developed through internal deliberations, discussions with the diverse stakeholders involved in drinking water and its protection, and recommendations of the NDWAC Working Group (WG) that have been approved by the full NDWAC.

EPA plans to complete the first review by August 2002. That review will include all NPDWRs promulgated prior to 1996. Those contaminants that are the subject of current rulemaking activities or are being reviewed on a separate schedule will not be included in the first six-year review cycle. See Appendix 1 for a full listing of contaminants regulated prior to the SDWA Amendments of 1996. This Appendix indicates whether each contaminant falls within the scope of this guidance, as it will be applied for the August 2002 review. Drinking water standards promulgated after 1996 will be reviewed at a later date. Appendix 2 indicates the NPDWRs that have been promulgated since 1996, or that are planned for promulgation by 2002.

EPA presented its draft guidance and related assumptions at a stakeholder meeting in November 1999. The guidance was subsequently revised to reflect stakeholder suggestions. Some of the changes included: clarifying the role of research in this process; and discussion of the potential need to review/revise a NPDWR. The guidance was subsequently reviewed and revised by the NDWAC WG. During a series of meetings in the year 2000, the NDWAC WG developed significant revisions and additions to the guidance document. The final recommendations, as approved by the full NDWAC, are the result of these extensive efforts.

II. THE SIX-YEAR REVIEW PROCESS

To most efficiently utilize limited resources, EPA plans to perform a series of analyses at the beginning of each review cycle, intended to target those NPDWRs that are the most appropriate candidates for revision. The Agency plans to use available, scientifically-sound data to make decisions regarding whether or not to revise a regulation. Key information that EPA will review to make decisions regarding regulatory changes include: health effects studies; technology assessments; and, occurrence and exposure analyses. The Agency also plans to conduct a rough analysis of costs and benefits as part of the review process. The NDWAC recommends that the Agency consider non-regulatory options that could augment regulatory actions to achieve the goal of public health protection.

A. Goal of the Review

The goal of the ***review*** process is to identify priorities for regulatory revision. As a part of the review process, EPA plans to evaluate regulated contaminants, based on sound science and available data, to determine whether rule revisions are necessary and appropriate. For example, new health effects findings and/or increased analytical method capabilities for analyzing a contaminant may be available that suggest the need to revise a maximum contaminant level goal

(MCLG) and/or a maximum contaminant level (MCL). The key elements of the review described in Section III (entitled "Key Elements of the Review Process") include: health effects review, technology assessment, occurrence and exposure analysis, consideration of regulatory revisions that do not impact the MCLG, MCL, or TT requirements (such as monitoring and reporting), and consideration of the costs and benefits of identified alternatives. EPA plans to use these key elements to identify possible candidates for regulatory revision. Once preliminary candidates for revision have been identified, EPA plans to further analyze those contaminants to target the revisions that are most likely to result in improvements in the level of public health protection and/or result in cost savings while at least maintaining the level of public health protection.

For each NPDWR being evaluated, the review will end with a decision by EPA whether or not to undertake rulemaking efforts to ***revise*** the NPDWR. A NPDWR conceivably could be revised in one or more of the following ways: change the MCLG; change the MCL; modify monitoring, treatment, and/or other requirements. In rare instances, EPA may determine that it is appropriate to drop a contaminant from regulation if it is no longer a public health concern. As required by the SDWA amendment, any revision to a regulation must maintain the level of public health protection that exists under the current regulation, or must provide for greater public health protection than the current regulation. Section II.C.(ii), entitled "Potential Types of Regulatory Changes" more fully describes the conditions under which changes may be appropriate.

For the first review cycle, EPA plans to propose and promulgate any revisions determined to be appropriate after the completion of the review cycle (i.e., after August 2002). This will be a separate activity and will be completed consistent with EPA rulemaking policies and procedures. The actual details of the regulatory change (e.g., specific changes to the MCLG) will be determined as a part of this rulemaking process and not as a part of the review process. In subsequent six-year cycles, EPA plans to complete both the review and any appropriate NPDWR revisions within a six-year window (i.e., specific regulatory changes will be part of the review process).

As long as NPDWR revisions maintain or provide for greater protection of the health of persons, the SDWA 1996 amendments give the Administrator discretion to determine if it is appropriate to revise an existing NPDWR. In order to determine that a revision is appropriate, the revision must continue to meet the basic statutory requirements of the SDWA (e.g., set the MCL as close to the MCLG as is feasible) and:

- Present a significant opportunity to improve the level of public health protection; and/or,
- Present a significant opportunity for cost savings while maintaining, or improving, the level of public health protection.

Risk management considerations should drive the final decision to proceed with a potential regulatory revision. As a part of this guidance, the NDWAC has defined the risk management considerations that the Agency should use in its decision-making process. These considerations include: public health protection, and cost and benefit considerations.

The first part of the review is an information-gathering effort that is science-based and consists of several inter-related analyses designed to identify potential candidates for regulatory revision. Some of these analyses examine the health basis and technology basis for setting an MCLG and an MCL (or TT requirement) to determine whether there have been changes since the NPDWR was promulgated (or revised). Provision is made for the consideration of other factors that might identify appropriate revisions, such as changes in monitoring requirements. Other steps in the decision-making process include review of occurrence and exposure information, and consideration of potential benefits and costs associated with each prospective revision. Finally, each prospective revision is assessed, based on the risk management considerations, to determine the extent to which is it likely to improve public health protection and/or result in cost savings.

At each phase of the review process, some contaminants will be identified as not requiring additional review during a cycle. These contaminants will be eliminated from further consideration during that review cycle, since no new acceptable data are available that suggest the need for regulatory revision. Other contaminants may be identified as a concern due to the occurrence of the contaminant; due to a technology that may need to be developed or improved; or; due to a health assessment under way that will not be available for the current review. Thus, a full review may be needed but the Agency must await additional information to complete that review. The review of these contaminants may "roll over" to the next review cycle. If the new data, when available, are significant, EPA should make case-by-case decisions whether to complete the review of that contaminant and initiate any appropriate rulemaking ahead of schedule for that review cycle. In addition, EPA should identify data gaps for future research needs that may support a later review.

Further, in developing this guidance, the NDWAC recognizes there are subject areas that would benefit from further research. The NDWAC believes this research would make the review process more conducive to future action by the Agency. A preliminary list of these research areas, as they relate to all of the key elements of the review process (see Section III), is provided in Appendix 3. Note that this list is not intended to be comprehensive.

B. Basic Principles of the Review Process

(i) Underlying Assumptions

In order to define the scope of the six-year review process, EPA should apply the following key assumptions:

1. For the first six-year review period, EPA should review existing data on which the MCL or TT was based (see description of individual key elements of the review in Section III for a discussion of the level of scrutiny that will be applied). Thus, EPA should revisit data on which previous regulatory decisions were made, effectively identifying data gaps that need to be filled (see Assumption 4 for further discussion of data gaps). In future six-year review cycles, EPA should assume that existing regulations are adequate, except in those instances where reliable more current data are available that indicate a need to re-evaluate an NPDWR (e.g., where a new health effects assessment has been conducted). Where new data are

available, EPA should utilize the guidance and any other established Agency policies and procedures to determine whether changes to existing standards are warranted in light of the new data.

2. For the second and subsequent review cycles, EPA should group regulated contaminants for review based on the following considerations: health risk, based on the availability of new data (e.g., health effects, occurrence); other regulatory activities that may affect contaminants that are in process or are already planned; and contaminant type (e.g., volatile organic chemicals (VOCs), synthetic organic chemicals (SOCs), radionuclides, microbes, etc.).

3. EPA should, as proposed, primarily rely on data available to the Agency in a timeframe that allows the Agency sufficient time to assess the information prior to the completion of the review process. For example, for the first review to be completed in August 2002, contaminants for which revised health effects assessments are not completed by early calendar 2001 would not be reviewed for possible MCLG/MCL changes during that cycle. In some cases, as noted in the previous Section, EPA may decide to review a contaminant for which the Agency has significant new data on an accelerated schedule.

4. EPA does not plan to fill in significant data gaps through the review process, per se. However, as a result of the review, the Agency should identify areas where significant data gaps exist and initiate activities (e.g., a health re-assessment or research) to fill those gaps for subsequent review rounds. One example of this may be the identification of chemicals for which the most recent health effects re-assessment is more than two review cycles old.

5. To the greatest extent possible, the Agency should use defensible, scientific methods to carry out a review leading to a revision, including quality assurance measures, to ensure that scientifically sound results are used in final decisions for regulatory revisions. Also, as needed, the Agency's peer review policy should be utilized as a final check regarding any new analyses stemming from the review and/or revision of an NPDWR.

(ii) Risk Management in the Review Process

Throughout the review and revision process, EPA should apply the basic principles of risk management in order to make the most protective and cost-effective decisions possible. While at different phases of the review process, the risk management assessment may be primarily qualitative, consideration of the risk management factors -- outlined below -- can significantly aid Agency decision-makers in the prioritization of potential revisions.

1. Identify the risk.

2. Identify any regulatory revisions that may reduce the risk, including:

- Changes to MCLG, MCL, or TT requirements that appear feasible; and
- Changes to other regulatory requirements.

3. Identify the estimated costs and benefits of the regulatory revision option(s).
4. Identify feasible non-regulatory approaches, on a case-by-case basis, to be utilized under the following conditions:
    - As an interim measure until regulatory revisions take effect;
    - To supplement and improve the protectiveness of regulatory revisions; and
    - In lieu of regulatory revisions, only if no regulatory revisions can address the problem, (e.g., the MCL already is as low as can be practically measured or would be cost-prohibitive).

C. Scope of the Review

(i) The Review Process

Resource constraints impose practical limitations on the Agency's ability to conduct in-depth reviews on an increasing number of NPDWRs every six years. For this reason, the Agency plans to perform a series of analyses, intended to target those NPDWRs most likely to be candidates for revision, in order to most efficiently utilize scarce resources to achieve maximum public health benefits.

Figure 1, at the end of Section II.C.(i), illustrates the flow of the review process.[2] Initially, all existing NPDWRs that are under review will be assessed. At the beginning of the review process, EPA plans to focus on identifying those contaminants for which data are available that are more current, and different than, the data used as the basis for promulgating or revising the NPDWR. Key elements of this identification phase include an:

- Initial technical review which is comprised of:

  - health effects data on which an NPDWR was based;

  - current technology requirements (analytical methods and treatment) of the NPDWR; and,

  - potential regulatory changes that do not impact the MCLG, MCL, or TT requirements, such as revisions to monitoring or reporting (also referred as other regulatory revisions).

- Initial occurrence and exposure analysis,[3] and,

[2] Figure 2 illustrates how the separate analyses interrelate.

[3] See Appendix 4 for a description of the occurrence analysis that will be performed during the first review cycle for chemical contaminants. Similar occurrence analysis will be performed for chemical and radiological

- Identification of areas that may need further research.

Through these analyses, EPA plans to identify:

- NPDWRs for which the Agency has revised health effects assessments suggesting possible MCLG changes;
- Contaminants where new or improved analytical methods or treatment would allow the MCL to be established closer to the MCLG, or where adjustments in TT requirements may be appropriate (see Section III.B of this document for discussion of TT requirements); and
- Contaminants where the Agency has identified other regulatory revisions that merit further consideration.

EPA plans to identify these NPDWRs as potential candidates for revision.

EPA proposes to drop the other NPDWRs from consideration for possible revision during the review round. Research needs that have been identified will be forwarded to the Office of Ground Water and Drinking Water (OGWDW) research prioritization process for further consideration.

EPA plans to conduct more in-depth analyses of those NPDWRs that were identified as possible candidates for revision. EPA plans to conduct in-depth analysis of health effects data for those NPDWRs identified as potential candidates for MCLG revision. Where the health effects data suggest that a lower MCLG may be indicated, EPA plans to review the appropriate current technologies to determine if technology will support a lower MCL or more efficient TT requirements. As necessary, EPA plans to review other regulatory requirements (e.g., monitoring) to determine if any changes to these requirements are appropriate. Further, the Agency plans to conduct a more in-depth occurrence and exposure assessment, and to perform a rough cost/benefit analysis. After completing this review and analysis, EPA plans to identify those NPDWRs the Agency believes should be revised.

For the first review cycle, to be completed in August 2002, EPA plans to publish an Advance Notice of Proposed Rule Making (ANPRM) in the *Federal Register* following this in-depth analysis. The ANPRM will contain the Agency's draft decisions, and the basis for those decisions, for each NPDWR reviewed, including whether or not the Agency believes the NPDWR should be revised. Based on the public comments received, EPA will revisit key elements of the review, where necessary. The Agency will conclude this first six-year cycle of review by publishing its final decisions in the *Federal Register* along with a schedule for proposing and promulgating revisions.

The process for public notice and rule revisions will be somewhat different for subsequent review cycles, because the Agency plans to complete both the review and any necessary revisions

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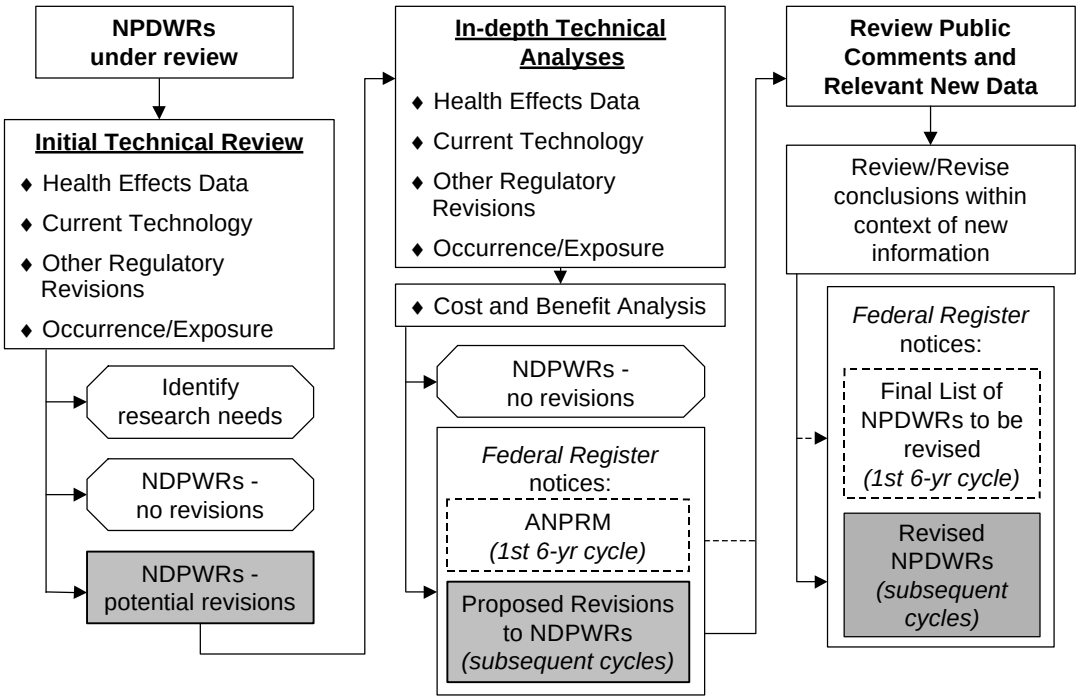
contaminants in subsequent review cycles. However, EPA expects to have a more extensive occurrence database for these reviews than will be available during the initial review cycle.

within the six-year cycle. Therefore, in lieu of publishing an ANPRM, EPA plans to publish proposed revisions. The preamble of the *Federal Register* notice containing the proposal will also identify those NPDWRs that the Agency has reviewed and determined that no revisions are appropriate. The Agency will develop final rule revisions based on public comments and any new data. EPA expects to promulgate final revisions approximately 18 months following proposal.

Figure 1: Overview of the Review Process



(ii) Potential Types of Regulatory Changes

As a part of the review, EPA will consider regulatory revisions, with the primary goal of public health protection. The types of revisions considered are based on the various components of each primary drinking water regulation. NPDWRs set enforceable MCLs for particular contaminants in drinking water, or require ways to treat water to remove contaminants. Each standard also includes requirements for water systems to test for contaminants in the water to make sure standards are achieved, specifies recordkeeping and reporting requirements, defines what constitutes compliance, and specifies language and delivery requirements for public notification. Some regulatory revisions that are not listed below (e.g., revisions to approved analytical methods) are already addressed through periodic rulemaking activities and will not be included in the six-year review. In addition, there are other ongoing non-regulatory programs, such as source water assessment and protection, which are central to the nation's overall pollution prevention strategy. These non-regulatory programs, which are described in Appendix 5, may eventually help reduce the introduction and occurrence of contaminants to out nation's waters, therefore reducing the need for drinking water regulations.

1. ***Changes to MCLGs/MRDLGs:*** The SDWA requires EPA to establish non-enforceable health-based MCLGs. For disinfectants, EPA establishes maximum residual disinfectant level goals (MRDLGs) instead of MCLGs to reflect the fact that these substances have beneficial disinfection properties.[4] As a part of each six-year review, EPA plans to consider MCLG changes only in those instances where a health effects re-assessment has been completed, since the MCLG was promulgated or last revised, and where the most current assessment results in a revised reference dose (RfD) and/or cancer classification that significantly affects the calculation of the MCLG.

   NOTE: In the rest of this document, unless otherwise noted, the term "MCLG" should be interpreted to mean "MCLG or MRDLG, as appropriate"

2. ***Changes to MCLs/MRDLs:*** An MCL is an enforceable standard for a contaminant. The SDWA requires the MCL to be set as close to the MCLG as is feasible. For disinfectants, EPA establishes maximum residual disinfectant levels (MRDLs) instead of MCLs.[5] As a part of the six-year review, EPA will consider MCL changes.

   NOTE: In the rest of this document, unless otherwise noted, the term "MCL" should be interpreted to mean "MCL or MRDL, as appropriate"

[4] As with MCLGs, MRDLGs are established at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. MRDLGs are non-enforceable health goals based only on health effects and exposure information and do not reflect the benefit of the addition of the chemical for control for waterborne microbial contaminants.

[5] MRDLs are enforceable standards analogous to MCLs, which recognize the benefits of adding a disinfectant to water on a continuous basis and to maintain a residual to control for pathogens in the distribution system. As with MCLs, EPA sets the MRDLs as close to the MRDLGs as feasible.

3. ***Changes to treatment technique requirements:*** When it is not economically or technically feasible to set an MCL, or when there is no reliable or economically feasible method to detect contaminants in the water, EPA instead sets a TT requirement. A TT specifies a type of treatment (e.g., filtration, disinfection, and/or chemical addition to limit contamination) and means for ensuring adequate treatment performance (e.g., monitoring of water quality to ensure treatment performance).

   Generally, water treatment technology may improve to the point where more protective drinking water standards may be considered. EPA plans to review new information as it becomes available. However, as with MCLG/MCL-based revisions, data would need to be scientifically valid. Moreover, before EPA would consider a revision to TT requirements, the treatment technology would have to be generally available and must have demonstrated consistent removal of the subject contaminant, at full scale.

4. ***Changes to other technology:***

   a. *Best Available Technology:* When EPA sets an MCL, the NPDWR also contains Best Available Technology (BAT) recommendations that address drinking water treatment processes. Although not required for compliance purposes, EPA sets BATs that have the capability to meet MCLs.

      EPA plans to review new information on water treatment technologies to determine if a change to a BAT may be warranted. Again, these data would need to be scientifically valid. Further, the technologies would need to be generally available and demonstrate consistent removal of the subject contaminant, at full scale.

   b. *Compliance and Variance Technology*[6]*:* In addition, EPA should continue to periodically review small system (i.e., systems serving up to 10,000 people) compliance and variance technologies, for both the MCL-type and the TT-type rules (however for microbiological contaminant regulations no variances are allowed).[7]

5. ***Changes to monitoring requirements:*** As part of an NPDWR, EPA establishes monitoring requirements, including the frequency and location of sampling. EPA should consider possible revisions to monitoring requirements as a part of the six-year review in those situations where such revisions are likely to significantly improve the level of public

[6] The 1996 SDWA Amendments identify two classes of technologies for systems serving 10,000 and fewer persons: compliance technologies and variance technologies. A compliance technology is defined in §1412(b)(4)(E)(ii) as a technology or other means that is affordable and achieves compliance with an MCL or satisfies a treatment technique requirement. Variance technologies, defined in §1412(b)(15)(A), are specified for those system size category/source water quality combinations for which there are no listed compliance technologies. Variance technologies, where they are permitted, may not achieve compliance with a particular MCL or TT requirement; however, they must achieve the maximum reduction in inactivation efficiency that is affordable, taking into consideration system size and source water quality. Variance technologies must also achieve a level of contaminant reduction that is protective of public health.

[7] EPA conducted this review in 1998, and plans to do so again in 2001.

health protection or result in a significant cost savings while at least maintaining the current level of public health protection.

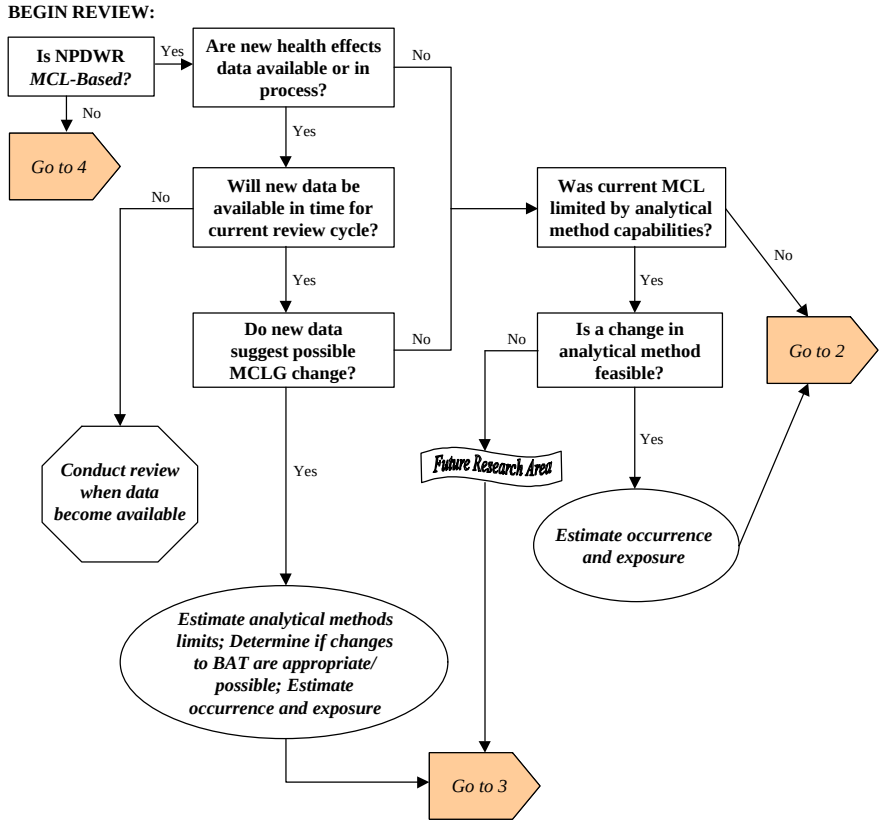
- ***Changes to other regulatory provisions:*** NPDWRs also specify requirements such as recordkeeping and reporting, what constitutes an out-of-compliance situation, and mandatory language that must be used for public notification or public education requirements. Based on actual implementation experience, and through written public comments or public meetings, the Agency may identify adjustments that warrant regulatory revision.

(7) Dropping a contaminant from regulation: In rare instances, new data may demonstrate that a contaminant does not, in fact, have adverse effects on the health of persons at levels known or likely to occur in drinking water. If such a situation should arise, EPA should consider whether it is appropriate to retain or drop the NPDWR for that contaminant. As with other regulatory revision options, dropping a contaminant from regulation would necessitate that EPA carry out the formal rulemaking process.

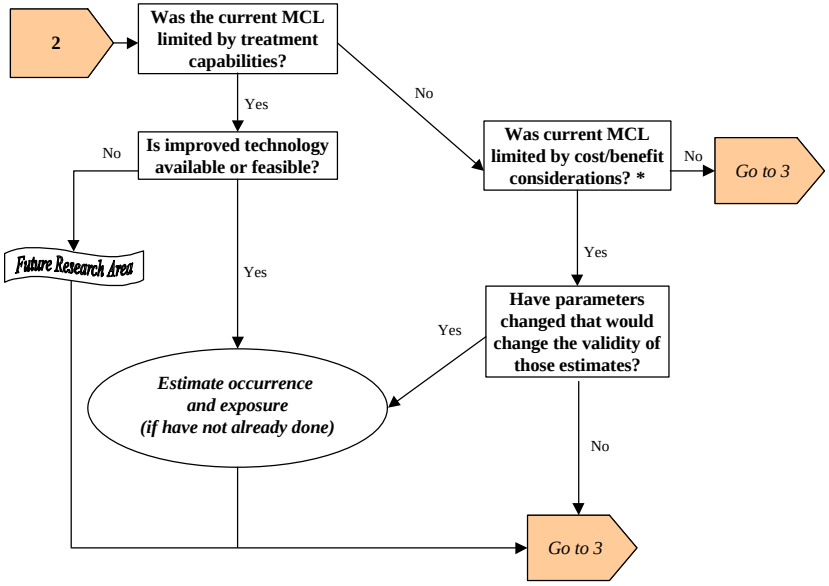
III. KEY ELEMENTS OF THE REVIEW PROCESS

This Section discusses in detail, the key information that the NDWAC recommends that EPA review to: (1) determine whether or not a rule revision is warranted, and (2) identify the need for additional research projects. More specifically, EPA should review and/or conduct health effects assessments, technology assessments, occurrence and exposure analyses, and a rough analysis of costs and benefits. The progression of the review process, and the interrelationships between the key elements of review are illustrated in the recommended decision tree, presented below in Figure 2.

Figure 2: Review Process for NPDWRs



Corresponds to Health Effects [III.A] and Analytical Methods [III.B.i]



Corresponds to Water Treatment [III.B.ii] and Occurrence and Exposure [III.C]

* This question will primarily apply to post-1996 rules.

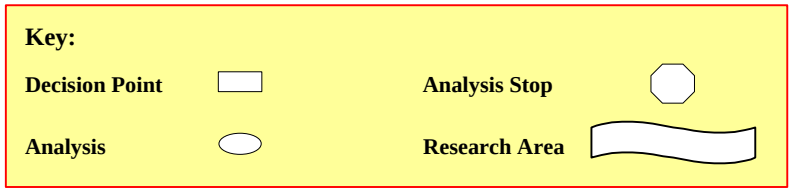
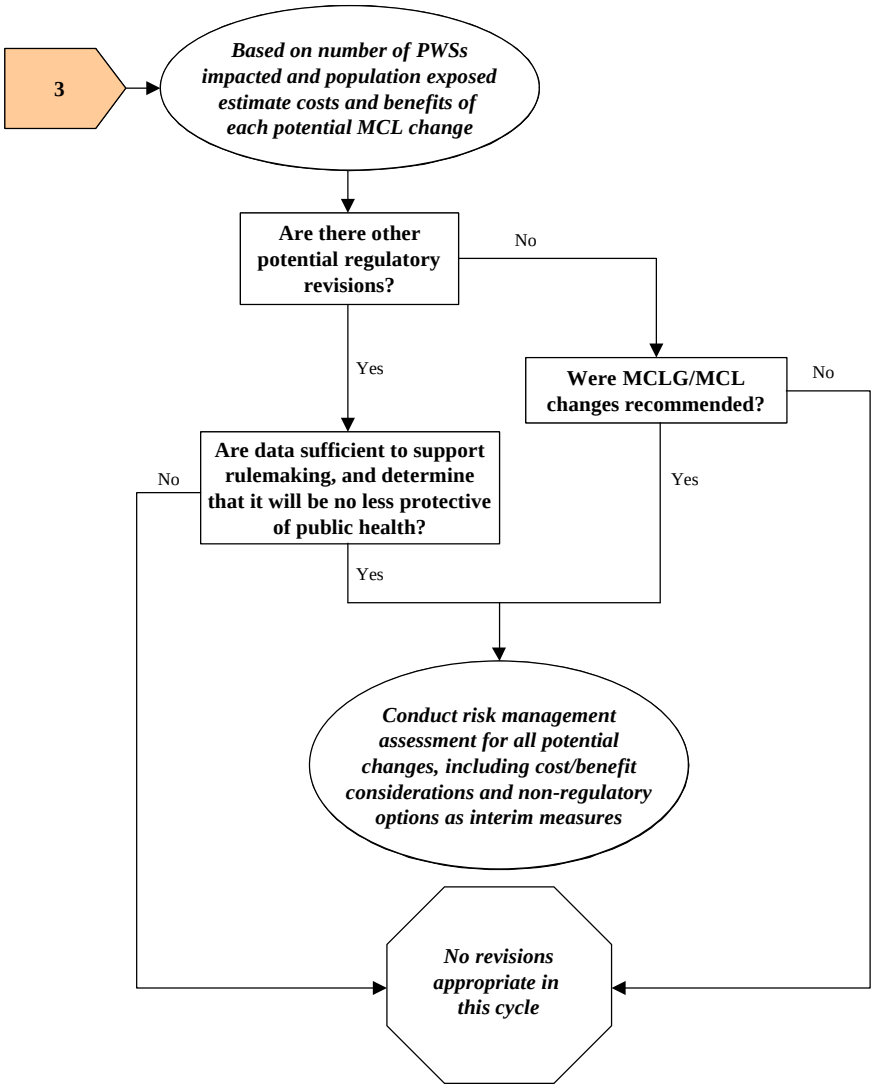
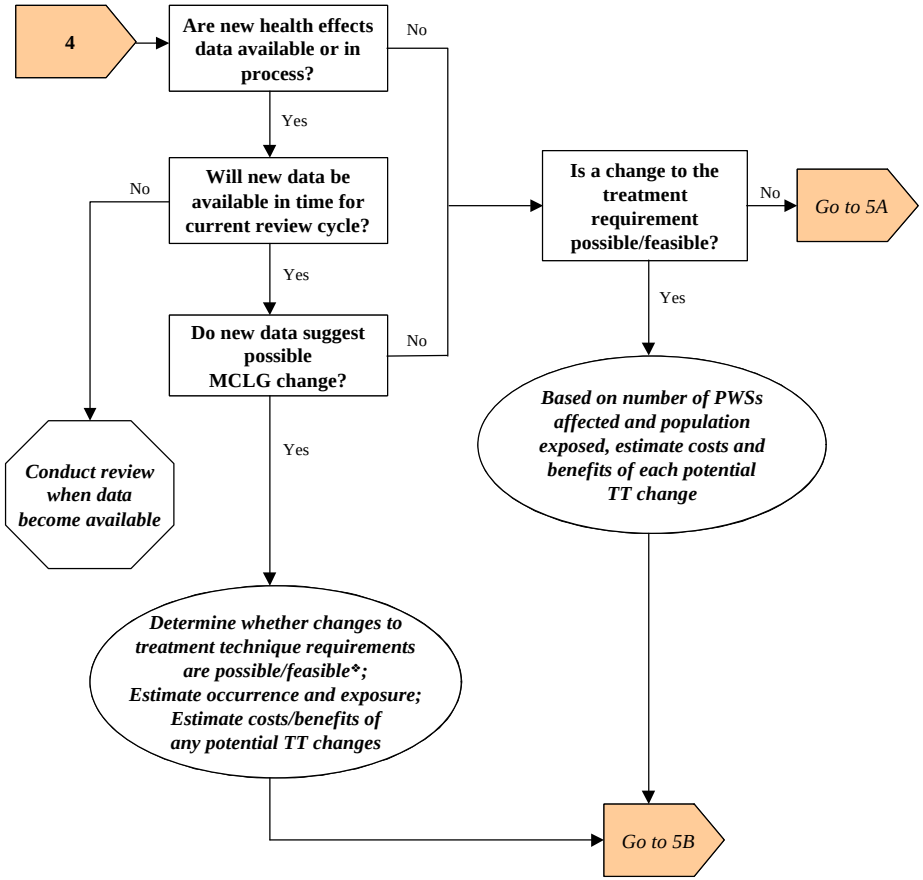


Figure 2: Review Process for NPDWRs (continued)



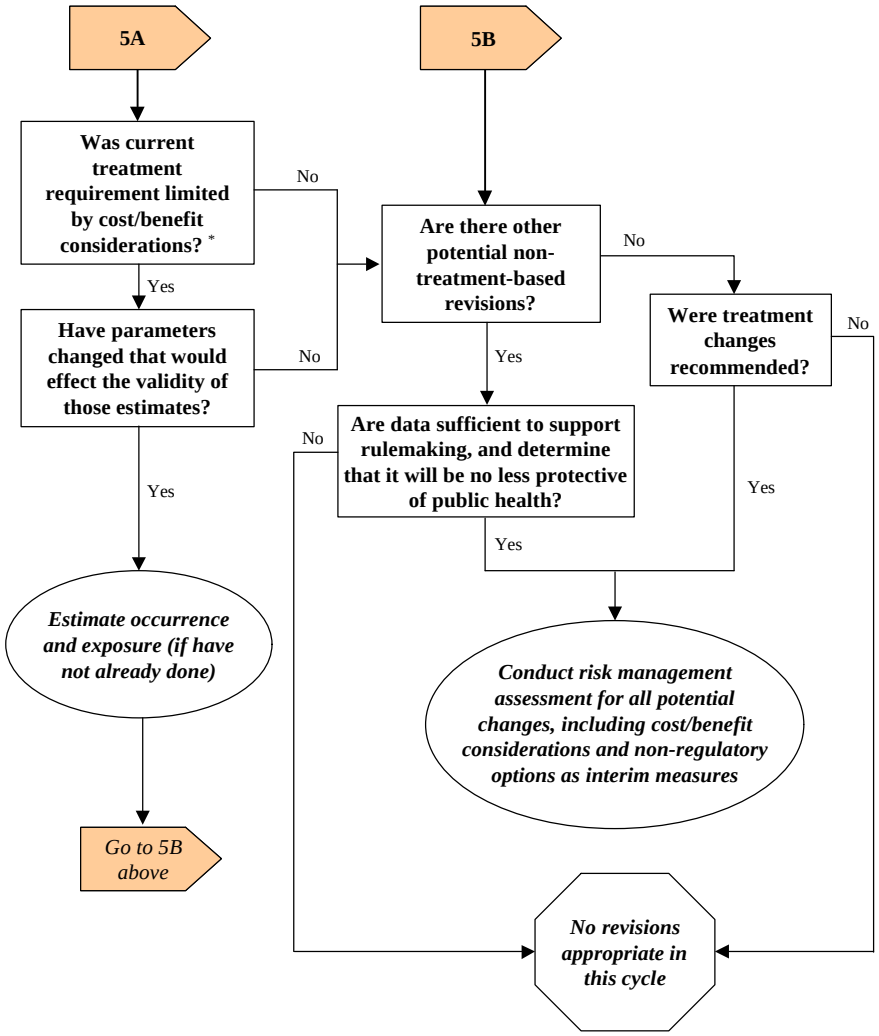
Corresponds to Cost and Benefit Considerations [III.E]



Corresponds to Treatment Technique NPDWRs: Health Effects [III.A] and Water Treatment [III.B.ii]

❖ A TT revision may be appropriate if there have been advances in treatment technology; advances in microbiological indicators; and/or information to show that the existing TT (in whole or in part) is ineffective in reducing exposure.

Figure 2: Review Process for NPDWRs (continued)



Corresponds to Treatment Technique NPDWRs: Cost and Benefit Considerations [III.E]

* This question will primarily apply to post-1996 rules.

A. Health Effects

The objectives for the examination of health effects under the six-year review are:

- To identify new health effects data for individual contaminants that could change the MCLG for the contaminant in question and affirm or change the MCL, thus, affording the same or greater protection of human health than provided by the present MCLG.
- To use existing or ongoing Agency health effects assessments in accomplishing the health effects data review.
- To ensure that the health effects data for each contaminant (with the exception of pesticides that are still in active use[8]) are reviewed at least once in every two six-year review cycles.
- To accomplish the review within the limitations imposed by Agency resources.

In order to accomplish the objectives outlined above, the review of health effects data should be accomplished as described in sub-sections *(i) - (iii)* below. The outcome of the health effects assessment should be a list of NPDWRs that are possible candidates for regulatory revisions based on changes in health considerations. The list should be combined with the lists of NPDWRs identified by other key elements of the review to develop a final list of NPDWRs that are candidates for additional evaluation.

(i) Chemical Contaminants (including disinfectants and disinfection by-products)

If there is evidence that a chemical is mutagenic and may cause cancer, and there is no dose below which the chemical is considered safe, the MCLG is set at zero. In these instances, according to EPA policy, the MCL is based on technology (analytical methods/treatment) rather than health effects. In these instances, health effects data have little impact on the MCL. If a chemical is carcinogenic and acts by a well documented, nonmutagenic mode of action, the MCLG may be set at a level above zero according to emerging Agency policy. This may provide regulatory options for some carcinogens that were not available at the time of regulation.

For non-carcinogenic chemicals, the MCLG is based on an oral RfD. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. A change in an Agency RfD for a chemical could accordingly lead to a change in an MCLG and MCL. In deriving the MCLG for a non-carcinogen, the Agency applies a Relative Source Contribution (RSC) factor to allocate a restricted portion of the total allowable exposure to drinking water. The RSC is one factor which will determine whether or not a change in RfD will lead to a change in the MCLG/MCL.

[8] The health effects for these contaminants are re-assessed no less frequently than every 15 years. Within EPA, health effects assessments for pesticides are conducted by the OPP under authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A goal of FIFRA is that EPA review each pesticide's registration every 15 years. Under some circumstances, a pesticide's health effects may be re-assessed more frequently.

In the past, it has been the Agency policy to apply a risk management factor to the RfD for chemicals with equivocal data on carcinogenicity. This policy is a second factor that must be evaluated to determine the impact of a change in RfD on the MCLG/MCL for a noncarcinogen.

Against the background described above, the six-year review of chemical health effects should be accomplished using the following screening steps. The following does not imply that analyses should be done in a specified order. Analyses should proceed based upon availability of appropriate data.

Step I

Recent health effects reviews for chemical contaminants completed under the following programs should be examined. Where possible, an oral RfD or comparable value should be derived and a carcinogen assessment from oral exposure should be conducted during these reviews.

- EPA Integrated Risk Information System (IRIS) (see Appendix 6)
- Office of Pesticide Programs (OPP) registration (see Appendix 7)
- Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles
- National Academy of Sciences (NAS) Assessments

In cases where there has been a change in the critical effect, or the dose-response pattern for a regulated contaminant, and where that change could result in a change in the MCLG and MCL, that contaminant will be selected as a candidate for possible regulatory revision.

Step II

The 1996 revisions to SDWA mandate consideration of special subpopulations during the regulation development process.[9] As a reflection of that mandate, the Agency is performing focused assessment of the risks to the fetus, infants and children during the development of new regulations. For some regulated contaminants, particularly those regulated prior to 1990, the data for developmental and reproductive effects were limited. Accordingly, the Agency should conduct a literature search for peer-reviewed papers published over a period from five years prior to regulation to the present, to determine if there are new data which identify a developmental or reproductive effect as the critical effect from exposure or if the data for developmental or reproductive effects are inadequate to support an assessment of this endpoint. Any contaminant for which developmental or reproductive effects now appear to be the critical effect, or where there was no consideration of development or reproductive data gaps during the regulatory risk assessment, should be considered as a candidate for possible regulatory revision.

[9] The Food Quality Protection Act (FQPA), which amended FIFRA in 1996, also requires the consideration of special subpopulations in the risk assessment. This requirement has been met for most pesticides for which there is an NPDWR, and OPP is scheduled to have met the requirement for all pesticides currently registered, by 2006.

Pesticides that are still in use will be reviewed using a different process.[10] As a condition of registration and/or re-registration, the pesticide program requires the submission of reproduction and developmental toxicity studies for most pesticides. OPP also uses open literature data for weight of evidence when determining a developmental or reproductive effect. Once a pesticide that is being considered for regulatory revision is determined to have a developmental or reproductive effect, OPP, through agreements under the Office of Water (OW)/OPP Coordinating Steering Committee, will provide health effects data to OW's various programs for decision making.

Step III

Some regulated chemicals (including disinfectants and disinfection by-products) may not have been the subject of recent health effects assessment under the programs identified above and may not have developmental or reproductive effects as their critical effect or as a data gap. The reviews for these contaminants should be prioritized as follows.

1. In cases where an IRIS or OPP review has been, or will be, initiated during the review period, the six-year review should be deferred until the completion of the IRIS/OPP review. This may move some of the contaminants to the next six-year cycle (see Assumption 3 in Section II.B.(i)).

2. A literature search for new data should be executed for all chemicals (other than pesticides that still are in active use) that have not been either selected or removed from consideration in Screening Steps I and II, and are not the topics of an IRIS or OPP review-in-process. If the literature search indicates that there is a change in either the critical effect of dose-response characteristics that could result in a change in the MCLG and MCL, that contaminant will be nominated for an IRIS review by OW. This may move some of the contaminants to the next six-year cycle.

Once the final list of NPDWRs requiring review is established, EPA should assess the health effects data that "triggered" any change in RfD, cancer classification, or cancer slope factor. As required by the 1996 SDWA amendments, EPA will continue its program of studies to identify special subpopulations that may be at greater risk than the general population to adverse health effects from exposure to contaminants in drinking water. The health data should be integrated with available RSC and risk management (policy) adjustments for possible carcinogenicity used in the original EPA assessment to determine if the revised health

[10] As noted above, FIFRA has a goal that each pesticide be reviewed every 15 years. In addition, FIFRA has provision to permit the evaluation of a registration through various conditions such as the submission of additional data, at which time EPA would re-evaluate the toxicity and risk. Finally, the Administrator can initiate a Special Review of any pesticide that may pose an unreasonable risk to humans or the environment. This request may be initiated by the Administrator or at the suggestion of any interested party. Therefore, a pesticide that would appear to be an unlikely candidate during a current six-year review cycle, because its review is not imminent under the 15-year FIFRA review goal, could in fact be a candidate because of one or more special conditions.

assessment is likely to alter the present MCLG.[11] Where necessary, and with an adequate allotment of time within the six-year review process, new studies published after the RfD or cancer change should be reviewed for their impact on the MCLG.

(ii) Radiological Contaminants[12]

Reviews for radiological contaminants should be treated differently than reviews for chemical contaminants. This is because sources of scientific data, and the reviews by US and international agencies, which are used in developing EPA risk coefficients are different than are used for chemicals, as described in Section A.(i) above. A brief summary of radiation health effects reviews is provided below: this guidance should reflect the fact that EPA has a program and mechanisms in place to utilize these radiation assessments. These help EPA incorporate peer-reviewed scientific data into the Agency risk coefficients used in its analyses. When such risk coefficients and analyses change, this would by necessity lead the Agency to a review of the affected drinking water standard. Therefore, this guidance incorporates the analyses that are described below.

All radiological contaminants can be addressed at the same time, since all emit ionizing radiation. There is a constant influx of papers on ionizing radiation and on radionuclides, addressing exposures, dose-response relationships, types of effects, etc. There are also periodic reviews of new information by international groups, such as the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the International Commission on Radiation Protection (ICRP), national groups such as National Committee on Radiation Protection (NCRP) and National Radiation Protection Board (NRPB), and others. When there has been enough new information, the Agency has tasked the NAS to provide a review of new data and develop models to estimate numeric risk of radiation exposure. The Agency then uses the new information and models to develop the models the Agency will use in risk assessments involving exposure to ionizing radiation or radionuclides.

Within EPA, the Office of Radiation and Indoor Air (ORIA) is responsible for assessing the health risks for radioactive contaminants (radionuclides) in the environment. ORIA has initiated major re-assessments approximately every 10 years, depending on the availability of new data and resources. After these re-assessments, the estimated risk per unit intake of radionuclides is revised.

Ionizing radiation is a known human carcinogen. Since all emit ionizing radiation, all radiological contaminants are classified as human carcinogens. Consistent with the SDWA,

[11] Risk assessment options could include NOAEL/LOAEL approach, benchmark dose approach, categorical regression approach, linear multistage approach, point of departure approach, and mode of action approach. The nature of the effects and the characteristics of the data are used in determining which approach is best for a particular data set.

[12] Radiological contaminants that are regulated, or proposed to be regulated, in drinking water, as of November 2000 include the following categories: radium-226 and radium-228 (combined), gross alpha particle radioactivity, man-made beta particle and photon radioactivity, uranium, and radon.

MCLGs for known or probable carcinogens are typically set at zero because it is assumed, in the absence of conclusive data to the contrary, that there is no "safe" level of exposure.

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

In assessing health risks for radionuclides other than radon, EPA relies primarily on data and models presented in reports from the Federal Radiation Council (FRC); the National Academy of Science Committee on the Biological Effects of Ionizing Radiation (BEIR); the UNSCEAR; the ICRP; and published, peer-reviewed epidemiological and animal studies.

In assessing health risks for radon, EPA relies primarily on data and models presented in reports from BEIR, the U.S. Department of Health and Human Services, and the World Health Organization's International Agency for Research on Cancer (IARC).

(iii) Microbial Pathogens

The MCLG is set at zero for any regulated organism that has caused, or has the potential of causing, a waterborne disease outbreak, since a probability exists that low doses may cause infection in some percentage of special subpopulations. To control the pathogen, EPA either sets a TT requirement or an MCL for an easily and reliably measured surrogate (e.g., total coliforms). If human infectious dose data are available, they will be used to review the level of treatment needed and the associated risk of exposure and disease.

(iv) Review of Standards and Guidelines of Other Organizations

EPA plans to include in its review of NPDWRs an update of standards and guidelines of other organizations, such as the World Health Organization, the European Union and others. Where any difference in health standards or goals is found to exist, EPA plans to, where possible, determine the rationale for that difference. While some differences may clearly be matters of policy, others may be science- (or technology-) based, and therefore require further analysis.

To best assess the health effects of a contaminant, scientifically valid studies must be conducted and/or reviewed from the peer-reviewed literature. Some areas of general research for

health effects are listed in Appendix 3. The list is not exhaustive, but studies in those areas may provide the necessary information to best assess risk.

B. Technology Assessment

The SDWA generally requires that MCLs be set as close to the MCLG as is feasible. When determining feasibility, factors that the Agency considers are: the cost and ability of the analytical and treatment methods; and, the availability of these technologies. In some cases, particularly when the Agency sets a zero MCLG, EPA establishes the MCL based on the limitations of analytical methods or treatment. Where these constraints apply to the current MCL, EPA should assess whether changes in approved methods and/or the availability of new treatment technologies would support a lower MCL.

(i) Analytical Methods

As described in Appendix 8, EPA already has a program in place to approve new analytical methods for drinking water contaminants. The review and approval of potential new methods, therefore, is outside the scope of the six-year review. In those instances where the MCL has been established based on analytical capability limitations and/or the health effects analysis suggests that the MCLG/MCL should be lowered, EPA should review the existing approved methods for the contaminant to determine whether the currently approved methods provide sufficient analytical capability to reliably measure the contaminant at levels lower than the current MCL. If it appears that the currently approved method capabilities are the limiting factor for revising an MCL, EPA should include a request in the *Federal Register* for potential new and/or improved methods which are technologically and economically feasible to address a lower level of quantitation. It should be noted that before a method can be used as a basis for revision of an MCL, however, the method must be approved, affordable, and be in general use with sufficient laboratory capacity existing. Therefore, it is unlikely that any method submitted in response to the *Federal Register* notice would be used to revise an MCL in the same review cycle in which the method was submitted.

(a) Chemical Contaminants

OGWDW uses the Practical Quantitation Level (PQL) to estimate the level at which laboratories can routinely measure a chemical contaminant in drinking water. The process for setting the PQL is presented in Appendix 8. Historically, OGWDW has used two main approaches to determine a PQL for SDWA analytes. The preferred approach uses data from Water Supply (WS) studies (which have mainly been used to certify drinking water laboratories). In most cases, OGWDW uses the WS method when sufficient WS data are available to calculate a PQL. In the absence of sufficient WS data, OGWDW uses the multiplier method, in which the PQL is calculated by multiplying the EPA-derived method detection limit (MDL) by a factor of 5 or 10. Because analytical methods may have been updated and/or measurement capabilities by laboratories may have improved since an MCL was promulgated/last revised, EPA should re-evaluate the PQLs for some regulated contaminants.

The analytical capabilities should be reviewed for contaminants which are: (1) not undergoing a health effects review, but the MCL was previously set at the lower level of quantitation level (or PQL); and (2) undergoing a health effects review and the potential new MCLG is less than the current MCL. Initially the re-evaluation process should identify the contaminants (not undergoing a health effects review), whose MCL was limited by the measurement capabilities (i.e., where the MCL was set at the PQL). EPA should compare the analytical method capabilities that were available at the time the MCL was set to currently approved analytical methods. This method comparison should delineate if improvements in measurement capabilities have occurred (this could be an indication that the PQL may have changed). In addition and if necessary, EPA should use more recent WS studies to determine if the PQL may have changed. For contaminants undergoing health effects review (where a potentially new MCLG is less than the current MCL), the Agency also should use the method comparison and WS analysis approaches to assess the limits of our analytical capabilities. The method comparisons and the analysis of WS data should be used to identify contaminants that need further PQL assessment. The purpose of this analysis is to determine whether the analytical method capabilities would support a lower MCL.

(b) Radiological Contaminants

Appendix 8.G describes the process EPA has used in the past to assess analytical feasibility for radiological contaminants. Historically, the determination of measurement feasibility for radionuclides has not relied on a PQL convention as is used with chemical analytes. Instead, measurement reliability was computed using the grand average of the means and reproducibility (total error) of the study population of laboratories that participated in Radiochemical Performance Evaluation (PE) studies. The distribution of laboratory averages (around the known value) reflected both random uncertainty and bias introduced by a laboratory. This distribution around the known value (or reproducibility) represented an empirical measure of the reliability or feasibility of laboratories to measure a nuclide, all factors considered. The goal of determining the reproducibility for the population of laboratories was to provide an upper limit on accuracy for any laboratory result provided by a certified laboratory and is not obtainable except by multiple laboratory testing.

Although the feasibility of measurement for radionuclides in drinking water will not be assessed under the current six-year process, EPA plans to include them as part of future six-year reviews. In reviewing measurement feasibility for these future reviews, the first step should be to assess if new radiochemical methodologies or method modifications have been approved which could potentially lower the measurement feasibility. Because the PE program has been externalized, the Agency should determine the means to assess the multiple laboratory data as needed for the determination of measurement feasibility for the various program needs. Before the next six-year review, the Agency should detail a more specific process to determine measurement feasibility for radionuclides on a large scale.

(c) Microbiological Contaminants

For microbes, EPA does not have, or currently envision, a routine pathogen monitoring requirement, but rather employs indicators of water quality (e.g., total coliforms, *E. coli*). PQLs

have not been used for microbial indicators because, for approval, the method must be able to detect a single cell (i.e., MDL and PQL must both be one cell) in a 100 ml water sample. In addition, the false-positive and false-negative (i.e., recovery) rates must be reasonable. EPA is considering whether to define "reasonable" in numerical terms.

Occasionally, EPA may require limited quantitative pathogen monitoring in source water (e.g., *Cryptosporidium*). In such a case, it may be possible to determine a method's MDL and PQL, because the best available methods may not be sensitive enough to detect a single cell. However, EPA normally uses MDLs and PQLs to set an MCL. Because the Agency does not set MCLs for pathogens in the source water, it might be inappropriate to set MDLs and PQLs for this purpose. It may be appropriate to determine an MDL and PQL for some required non-microbial measurements associated with microbial water quality such as turbidity, disinfection residual and algal microcystins.[13]

(ii) Treatment Technologies

As discussed previously, an NPDWR either identifies the BAT for meeting the MCL (even though BAT is not required for compliance purposes), or establishes enforceable TT requirements. In those instances where lowering an MCL for a contaminant may be warranted, based on improved analytical method capabilities or health effects data that support lowering an MCLG, EPA should review the BAT for that contaminant. In some cases, EPA may also consider revisions that clarify existing BAT and/or TT requirements where existing requirements are confusing or incorrectly specified.

If new information requires EPA consideration of a more stringent regulated level, to a point that an MCL would no longer be feasible, the SDWA requires that EPA set a TT requirement for that contaminant.

For the treatment analysis, EPA plans to utilize the same sources that have been the primary resources in development of EPA regulations and guidance. These include EPA's treatment technologies and cost reports, peer review journals, and other technology sources, including information received from stakeholders.

EPA plans to include in its review of NPDWRs, any updates of standards and guidelines of other parties, such as the World Health Organization, the European Union and others. Where any difference in technology-related standards or goals are found to exist, EPA plans to, where possible, determine the rationale for that difference. While some differences may clearly be matters of policy, others may be science- (or technology-) based and therefore require further analysis.

[13] However, it is not clear whether the process, as described in Appendix 8, for setting the PQL for chemicals is applicable to microorganisms or related parameters. In principle, the process for setting PQLs for microorganisms should be similar to that of chemicals. However methods for determining microbial density suffer greatly from inherent problems associated with the organisms. These include, but are not limited to, the level of injury, uneven distribution of the organism in the environment, the ability to selectively isolate the target microorganism, the lack of method precision, and the difficulty to determine infectivity and/or disease causation.

Research in the area of technology assessment should focus on areas of water treatment and analytical methodologies. Scientifically valid studies should be conducted and/or reviewed from the peer-reviewed literature. Some areas of general research for technology assessment are listed below in Appendix 3. The list is meant as a guide to begin research into those areas that may best provide protection for public health. Studies in these areas may provide the necessary information to best assess occurrence and possibly to control the contaminant.

C. Occurrence and Exposure Analysis

The goal of the occurrence and exposure analysis during the review process is to generally quantify the extent of regulated contaminant occurrence and human exposure levels. Results of this analysis include estimated numbers of PWSs and populations impacted by a contaminant in water. For some microbes, this may not be the case. Combined with results of the other technical analyses described in this Section (e.g., health effects related to contaminant exposure) these results will be used to help determine which revisions are most likely to provide the greatest public benefit. In some cases, these results may also be used as a factor when recalculating relative source contributions (RSCs).[14] EPA plans to perform further, in-depth, occurrence and exposure analysis prior to any proposed revision to an NPDWR.

This guidance document Section describes the occurrence and exposure analytical processes that are more specific to the first round of review, i.e., that which is to be completed by 2002. EPA expects to make refinements to this review in subsequent rounds as more data become available and as the methodology evolves. Thus, the guidance mentions future reviews but does not contain a detailed description of how these reviews will be conducted.

For the chemicals to be reviewed in the first round of review, Appendix 4 describes: (1) the current analyses of State regulated contaminant data sets; (2) the development of a nationally representative sample, including analysis and ranking of States' pollution potential and geographic diversity; (3) the resultant 8 'cross-section States'; (4) the potential addition of State data sets based primarily on data availability, pollution potential ranking, and geographic representation; (5) the limitations of these data; and, (6) alternative approaches to producing a national occurrence estimate. The alternatives described are founded on methodologies utilized in 1999 for the analysis of occurrence of regulated chemical contaminants, and in 2000 of arsenic in public water supplies. Some pros and cons of the 1999 analysis and the recent arsenic analysis are mentioned, as is the general problem of uncertainties of extrapolation of results from a limited database to a national estimate. EPA plans to use the analyses as described and additional analyses as appropriate. However, the above noted analysis of chemical contaminant occurrence in public water supplies, which was peer reviewed in 1999, is considered the basis for the first six-year review occurrence analysis.

[14] While occurrence and exposure estimates factor into the derivation of an RSC a much more important factor is exposure information for other media (air, food, etc.) relative to that for water. Exposure information for other media will be assessed as a part of the health effects assessment described in Section III.A. of this document, and not as a part of the occurrence and exposure assessment described in this section. For most contaminants, (e.g., those with zero MCLGs and those where the RSC was set by default at the 20% floor), recalculation of the RSC may not be necessary.

Ambient water data, if available, may supply the Agency with a correlation to drinking water systems' finished water levels. This may be of some value in providing a raw/finished water comparison, indicative of water treatment effectiveness in removing contamination from water.

Future review cycles should benefit from the statutorily required National Drinking Water Contaminant Occurrence Database (NCOD). In addition to this, EPA maintains other data systems containing information on microbial contaminants and disinfection/disinfection by-products (D/DBPs). The NCOD, its current limitations, and other data systems are described more fully in Appendix 4.

In addition, EPA continues to assess methods for extrapolating quality data sets to assess national-scale, contaminant levels for use in the regulatory program. Thus, the current guidance cannot establish a sole methodology for estimating national occurrence/exposure, since methods are expected to evolve during the early years of the six-year NPDWR review program.

Where cost and benefit considerations were major factors in setting MCLs, EPA should assess if occurrence and exposure are substantially different from what was assumed during the original rulemaking. A revision to the NPDWR should be considered if new occurrence and exposure estimates show that public health is affected to a greater degree than EPA had anticipated in the original cost and benefit analysis.

Research to date in the occurrence and exposure area has been limited. The problem being, not so much that the contaminants have not been found, but that there has not been a concise study of these contaminants nationally, at levels related to the MCL. In research, the issue has often been the accuracy of the testing method, rather than an issue of actual occurrence.

As noted in this guidance, State agencies often supply data on contaminant occurrence which is of some value to EPA. In addition, United States Geological Survey (USGS) source water testing may be one of the most valuable sources of occurrence data from untreated water, especially when it provides accurate temporal data. Related to this, some areas that would benefit from future research are listed in Appendix 3.

D. Consideration of Other Regulatory Revisions

In addition to possible revisions to MCLGs, MCLs, and treatment techniques, EPA should also consider other regulatory revisions not related to these requirements, (such as monitoring, or reporting requirements), and should consider options that may lead to non-regulatory revisions, (such as source water protection and others, as outlined in Appendix 5). These options should be considered independently, and in addition to, possible MCLG, MCL, or TT revisions. If new information is available that may demonstrate the effectiveness of a non-MCL, non-MCLG, or non-TT approach in improving public health protection with respect to a contaminant or group of contaminants, then this information should be included in the risk management assessment. These options could be especially important if the costs of other regulatory compliance are considered to be too high, or if interim measures are needed pending promulgation of a rule. As with other aspects of the six-year review, input from stakeholders should be sought regarding these potential

changes. Within the constraints of the SDWA, EPA strive to create an integrated package of drinking water regulations that complement each other. EPA should also consider simplifying rules to reduce the regulatory burden on States and water suppliers if such simplification can be shown to be equally protective of public health.

Changes to monitoring requirements: As part of an NPDWR, EPA establishes monitoring requirements, including the frequency and location of sampling. EPA should consider possible revisions to monitoring requirements as a part of the six-year review in those situations where such revisions are likely to significantly improve the level of public health protection or result in a significant cost savings while at least maintaining the current level of public health protection. Monitoring revisions may include (but are not limited to) changes in one or more of the following: frequency of monitoring; timing of sample collection; sample site location; or sample volume. In some situations, monitoring changes may affect an entire class of contaminants (e.g., all SOCs); in other cases, adjustments to the monitoring requirements for individual contaminants may be appropriate. As a part of evaluating potential monitoring revisions, the Agency proposes to perform in-depth statistical testing, to determine the probability that the potential modification would best capture and not bias representation of contaminant occurrence in water.

Occurrence data from both finished drinking water (such as EPA's recent report on drinking water contaminants in finished water) and from source water (such as USGS' National Water Quality Assessment Program (NAWQA) data) show that many contaminants, especially pesticides, have strong seasonal trends in occurrence. It may be more appropriate to require monthly sampling for some of these compounds during the season of greatest use, and little or no sampling during the rest of the year. Occurrence data can also be used to demonstrate a lack of vulnerability of certain intakes to certain contaminants, and this information can be useful in granting monitoring waivers.

Changes in data reporting requirements: NPDWRs also specify requirements, such as recordkeeping and reporting, to EPA and to the public. States, which are EPA's partners in ensuring safe drinking water, are willing to submit necessary data elements to meet this need, but EPA data reporting requirements may go beyond State capabilities. Some of the required data elements may not be necessary, and based on past experience, may not even be used by the Agency. We recommend that EPA with assistance from States and other stakeholders evaluate what data are the minimum data elements that must be reported in order to safeguard public health. Data management should be considered at the time of rule development, not after the rule is adopted. An implementation plan should be developed at the same time that the rule is drafted, so States and public water systems (PWSs) can see the impact of the proposed rule.

Multi-media mitigation: Opportunities exist for improving public health by regulating exposure to drinking water contaminants that also occur in other media. One example is the radon program, where PWSs are to be involved in promoting changes in building codes in order to have new homes constructed with radon venting.

Contaminant reduction can be achieved through other environmental programs that regulate use, storage, or transfer of the contaminant. Examples include the air/water cooperative program for radon, the recent policy memo of Charles Fox, EPA Assistant Administrator, to achieve reduction of waterborne pathogens through cooperative efforts of wastewater and drinking water programs, and the pesticide registration and regulatory program.

Some possible areas of research into other regulatory revisions (e.g., non-MCL/TT, and non-MCLG regulations) are listed in Appendix 3. The list is meant as a guide to begin research into those areas that may best provide protection for public health.

E. Cost and Benefit Considerations

(i) Cost and Benefit Assumptions of Current NPDWR

In some instances for NPDWRs promulgated after August 1996, cost and benefit considerations may have been a factor in setting the regulatory requirements. For these "post-1996" NPDWRs, if other technical assessments described in this guidance do not identify an additional need to revisit an NPDWR, then EPA should review the cost and benefit assumptions of the current NPDWR to determine whether they still are valid. If the original assumptions no longer are valid in light of more current data, EPA should assess whether changes to the regulatory requirements might be appropriate as a result of adjustments to the assumptions. These NPDWRs will be identified as candidates for possible regulatory revision.

(ii) Cost and Benefit Estimation of Potential Regulatory Revisions

Analyses of costs and benefits may play a role in risk management decisions associated with an NPDWR review. However, it is not anticipated that the level of analysis will be comparable to that cost and benefit studies that must accompany a formal regulation development process.

Where possible, the Agency should first develop a qualitative listing of potential costs and benefits associated with a proposed revision. Where data such as occurrence and exposure information are available, the Agency should develop associated quantitative, albeit possibly preliminary, estimates of costs and benefits. 'Major' items such as health effects averted (monetized where feasible), and construction and installation of treatment facilities should be estimated. Quantification would depend upon the availability of national health, chemical occurrence, exposure and cost data.

At a minimum, EPA's cost assessment should include consideration of cost for treatment associated with the MCLs being considered, including: capital costs, operation and maintenance costs, monitoring costs, and administrative costs (both to the water supplier and the State and Federal agencies).

Where possible and appropriate, EPA's benefit assessment should include, but not be limited to, an estimate of the number of illnesses and/or diseases prevented by reducing the MCL or improving the TT. The assessment should include discussion of the following:

- Infants, children, the elderly and immunocompromised, and any other known sensitive subpopulations;
- Reductions in adverse, synergistic health effects caused by a contaminant of concern existing in combination with other co-occurring contaminants;
- Illness or disease prevented by the simultaneous reductions of levels in other regulated contaminants by treatment process(es) necessary to control the contaminant of concern; and
- Reductions in adverse health effects caused by an accompanying reduction of a contaminant's degradation products co-existing with the contaminant.

Other "benefits" that be considered are any expected reductions to monitoring and administrative costs (both to water suppliers and State agencies) that are associated with the regulatory changes that are being considered.

During the regulatory review period, there may be uncertainty regarding actual targets, (i.e., to what level an MCL or MCLG may later be proposed), pending additional technical review. If it is known that a regulatory level may change, although to an unknown level, costs and benefits should be estimated, or listed, for a series of possible levels, for consideration in the decision-making process.

STAKEHOLDER INVOLVEMENT

A. Key Stakeholders

EPA plans extensive opportunity for stakeholder involvement in the six-year review process. Key stakeholders include (but are not limited to) members of the following:

- The general public
- Members of Congress
- Other Federal agencies
- State, Tribal, and local officials
- Public Health/Health Care Providers
- Manufacturers
- Public interest groups
- Public water suppliers
- National trade associations
- Other EPA offices
- Environmental groups
- Agricultural Producers

B. Stakeholder Meetings

For the first review cycle, EPA plans to hold three stakeholder meetings during the review process. The purpose of each meeting will be to inform stakeholders of the Agency's progress and to solicit additional input and advice. The general topics to be covered at each of the meeting is as follows:

- *First Meeting:* the NPDWRs to be included in the review; the general analytical approach to be utilized; and the primary data sources for the review round.

- *Second Meeting:* the guidance recommended by NDWAC; the preliminary results of analysis to date; and EPA's preliminary selection of NPDWRs for revision.

- *Third Meeting:* follow-up comments to the ANPRM.

During subsequent review cycles, EPA plans to hold two stakeholder meetings prior to proposing any NPDWR revisions. The purpose of the first meeting will be to discuss the NPDWRs to be included in the review and any refinements to the Six-Year Review Guidance that may be appropriate (e.g., adjustments to general analytical approach and/or primary data sources). The second meeting will discuss the preliminary results of analysis to date and EPA's preliminary selection of NPDWRs for revisions. If appropriate, EPA also may hold a third stakeholder meeting following proposal of revisions to discuss public comments received in response to the proposal.

If EPA has available travel funds, the Agency will try to hold at least one of these meetings in a location other than the East Coast.

C. Other Stakeholder Outreach

In addition to the stakeholder meetings, EPA intends to keep stakeholders informed and involved through the following mechanisms.

- Participation in national meetings, workshops, technical forums.
- Informal meetings with groups and association and individual discussions with technical experts at least once a year. In some cases, EPA may benefit from such discussions in terms of gaining greater awareness of specific issues, and/or direct transfer of applicable data from stakeholders or other public entities.
- Information posted on the OGWDW web page. Issue papers, dates and locations of public meetings, summaries of stakeholder meetings, summaries of informal meetings, etc., will be placed on the web page. This information will be updated periodically.
- *Federal Register* Notices pertaining to the six-year review.
- Supporting documents explaining the Agency's rationale and approach to the regulatory review and decision-making process. The Agency will request input through the peer review process.

APPENDICES

Appendix 1: Contaminants Regulated Prior to August 1996

Note: The purpose of this table is to indicate those NPDWRs which will be reviewed under the initial six-year review period that ends August 2002.

Contaminant	Pre 8/96 Rule	Within Scope of 1st Review Cycle	Reason for Not Including
Inorganic Chemicals			
Antimony	Phase V Rule	Yes	
Arsenic	Pre 1986 NIPDWR	No	Subject of ongoing rulemaking activity
Asbestos	Phase II Rule	Yes	
Barium	Phase IIB Rule	Yes	
Beryllium	Phase V Rule	Yes	
Cadmium	Phase II Rule	Yes	
Chromium	Phase II Rule	Yes	
Copper	Lead and Copper Rule (LCR)	No	Reviewed March 2000
Cyanide	Phase V Rule	Yes	
Fluoride	Phase II Rule	Yes	
Lead	LCR	Yes	
Inorganic Mercury	Phase II Rule	Yes	
Nitrate (as N)	Phase II Rule	Yes	
Nitrite (as N)	Phase II Rule	Yes	
Selenium	Phase II Rule	Yes	
Thallium	Phase V Rule	Yes	
Organic Chemicals			
Acrylamide	Phase II Rule	Yes	
Alachlor	Phase II Rule	Yes	
Atrazine	Phase II Rule	No	Subject of ongoing review
Benzene	VOC Rule	Yes	
Benzo(a)pyrene	Phase V Rule	Yes	
Carbofuran	Phase II Rule	Yes	
Carbon Tetrachloride	Phase II Rule	Yes	
Chlordane	Phase II Rule	Yes	
2,4-D	Phase II Rule	Yes	
Dalapon	Phase V Rule	Yes	

Contaminant	Pre 8/96 Rule	Within Scope of 1st Review Cycle	Reason for Not Including
1,2-Dibromo-3-chloropropane (DBCP)	Phase II Rule	Yes	
o-Dichlorobenzene	Phase II Rule	Yes	
p-Dichlorobenzene	VOC Rule	Yes	
1,2-Dichloroethane	VOC Rule	Yes	
1,1-Dichloroethylene	VOC Rule	Yes	
Cis-1,2-Dichloroethylene	Phase II Rule	Yes	
trans-1,2-Dichloroethylene	Phase II Rule	Yes	
Dichloromethane	Phase V Rule	Yes	
1,2-Dichloropropane	Phase II Rule	Yes	
Di(2-ethylhexyl)adipate	Phase V Rule	Yes	
Di(2-ethylhexyl)phthalate	Phase II Rule	Yes	
Dinoseb	Phase V Rule	Yes	
Dioxin (2,3,7,8-TCDD)	Phase V Rule	Yes	
Diquat	Phase V Rule	Yes	
Endothall	Phase V Rule	Yes	
Endrin	Phase V Rule	Yes	
Epichlorohydrin	Phase II Rule	Yes	
Ethylbenzene	Phase II Rule	Yes	
Ethylene Dibromide	Phase II Rule	Yes	
Glyphosate	Phase V Rule	Yes	
Heptachlor	Phase II Rule	Yes	
Heptachlor epoxide	Phase II Rule	Yes	
Hexachlorobenzene	Phase V Rule	Yes	
Hexachlorocyclopentadiene	Phase V Rule	Yes	
Lindane	Phase II Rule	Yes	
Methoxychlor	Phase II Rule	Yes	
Monochlorobenzene	Phase II Rule	Yes	
Oxamyl (Vydate)	Phase V Rule	Yes	
Polychlorinated biphenyls (PCBs)	Phase II Rule	Yes	
Pentachlorophenol	Phase IIB Rule	Yes	
Picloram	Phase V Rule	Yes	
Simazine	Phase V Rule	Yes	
Styrene	Phase II Rule	Yes	

Contaminant	Pre 8/96 Rule	Within Scope of 1st Review Cycle	Reason for Not Including
Tetrachloroethylene	Phase II Rule	Yes	
Toluene	Phase II Rule	Yes	
Total Trihalomethanes (THMs)	Stage I DBP Rule	No	Subject of ongoing rulemaking activity
Toxaphene	Phase II Rule	Yes	
2,4,5-TP (Silvex)	Phase II Rule	Yes	
1,2,4-Trichlorobenzene	Phase V Rule	Yes	
1,1,1-Trichloroethane	Phase V Rule	Yes	
1,1,2-Trichloroethane	Phase V Rule	Yes	
Trichloroethylene	VOC Rule	Yes	
Vinyl chloride	VOC Rule	Yes	
Xylenes	Phase II Rule	Yes	
Radionuclides			
Beta particles and photon emitters	Pre 1986 NIPDWRs	No	Subject of ongoing rulemaking activity
Gross alpha particle activity	Pre 1986 NIPDWRs	No	Subject of ongoing rulemaking activity
Radium-226/228 (combined)	Pre 1986 NIPDWRs	No	Subject of ongoing rulemaking activity
Microorganisms			
Giardia lambia	Surface Water Treatment Rule (SWTR)	No	Subject of ongoing rulemaking activity
Heterotrophic plate count (HPC)	SWTR	No	Subject of ongoing rulemaking activity
Legionella		No	Subject of ongoing rulemaking activity
Total Coliforms (including fecal coliform and *E. coli*)	Total Coliforms Rule	Yes	NOTE: EPA may publish the revise/not revise decision in a separate *FR* notice
Turbidity	SWTR	No	Subject of ongoing rulemaking activity
Viruses	SWTR	No	Subject of ongoing rulemaking activity

Appendix 2: National Primary Drinking Water Regulations (NPDWRs) Promulgated After August 1996 and NPDWRs Anticipated to be Promulgated Prior to August 2002

Note: The purpose of this table is to indicate those NPDWRs which will not be reviewed under the initial six-year review as these regulations will have not been in effect for 6 years by August 2002.

Regulation	Date of Promulgation
Disinfectants and Disinfection By-Products Rule (Stage 1)	December 1999
Interim Enhanced Surface Water Treatment Rule	December 1999
Radon	Early 2001*
Radium, Gross Alpha and Beta/Photon Emitters	November 2000*
Uranium	November 2000*
Filter Backwash Recycling Rule	December 2000*
Enhanced Surface Water Treatment Rule (Long Term 1)	December 2000*
Arsenic	June 2001*
Ground Water Rule	May 2002*
Disinfectants and Disinfection By-Products Rule (Stage 2)	May 2002*
Enhanced Surface Water Treatment Rule (Long Term 2)	May 2002*

* Indicates anticipated date of promulgation as of November 2000.

Appendix 3: Areas that Would Benefit from Future Research

In developing this guidance, the NDWAC recognizes there are subject areas that would benefit from further research. NDWAC believes this research would make the review process more conducive to future action by the Agency. Below, is a preliminary list of these research areas, as they relate to all of the key elements of the review process (see Section III). Note that this list is not intended to be comprehensive.

Health Effects

- General toxicity studies.
- Collecting data on "banned" contaminants.
- Data to assess the synergistic effects of contaminants when assessing health effects.
- Dose response profiles for microbial pathogens.
- Studies to identify new, and previously unrecognized waterborne disease agents, for assessing the relative contribution from water in the incidence of disease and for assessing the level of endemic disease.
- Studies on the ecology of pathogens (e.g., survival, replication, interaction with other microbial pathogens).

Technology Assessment

Research in the area of technology assessment should include focus areas of water treatment and analytical methodologies. Scientifically valid studies should be conducted and/or reviewed from the peer-reviewed literature. Some areas of general research for technology assessment are listed below. The list is meant as a guide to begin research into those areas that may best provide protection for public health.

- Data, information and technology.
- New methods for monitoring to generate occurrence data.
- New method for selected pathogens (or chemicals) or surrogates.

Occurrence and Exposure Analysis

Research to date in the occurrence and exposure area has been limited. The problem being, not so much that the contaminants have not been found, but that there has not been a concise study of these contaminants nationally, at levels related to the MCL. In research, the issue has often been the accuracy of the testing method, rather than an issue of actual occurrence. As noted in this guidance, State agencies often supply data on contaminant occurrence which is of some value to EPA. In addition, United States Geological Survey (USGS) source water testing may be one of the most valuable sources of occurrence data from untreated water, especially

when it provides accurate temporal data. Related to this, some areas that would benefit from future research are listed below.

- Research on contaminants exhibiting temporal occurrence patterns including: the necessity to characterize chemical application/use; seasonal weather patterns; physical or chemical degradation; and resultant impacts on occurrence levels.
- In unique cases, research to determine relationships between raw and finished water contaminant levels such that projection of finished water (i.e., regulated water) may be improved. Such studies may also help in understanding of treatment and/or monitoring issues.
- Research, e.g., pathway absorption research, may assist in the Agency's understanding of human exposure to chemicals, perhaps singly or by chemical group as needed. Exposure via alternative routes may be an area of concern for certain contaminants.
- Research in advanced statistical methodologies may allow development of alternate models for more accurately estimating national chemical occurrence.

Other Regulatory Revisions

Research is needed on optimization of monitoring design in terms of parameter selection and timing of sampling, to provide maximum representation of actual variation in relevant water quality indicators at minimum cost. Research is also needed on innovative sampling, analytical, and monitoring technology, including real-time sensors.

- Surrogate parameters: Research is needed to identify appropriate surrogate parameters for drinking water contaminants that are difficult to measure such as pathogens and disinfection by-product formation potential.
- Data reporting requirements: Research is needed on data reporting requirements that will provide the appropriate information to State and Federal regulators, in relation to the ultimate questions that need to be answered, without excessive cost or burden to water providers.
- Treatment technology: Research is needed on new drinking water treatment techniques that will provide greater protection from multiple contaminants at less cost.
- Effectiveness of source water protection measures: Research is needed on the effectiveness of various source water protection measures in improving water quality.
- Proper water system operation: Many aspects of water system operation can help ensure high water quality. Research needs include identifying what percent of backflow devices are tested each year, and what are the success/failure rates of these backflow devices. Other topic areas include: Re-growth, Pressure Surges, etc.

Appendix 4: Determination of National Occurrence of Contaminants

In reviewing existing chemical occurrence data, the Agency will determine which NPDWR contaminants are occurring at significantly high or low levels and, furthermore, develop nationally-representative contaminant occurrence and exposure profiles. The Agency may be able to utilize results of these analyses in combination with the analytical results of the primary health-based and technology analyses described within this guidance for the purpose of determining the level of priority of potential regulatory revisions (for some microbial contaminants this type of analysis may not apply).

EPA will use simple statistical tools to identify contaminants which occur at either high or low levels and then use these findings to estimate the number of people exposed to various levels of each contaminant. These initial occurrence and exposure findings will be evaluated together with other health-based or technology considerations (e.g., contaminants considered for MCL or MCLG changes). These combined evaluations will serve to identify a list of contaminants for which EPA will analyze available occurrence data in greater detail to produce occurrence and exposure profiles that are more statistically representative of the nation.

The result of this effort will be improved EPA occurrence and human exposure assessments for priority chemical contaminants. The Agency has already completed part of the initial occurrence analysis using the analytical approach as described below (Section A). The Agency may augment these initial analyses with other analyses as appropriate (see Section B).

In future reviews, the Agency expects to have a larger, centralized database providing access to high quality regulated and unregulated contaminant monitoring information. The National Drinking Water Contaminant Occurrence Database (NCOD) is being developed to satisfy the statutory requirements set by Congress in the 1996 SDWA amendments. The purpose of NCOD is to provide support for EPA's decisions regarding contaminants to be selected for regulation; for subsequent regulation development; and, for the six-year regulatory review process.

NCOD is expected to contain occurrence data from both PWSs and other sources such as the US Geological Survey's National Survey Water Information System (NWIS). NCOD does not currently contain occurrence data from all water systems and all States, *and as such, will not be supportive of the first cycle (2002) of NPDWR review.* The only PWS data contained in NCOD is compliance status information that has been reported voluntarily by States to the Safe Drinking Water Information System (SDWIS). Occurrence data at levels below and above current MCLs, are expected to populate NCOD. As of August 2000, the NCOD is operational, although in a developmental stage. It is not yet available to support nationwide estimates of occurrence of regulated contaminants: regulated contaminant occurrence data would need to be collected and entered into the appropriate database. As noted below, the first six-year review cycle is relying on analyses of available data that was provided by State agencies, outside of the context of NCOD development.

The NCOD is not structured to store data on microbial and disinfection by-products (MDBP) contaminant levels in water. For MDBP data, the EPA drinking water program relies on several sources:

- The EPA Information Collection Rule (ICR) of May1996 includes source and finished water sampling at large PWSs. Included in the ICR are extensive monitoring requirements for 300 PWSs operating 500 treatment plants. Analytes include: *Cryptosporidium* and *Giardia* oocysts/cysts, enteric viruses, and chemical by-products of treatment (as well as treatment information). Data from this effort have been placed in ICR Auxiliary Databases.
- The "ICR Supplemental Survey" monitoring included protozoa (*Cryptosporidium* and *Giardia*), DBP precursors, *E. coli*, fecal coliform, and total coliform data from medium/large systems (47 large, 40 medium systems). This survey also collected occurrence information (except for protozoa) from small systems. This survey represents a 12-month data set. The survey data, like the ICR Auxiliary Database, is contained in an Microsoft 97 Access file (July 2000, for EPA internal use); it is to be made available to the public, in condensed form, in Fall 2000.
- The Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), to be proposed in 2001, would as drafted require 1,800 medium/large systems to test for *Cryptosporidium*, *E. coli*, and turbidity. These data would be collected, entered into a data system, and used to place systems into defined 'bins' that will relate to treatment requirements.
- Small systems monitoring: The National Rural Water Association (NRWA) is taking on the task of collecting DBP precursor information at small systems in United States. The survey data are to be stored in a Microsoft Access database.

Note that the above listing of MDBP occurrence collection efforts is not necessarily an exhaustive list of data sources available to the Agency; nor does it describe MDBP data analyses which have or will have occurred in future regulatory actions (e.g., DBP II, LT2ESWTR) and future MDBP reviews.

A. Current Analyses of State Chemical Occurrence Data

Several sources of data were used in the current occurrence analysis. The primary source of data, used as the basis of most of these analyses, was compliance monitoring data from PWSs as volunteered by States. More than 70% of these data, referred to as the "State data sets," date from approximately 1993 to 1997. The secondary source of data was other SDWA compliance monitoring data from public drinking water systems, dating from 1983 to 1992. These are referred to as the "Unregulated Contaminant Information System (URCIS) Round 1 Data" and are from EPA sources. The URCIS data were used for comparison analyses for eight regulated VOCs and two regulated SOCs. Other privately- and publicly-available data sources were also used for comparative purposes. For greater detail regarding the proposed approach refer to the reader to *A Review of Contaminant Occurrence in Public Water Systems* (1999), also known as the "Drinking Water Contaminant Occurrence Report," EPA 816-R-99-006. (The full document

can be found at the EPA website: www.epa.gov/safewater/occur/occur.html. From the Office of Ground Water and Drinking Water website, readers may also search on the term "contaminant occurrence.")

State data sets. The most important source of data used in the contaminant occurrence analyses were State-derived data sets. These data sets were compiled by State drinking water agencies. The eight (8) State data sets used represent over 25% of the U.S. population served by PWSs, and over 20% of the PWSs, a substantial sample. These data represent more than 10.7 million analytical results from nearly 26,000 PWSs. For the initial stage of analyses, an overview of contaminant occurrence was prepared based on all data (including the full group of 12 State data sets as well as supplemental data). The 12 State data sets were used to identify the range of contaminant occurrence findings. Data sets from 8 States were selected for use in a national analysis as providing the best data quality and completeness, and for providing a balanced national cross-section of occurrence data. The States included in the national cross-section provide a nationally balanced geographic coverage, and a balanced representation of States distributed across the full range of State pollution potential rankings. (See the "National Representation" section below for more detail.) This group of 8 States, referred to as the "8 cross-section States," reflects a national cross-section of States that is indicative (though not strictly statistically representative) of national contaminant occurrence. This compilation and analysis of data can be found in the "Drinking Water Contaminant Occurrence Report."

Selection of appropriate State data sets and management of the data (handling, editing, formatting, "cleaning," etc.) was necessary for the simple non-parametric analyses conducted. The primary objective regarding the data used in these contaminant occurrence analyses was development of a consistent and repeatable data management approach that would allow valid comparisons between and among the various data sets, and allow the State data sets to be evaluated in aggregate to provide an overview of occurrence patterns at the national level.

URCIS data. The URCIS database includes information on 62 regulated contaminants, from 40 U.S. States or Territories. These records represent data for contaminants monitored from 1983 through April 1992 (including, 56 VOCs, 2 SOCs, and 4 trihalomethanes (THMs)). The majority of the data are from the first round of required unregulated contaminant monitoring that began in 1987. Because of the age of the data, especially in relation to subsequent significant improvements made in data processing systems, the quality of data received by EPA for URCIS is highly variable. Approximately 3.5 million records, primarily of VOC occurrence, were of adequate quality for analytical uses. This data from EPA's URCIS database was analyzed to provide a supplemental comparison (primarily for VOC data) to the occurrence findings for the State data sets.

National representation. Two broad factors were considered in development of a nationally representative compilation of State data sets: geographic or spatial diversity, and pollution potential. Consideration of States that together provide a geographic diversity was a means by which to include contaminant occurrence data from the wide, national range of climatic and hydrologic conditions across the United States. The representative group of State data sets

was also selected to represent the range of indicators of pollution potential for manufacturing and agricultural sectors.

The pollution potential for each State was evaluated in a number of ways. For a number of reasons it was decided, that the total manufacturing facilities per square mile (and EPA's Toxic Release Inventory (TRI) releases as a secondary indicator) and total dollars spent on agricultural chemicals (excluding fertilizers) were the best indicators of potential contamination from volatile and synthetic organic contaminants. (The reasoning for selection of these indicators is described in the section, "More on Pollution Potential Indicators" below and is fully described in the referenced 1999 "Drinking Water Contaminant Occurrence Report.") The 50 States were ranked based on these broad pollution potential indicators and divided into quartiles. The rankings were reviewed to select States in approximate balance from each quartile. The 8 cross-section States that were selected provided a broad distribution, geographically, and across the pollution potential rankings. The broad geographic coverage was also intended to provide a national distribution across the range of potential inorganic contaminant occurrence conditions.

The data from the cross-section States were used to compute aggregate occurrence values, i.e., the percentage of water systems that had a detection of contaminant X, as an approximation of contaminant occurrence at a national level. Analyses were conducted to establish the number and percentage of PWSs that had a sample detection less than the minimum reporting level (MRL), greater than one-half the maximum contaminant limit (1/2 the MCL) and greater than the MCL.

Using the pollution potential indicators and geographic distribution, the cross-section of States were selected to represent both the central tendency and the range of national pollutant occurrence. However, any extrapolation from eight States to a national estimate is inherently uncertain. These occurrence estimates cannot be considered a truly statistically "representative" sample of nation-wide occurrence for any given contaminant. As a preliminary evaluation of the national "representativeness" of the 8 cross-section States, the aggregated occurrence data were compared to three sources of data to provide perspective: (1) the URCIS data; (2) the atrazine and simazine studies by Novartis (see references); and (3) data from the USGS. While the URCIS data has data quality limitations it also has greater State representation (some data from 39 States and 1 Territory) than the cross-section States. Recognizing the differences between these data sets, the comparison to URCIS data showed that, in the majority of cases (about 67%), the cross-section had a slightly higher proportion of systems with detections of a contaminant and for about one-third of contaminants, URCIS shows an equal or slightly greater percentage. In all cases, the values are comparable; no values for systems with detections stand out as markedly or unexpectedly different. In summary, the aggregated national cross section of contaminant occurrence data compiled in the "Drinking Water Contaminant Occurrence Report" appears to provide a slightly high, but reasonable approximation of national occurrence values.

To expand the coverage of the existing occurrence analysis based on the cross-section States, additional State data sets will be obtained (as available) and included in the analyses. The addition of representative State data sets will be evaluated as above, through a process that includes:

- Ranking of States' pollution potential;
- Dividing States into quartiles based on the pollution potential rankings; and
- Selecting States that are representative geographically and that equally represent the different quartiles.

By adding State data sets based on the same pollution potential indicators and geographic criteria previously used to define the original 8 cross-section States, additional analyses of contaminant occurrence under the first six-year review may be conducted in a manner that maintains consistency with, and builds upon, the 1999 "Drinking Water Contaminant Occurrence Report."

Another analysis that could expand the understanding is comparison of source water quality data to the occurrence analyses. The extent of this comparison, and other possible analyses (such as co-occurrence, trend analyses, and relation of occurrence to various land use and contaminant source parameters) will depend on, and may be limited by, the availability of source water quality data.

More on Pollution Potential Indicators. Many past EPA and USGS studies have shown that some simple measures such as population (or population density) are closely associated with pollution. This is intuitively (as well as empirically) apparent, since it is human activity and its related land use -- be it manufacturing or agricultural activity -- that is the source of most pollutants, particularly the organic chemicals.

The primary indicators used in the current analysis, as reported in the 1999 EPA "Drinking Water Contaminant Occurrence Report," ranks each State by the potential for pollution from manufacturing and agriculture. In general, manufacturing/industrial activities typically associated with population density are considered the major sources of many VOCs (degreasers, solvents, petroleum compounds). Most SOCs are pesticides, and agriculture is the largest user of these compounds. While inorganic chemicals (IOCs) can have various uses in manufacturing, they also occur naturally. Ambient concentrations of IOCs also can be enhanced by mining or other diffuse activities. Natural geologic sources of IOCs were not directly considered in the assessment for representativeness, in part because whole States needed to be evaluated and such geologic sources are often localized. However, by including geographic or spatial coverage across the United States as a factor, from New Jersey to Montana for example, a range of geologic conditions are inherently included in addition to a broad range of hydrogeologic and climatic variation.

Numerous factors were considered as potential indicators of manufacturing-related pollution, including EPA's TRI (including total releases, releases per square mile, and releases excluding air releases), the number of manufacturing establishments, the number of manufacturing establishments per square mile, the number of manufacturing employees, the value added by manufacturers, and the value added per capita (see *Annual Survey of Manufacturers*, 1995; *Census of Manufacturers*, 1992; and *Toxic Release Inventory*, 1995). These factors were each

considered in terms of their inherent value as pollution potential indicators, their range and variance (in providing a relative ranking of the States), and their inter-relationships.

The total TRI releases per square mile, number of manufacturing establishments per square mile, and value added per capita were considered the three most useful indicators for the pollution potential associated with VOCs. The TRI was considered useful because it is a measure of how many pounds of toxic chemicals are released within the State. While there are problems with the TRI (e.g., some inconsistent release estimation techniques; omission of many small establishments, or unreported releases below specified thresholds), it validly can be used as a direct indicator of potential pollutants released. The number of manufacturing establishments per square mile takes into account how many factories are actually engaged in manufacturing and thus how many establishments potentially contribute to pollution. The final factor that was considered to be viable was the value added to products by manufacturers on a per capita basis. Initially this seemed to be a well-suited measure because of the presumed correlation between value added and the level of production (and by-product pollution) within the State. The problem with this measure (and also with the measure of number of manufacturing establishments per square mile), is that it does not take into account the variation in pollution released by different industries. For example, an industry that adds a lot of value to a product may cause little pollution while another industry that does not add much value may contribute more pollution.

The data evaluated in the "Drinking Water Contaminant Occurrence Report" showed a close correlation between the number of manufacturing establishments per square mile and the population density in each State, as well as a clear linear association with the total TRI pounds released/square mile, number of manufacturing employees, and total value added. Hence, the number of manufacturing establishments per square mile was used as the primary indicator. The other key reason for choosing this factor was that it is a simple measure of how many establishments are actually engaged in manufacturing and thus are potentially polluting sources of drinking water. The TRI total pounds released per square mile was used as a secondary factor in determining representativeness. Squillace and others (1995) found a significant correlation between VOC occurrence in ambient ground water and population density in a USGS national NAWQA study. As noted, population density and manufacturing density are highly correlated. Manufacturing density and TRI data were used in this ranking because they were considered more direct measures of pollution potential for this study.

There is no complete measure of pesticide usage by States that is readily available. So, a variety of factors were considered to assess potential organic chemical pollution from agriculture in each State as indicators of pollution potential from SOCs. These factors included the percent of the State's population that is classified as rural, the percent of land in the State that is crop land, the percent of land that is grassland pasture and rangeland (a possible inverse indicator), and total farm agricultural chemical expenses. Like the manufacturing factors, these agricultural variables were considered in terms of their value in indicating potential sources of pollution and were plotted against one another to determine how closely they were correlated.

Of these factors, total farm agricultural chemical expenses was considered to be the best indicator of potential pollution. The percent of the State's population that lives in rural areas does not necessarily relate to agricultural chemical use or crop land. There is, of course, a correlation

between crop land and agricultural chemical use, but there are notable exceptions such as Florida and California which use a large amount of agricultural chemicals despite having more limited crop land area. While there are some incomplete surveys of pesticide use, the Census of Agriculture (1992) measure of dollars spent on agricultural chemicals is a more consistent and complete measure.

In summary, three specific measures were selected as reasonable indicators of pollution potential:

- The number of manufacturing facilities per square mile, to reflect the range of potential VOC occurrence;
- Total expenditures on farm agricultural chemicals, to reflect the range of potential SOC occurrence; and
- TRI releases, in total pounds per square mile, to reflect the releases of any type of chemical into the environment.

These measures were used to assess the pollution potential characteristics of the States. In addition, and as mentioned previously, in the development of a nationally representative group of States the geographic distribution of States must reflect the range of hydrologic, geologic, and climatic conditions.

B. Alternative Approaches to a National Occurrence Estimate

The current method for estimating national contaminant occurrence uses data from a cross-section of eight of the States from which data were available. Some other State data sets were available, but are excluded from the analysis, either because of poor data quality, or because they are too similar to other States already in the cross-section. For example, the cross-section excludes Ohio and Indiana, even though data is available from these States, because they are similar in location and pollution potential to Illinois and Michigan, which are already in the cross-section. This 0/1, or exclude/include approach has the advantage of simplicity, and it has been approved by external peer reviewers of the report. However, it has the weakness of not using potentially useful data.

An alternative to the exclude/include strategy is to assign a more general weight to each State, determined by the number of nearby or similar States in the data set, the size of the State, and/or the quality and size of the State's data set. A recent example of such a strategy is EPA's draft analysis of arsenic occurrence in drinking water (US EPA, 2000). This report used a geographical weighting scheme, in which State data sets were combined into regional occurrence estimates, and regions were combined into a national estimate. The effect was to use all of the available data, but to assign lower weight to States in regions with more data. Other weighting schemes could use pollution potential indicators in a similar way, assigning lower weight to States with pollution indicators that are similar to those of other States in the data set. Geographical and pollution-based weights could also be combined into a single weighting scheme.

The advantage of these more general weighting schemes is that they use all of the available data. If carefully designed, they can therefore be expected to reduce both the bias and variance of national occurrence estimates. These schemes have important disadvantages, however. First, they lose the simplicity of the 0/1 approach, and may be hard to explain or justify to the public. Second, a large amount of analysis may be required in order to make a reasonable and defensible choice of weights. This is especially true because each contaminant will probably require a separate set of State weights, because of differences in the quality of the data sets. Third, the choice of weights requires assumptions that may be hard to check or justify. For example, the arsenic analysis postulated certain geographic regions, in order to assign the distributions of "nearby" States to States without data.

Extrapolation from a sample of eight or more States to a national occurrence estimate is inherently uncertain. Any method of extrapolation, including the 0/1 approach and the more general weighting schemes described above, requires assumptions that may be challenged. At least as important as choosing a method of extrapolation, will be for EPA to, first, estimate the uncertainty due to the extrapolation, and second, obtain as much data as possible outside of the State data sets, in order to validate the results of its analysis.

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Appendix 5: Non-Regulatory Approaches

While the six-year review is a regulatory process, NDWAC believes it is appropriate to point out the importance of incorporating non-regulatory efforts to work in concert with the regulatory program in safeguarding drinking water. Ongoing non-regulatory programs are not a substitute for drinking water regulations, but may help to reduce the introduction and occurrence of contaminants to our nation's waters, therefore, reducing the need for drinking water regulations. Both new and existing programs can take advantage of education, voluntary actions, incentives, and program integration to channel resources and efforts toward safe drinking water goals.

Education, guidance and research: Public education can increase the general level of understanding about safe drinking water, and raise expectations for high-quality water. Special education programs should be aimed at healthcare providers, who are heavily involved in drinking water issues, have frequent contact with patients, and enjoy a high degree of trust. EPA can publish guidance documents on topics such as source water protection and data handling to help direct voluntary efforts at risk reduction. Operator certification and training programs can help assure proper operation of water and wastewater treatment facilities. Drinking water managers should have a convenient forum for sharing success stories of risk reduction. Drinking water managers should also have ample opportunities for influencing the direction of relevant research. EPA will carefully consider information gaps related to health effects and occurrence, and promote research to fill the gaps. Public education could be improved by taking advantage of recent advances in knowledge-based software. For example, a program developed under a recent American Water Works Association Research Foundation (AWWARF) grant helps to notify sensitive subpopulations when they may be at risk from their drinking water.

Safe drinking water can also be enhanced through guidance that promotes integration of source water assessments, hydrologic sensitivity analysis, Phase II/V waiver assessments, and radionuclide vulnerability assessments.

Voluntary actions: At all geographic levels, voluntary actions can help protect safe drinking water. For example, water systems can voluntarily adopt International Standards Organization (ISO) standards to improve water quality. These programs include ISO 9000 which sets goals of improving drinking water quality through treatment procedures, and ISO 14000 which improves the environmental health and safety policies and organizational structure of water systems. Water systems can also join the EPA Safe Water Partnership, which sets turbidity goals and self-assessment of operations to improve water quality. States can voluntarily offer monitoring waivers to systems known to be low risks for certain types of contamination. Volunteers can play a key role in source water monitoring and assessment.

Incentives: Monetary and non-monetary incentives can encourage voluntary efforts to protect water. One example comes from Europe, where water systems pay farmers to avoid pesticides and use organic farming methods in source areas. Similar payments could be offered to keep livestock away from streams. Another example is that where lower interest rates are offered through the State Revolving Loans for small systems.

Program integration: Some of the best opportunities for non-regulatory approaches involve joining forces with existing programs aimed at source water protection and watershed restoration. These programs, which can be established incrementally for cost-effective management, include:

- State, Tribal, and local efforts developed as part of source water assessment and protection plans. These are typically coordinated through State drinking water agencies and EPA regional offices.
- Watershed Restoration Action Strategies (WRAS) developed by States, Tribes, local governments, and watershed groups as part of the Clean Water Action Plan. These are typically coordinated through State clean water agencies. Many (but not all) are part of the EPA Clean Water Act Section 319 program.
- United States Department of Agriculture (USDA) programs such as Environmental Quality Incentives Program (EQIP) and others, which encourage agricultural producers to install best management practices (BMPs). These are typically coordinated through the State Technical Advisory Committees, under the Natural Resource Conservation Service (NRCS) State Conservationist.
- United States Department of Interior (USDOI) programs such as the Fish and Wildlife Service's Partners for Fish and Wildlife, the Office of Surface Mining's Appalachian Clean Streams Initiative, and the Bureau of Land Management's Abandoned Minelands Initiative.

More information on these programs, and others, can be found on the following web sites: *Clean Water Action Plan:* www.cleanwater.gov and *Surf Your Watershed*: www.epa.gov/surf.

Appendix 6: IRIS Assessments

The Integrated Risk Information System (IRIS) is an EPA database containing Agency consensus scientific positions on potential adverse human health effects that may result from chronic exposure to chemical substances found in the environment.[15] Assessments by IRIS undergo internal and external peer reviews by health scientists.

The main reasons for including a chemical in the IRIS program are (1) Agency statutory, regulatory, or program implementation needs, and (2) availability of new scientific information or methodology that might significantly change current IRIS assessment.

The Office of Water (OW), as well as other EPA offices, periodically nominates priority chemical substances requiring new or updated assessments in IRIS. Several chemicals nominated by OW are on the IRIS agenda. For example, in order to meet the statutory requirements of the 1996 SDWA, a number of disinfection by-products have been included in IRIS. New information has become available for several regulated chemicals (e.g. cadmium, xylenes, tetra- and trichloroethylenes, di(2-ethylhexyl)phthalate, etc.) , thus, these chemicals have been selected for updated IRIS reviews.

IRIS assessments are based solely on scientifically valid studies. Evaluations of original toxicological and epidemiological studies conducted by the National Toxicology Program, National Cancer Institute, National Institute of Environmental Health Sciences, EPA's National Center for Environmental Assessment, industry, universities, etc., are all used in risk assessment. These studies are individually evaluated for their soundness, methodological strength and weaknesses, and whether or not they have been conducted according to current quality standards.

IRIS reviews are not based on secondary sources such as reviews conducted by other national or international organizations (e.g. State of California, World Health Organization or the International Agency for Research on Cancer), although such assessments are often examined as part of the IRIS review.

A full list of chemicals assessed in IRIS and those for which assessments are planned can be found on IRIS web site (http://www.epa.gov/iris). A large number of these IRIS assessments are of direct relevance to the regulatory function of OW and more specifically to the six-year review.

[15] IRIS contains chemical specific health effects information. Information on synergistic effects of chemical mixtures is scarce and is seldom available for inclusion in IRIS.

Appendix 7: Overview of the Office of Pesticide Programs Process for Toxicity Assessments

Under the requirements of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a registrant (manufacturer) is required to submit animal toxicity data on the potential human health effects that may be posed by pesticide chemicals. Toxicity data are provided during the initial registration of a pesticide as well as during the periodic re-registration review of the pesticide as required by FIFRA. The schedule, priority, for when an existing pesticide enters a re-review is set in part by regulatory requirements which include provisions to give priority to certain active ingredients. The Office of Pesticides (OPP) will establish the review schedule taking into account the procedures outlined in the Act. A more complete discussion of the re-registration process can be found in Section 4(a)-(f) of FIFRA.

In 1998, OW's OGWDW and the OPP established major areas of coordination on cross-cutting scientific issues. Included in the major efforts was the harmonization of the human health hazard assessments and dose response relationships for pesticides. The two offices have agreed to share health effects data and coordinate activities on the issues such as end-point selection, dose response information, and quantifying risks. Therefore, the OW and OPP are working closely on establishing consistency in health effects end-points through resource and information sharing.

The OPP receives health effects data that are generated under specific scientific guidelines established by the Agency and conducted under the requirements of Good Laboratory Practices. These guidelines are available on the EPA's Internet site at the following location: http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/indexx.html.

In addition to the required guideline studies, the OPP will obtain and review open literature data on adverse effects to test species. Although these studies are not used in establishing health end-points (RfDs and cancer potency or threshold values), they are used in establishing the "weight of evidence" for an adverse effect. Data source include, but are not limited to, published, peer reviewed journal articles in the open literature and toxicity data submitted to other U.S. federal or international agencies that do not conform to the OPP's test guidelines.

Below is a brief overview of end-point selection.

Toxicity Assessment

Non-Cancer Effects:

Reference Dose. For non-cancer effects, toxicity is represented by a reference dose; it may be calculated for acute effects (aRfD) and chronic effects (cRfD). RfDs are calculated by determining the No-Observed-Adverse-Effect Level (NOAEL) from either acute or chronic toxicity studies (the choice of study depends on which type of RfD is being calculated - aRfD or cRfD) and dividing it by the appropriate uncertainty factors. Typically, an uncertainty factor is

applied to account for variation within the human population (i.e., intraspecies); and an additional uncertainty factor is applied to account for the differences between humans and animals as the animal data are translated to humans (interspecies).

If the RfD will be used in dietary risk assessment, then it is adjusted to take into account the FQPA Safety Factor for infants and children. Such an adjusted RfD is called a Population Adjusted Dose (PAD). Like the RfD, it may be acute (aPAD) or chronic (cPAD). In making the decision regarding the FQPA Safety Factor, the Agency takes into account both information on the toxicity of the pesticide and the completeness of the toxicity and exposure databases. For more information on how the Agency applies the FQPA Factor, see the document "Standard Operating Procedures for use of FQPA Safety Factor," April 26, 1999 at http://www.epa.gov/pesticides/trac/science/.

Cancer Effects:

Linear Effect - *Cancer Potency Factor* (*q1**). The cancer potency factor, which is commonly known as a q1*, is the relative strength of a carcinogen. The bigger the q1*, the more potent the carcinogen. It is calculated using a computer model that assumes linearity at doses below which the effect occurred in the studies.

Non-Linear Effect - *Margin of Exposure*. For some carcinogenic pesticides, it is not considered appropriate to calculate a potency factor. In these cases, the cancer effect is assumed to have a threshold, as for non-cancer effects, and as such, a Margin of Exposure (MOE) is derived. The MOE is a ratio, calculated by dividing the toxicity Point of Departure (such as a NOAEL) by the estimated or calculated exposure level. We have not yet established a policy on the level of risk that is of no concern for non-linear cancer risk assessment.

During the review of the toxicity data and the dose-response assessment, the pesticide being evaluated undergoes review by several in-house peer review committees.

Appendix 8: Analytical Methods

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

Section 1401 of SDWA directs EPA to promulgate NPDWRs which specify either MCLs or TTs for drinking water contaminants (42 USC 300g-1). SDWA requires EPA to set an MCL "*if, in the judgement of the Administrator, it is economically and technologically feasible to ascertain the level of a contaminant in water in public water systems*" [SDWA section 1401(1)(C)(i)]. Alternatively, if it is not economically or technologically feasible to so determine the level of a contaminant, the Administrator may identify known TTs, which sufficiently reduce the contaminant in drinking water, in lieu of an MCL [SDWA section 1401(1)(C)(ii)]. In addition, SDWA requires an NPDWR to include "*criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including accepted methods for quality control and testing procedures to insure compliance with such levels*" [SDWA section 1401(1)(D)].

B. What is the Typical Process for Approving Methods for SDWA Analytes?

Methods are initially approved as a part of an MCL or monitoring requirement rulemaking. Thereafter, as revisions to the approved methods are published or as new technologies are developed, the Agency, from time-to-time, will group a set of methods for proposal in a methods update rule. There is no set schedule for method updates, the drivers being the relative urgency for a revised or new compliance method, and Agency resources that can be diverted from other SDWA regulatory mandates and activities. The time from start to finish of a methods update rule is generally 18-24 months. This can increase significantly if there is adverse public comment on a proposed method.

The revised or new methods included in a methods update rule may be from EPA, other Federal or State agencies, or standards organizations (e.g. American Society for Testing and Materials (ASTM) or Standard Methods (SM)). These non-EPA entities have independent review and/or collaborative testing requirements. In addition, methods may also be developed by private laboratories, vendors or groups. Independent review and collaborative testing of these privately developed methods is accomplished by requiring submission of the method to the Agency under the alternate test procedure (ATP) program. Privately developed methods must pass the ATP process before they can be included in an EPA methods update rulemaking. Initially, many ATP applications are missing data. Once a completed ATP application is recorded by the Agency, the ATP pass/fail decision generally takes three to four months. For successful ATPs, this period is followed by the formal rulemaking process, which was described above as taking 18-24 months.

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

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

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

Regarding the first criteria (i.e., sensitivity), the MDL and the PQL are two performance measures used by EPA to estimate the limits of performance of analytic chemistry methods for measuring contaminants in drinking water. For SDWA analytes, EPA defines the MDL as "the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero"(40 CFR Part 136 Appendix B). MDLs can be operator, method, laboratory, and matrix specific. MDLs are not necessarily reproducible within a laboratory or between laboratories on a daily basis due to the day-to-day analytical variability that can occur and the difficulty of measuring an analyte at very low concentrations. In an effort to integrate this analytical chemistry data into regulation development, the Agency uses the PQL to estimate or evaluate the minimum, reliable quantitation level that most laboratories can be expected to meet during day-to-day operations. EPA's Drinking Water program defines the PQL as "the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions (50 FR 46906, November 13, 1985)." For several SDWA analytes, EPA set the MCL at the PQL.

D. How Are PQLs Typically Determined for SDWA Contaminants?

Historically, EPA's OGWDW uses two main approaches to determine a PQL for SDWA analytes. The preferred approach, the WS method, uses data from WS studies to calculate the lower limit of quantitation. The WS method is used in most cases when sufficient WS data are available to calculate a PQL. In the absence of WS data, the second approach that EPA uses is the multiplier method. In this approach, the PQL is calculated by multiplying the EPA-derived MDL by a factor of 5 or 10. The 5 or 10 multiplier is used to account for the variability and uncertainty that can occur at the MDL.

1. How Were Water Supply Studies Conducted?

Water supply laboratory PE studies have been an integral part of EPA's certification program for drinking water laboratories for over 20 years. Historically, EPA's National Exposure Research Laboratory (NERL) in Cincinnati, Ohio conducted WS studies for all current and proposed drinking water contaminants. Although EPA conducted the WS studies semi-annually, for certification purposes, laboratories were only required to demonstrate acceptable performance once a year.

Each WS study included WS samples (or sample concentrates) that were analyzed for both SDWA analytes and analytes being considered for regulation under the SDWA. During these WS studies, EPA-NERL sent participating laboratories a set of the stable WS sample concentrates in sealed glass ampules, a data reporting form, and appropriate instructions. EPA-NERL sent WS samples to all laboratories that conducted drinking water analyses, including utility laboratories, commercial laboratories, and State and EPA Regional laboratories. With appropriate dilution, the laboratory then analyzed the WS samples using the specified procedures. Afterwards, the laboratory sent the completed reporting form to EPA for evaluation. After evaluation, EPA returned a fully detailed report to each participating laboratory.

At this point in time, WS PE studies are no longer performed by EPA. Due to resource limitations, on July 18, 1996 (61 FR 37464; EPA 1996b), EPA proposed options for the externalization of the PE studies program (now referred to as the Proficiency Testing or PT program). After evaluating public comment, in the June 12, 1997 final notice (62 FR 32112; EPA 1997b) the Agency:

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

Since the last WS studies performed by EPA were done in the Fall of 1999, the externalization should not effect the data needed for the first six-year review process (1996-2002).

2. PQL Determinations - How Are WS Studies Evaluated and What Criteria Are Used?

a. Evaluation of WS Studies

For each analyte in the WS study, EPA evaluates the results using Kafadar's biweight estimates of the mean and standard deviation from all the study data, and separately, for the data reported by EPA and State laboratories. Where acceptance limits are not specified by regulations, and where there are data from at least 13 EPA and State laboratories, the biweight estimates from the EPA and State laboratory data are used to calculate a 95 percent prediction interval. If there are no regulatory limits, but fewer than 13 EPA and State laboratories reported data, then the prediction interval is calculated from the biweight estimates made from all the study data reported for the analyte.

For each analyte, 95 percent of the study data from laboratories operating in a State of statistical control, i.e., "in control," should theoretically be within the 95 percent prediction interval. Since 1986, such prediction intervals, or the limits set in regulations, have been used as the acceptance limits to judge laboratory performance in WS studies.

The recovery of an analyte is defined as the estimated biweight mean divided by the true concentration of the analyte in the study, and can be calculated as follows:

$$\%\ recovery\ =\ \frac{measured\ \ concentration}{spiked\ \ concentration}\ \times\ 100$$

Using the recovery of an analyte instead of the mean concentration facilitates comparisons across WS studies performed at different true concentrations.

The statistical derivation of the PQL involves determining the concentration of an analyte at which a set percentage of the laboratories achieve results within a specified range of the spiked value. Historically, the percentage of laboratories was set at 75 percent, while a range of acceptance limits around the spiked value were used. In many cases, EPA derived PQLs only from the data submitted by the EPA Regional and State laboratories that participate in the WS studies.

A PQL derived from WS data in such a manner is considered a stringent target for routine laboratory performance because:

- WS samples are prepared in reagent water and therefore do not contain the matrix interferences that may occur in field samples.
- Laboratories analyze only a small number of samples for the study and are aware that the samples are for the purposes of PE (i.e., they are not "blind" samples).

In deriving a PQL from WS study data, the Agency sets a fixed percentage acceptance window around the spiked value of the WS samples and plots the percentage of laboratories achieving results within that window (y-axis) against the spiked concentration of the WS study samples (x-axis). While the acceptance limits for inorganics typically range from 15 to 30 percent, the acceptance limits for organics generally range from 40 to 50 percent. Several SDWA analytes have acceptance limits of 2 sigma. The data are subjected to a linear regression analysis to determine the concentration at which 75 percent of EPA Regional and State laboratories achieve acceptable results.

E. What Approaches Will EPA Use to Re-evaluate the PQLs of Contaminants Identified from the Six-Year Review Process?

For the six-year review process, several approaches could be used for the re-assessment or re-evaluation of the PQLs for selected chemical contaminants. To be consistent with the process that the Agency has used in the past, only the "WS data method" and the "MDL 5 or 10 Multiplier method" will be considered for this six-year review process. Of these two approaches, the Agency prefers to use the WS data approach. The advantages and disadvantages for each of these PQL derivation methods are listed below.

1. *Analysis of WS Data* - Using the data from more recent WS studies, a new PQL will be derived and compared to the old PQL (i.e. the one that is currently in place).

The advantages of the WS Data method of deriving a PQL:

- Uses inter-laboratory data collected at concentrations near the MCL.
- More representative of what methods are being used for the analysis of that contaminant.
- May be the preferred approach for contaminants with MCLGs of zero.

The disadvantages of the WS Data method of deriving a PQL:

- The PQL derived for each contaminant is affected by the Agency's choice of an acceptable level of precision. Because the acceptance limits for many of the currently regulated SDWA contaminants are already set, it will not be necessary to derive new acceptance limits for this or future six-year reviews.
- The PQL may be influenced by the WS data used, i.e., all data or only data from EPA State and Regional laboratories.
- Some feel that laboratory performance on WS data may be skewed, because WS samples may be treated as special samples that are critical for laboratory certification.
- The derivation of PQLs from WS data is a resource- and time-intensive process.
- Because the WS samples are designed to test precision and accuracy around the MCL, the WS data may not cover concentrations several orders of magnitude below the current MCL. Hence, for some analytes, data points at lower levels may not be represented.

2. *The MDL-Multiplier Approach* - Using the MDL of the currently approved method(s) for each contaminant, a 5 or 10 multiplier method will be used to estimate the PQL. This value would then be compared to the PQL that was derived before the 1996 SDWA amendments.

The advantages of the PQL-by-MDL Multiplier approach:

- It is a relatively easy and clear process.

The disadvantages of the PQL-by-MDL Multiplier approach:

- The WS studies test laboratory performance near the MCL not near the MDL. A PQL derived from the MDL method may not be representative, because the reproducibility of a result obtained at the MDL is often not as good as that obtained near the MCL.
- Because several methods may be approved for the same contaminant, it can be difficult to decide which MDL to select for the PQL calculation.

F. Other Methods of Deriving a PQL

The discharge permit and pretreatment program for wastewater uses the Minimum Level (ML) MDL-Multiplier method to derive a PQL. The ML is calculated by multiplying a specified MDL for a contaminant by 3.18 and rounding to an integral number. Because the 3.18 ML method has not been peer reviewed for drinking water, it will not be used by OGWDW to derive PQLs for six-year review process. The EPA OGWDW will only use the wastewater ML method for comparison purposes (to see how this method of deriving a PQL compares to OGWDW's WS method of deriving PQLs).

G. Historical Determination of Radionuclides Analytical Feasibility

Since 1976, EPA has conducted a Radiochemistry PE Studies Program at the Las Vegas, Nevada EPA Laboratory (EPA-LV). The EPA-LV PE program was used to set standards for radiochemical methods, generate reports that compared the data from all radiochemical laboratories, and to define data quality using the data from these PE studies. All radiochemistry laboratories (both US and foreign) participated in these PE studies. This amount of participation by a wide range of laboratories permitted method and laboratory assessment on an unprecedented scale and was to be the backbone of performance-based radiochemistry methods. Any sample type of interest to the Agency (water, milk, food, soil, air, urine) was measured by all laboratories wishing to demonstrate proficiency with a given regulated nuclide or group of nuclides in a matrix of interest. The number of laboratories per study ranged from 50 to over 200 depending on the parameter of the PE study. The results from the studies were reduced to statistical parameters and scored relative to performance data quality objectives and reported relative to all the laboratories performing the same measurement. Performance accuracy was reported as the ratio of the relative difference of the reported mean to the known concentration (determined gravimetrically and verified analytically) and the normal deviate. The normal deviate was a weighted parameter taking into account random uncertainty and reasonable introduced errors. A ratio between 0 and 2 (95 percent confidence interval), between 2 and 3 in the warning range, and greater that 3, out of control and failure. The criteria were objective, empirical, not based on the population distribution (all, some, or none of the labs could pass), and defined measurement data quality on a sustained basis. The PE program's scope normalized performance expectations and challenged laboratories to the highest standards for accuracy because the performance standards were independent of any study group. PE studies were conducted 17 to 20 times per year and the data generated under these controlled conditions were used to demonstrate measurement data quality and method feasibility in support of regulatory MCLs and action levels.

With regards to radiochemical data quality and measurement feasibility, radiochemical measurements were (and still are) typically characterized by:

(1) system background,

(2) the counting time of the sample and background,

(3) the sample volume,

(4) counter efficiency,

(5) similarity of the standard to the target nuclides,

(6) chemical yield, if separation chemistry was employed,

(7) replicate precision (repeatability) within laboratories, and

(8) between laboratory accuracy (reproducibility) relative to a known concentration (this factor includes any systematic error(s) introduced by the laboratory).

Repeatability, both individually and collectively, demonstrated that within a laboratory, the dominant source of uncertainty was that due to the randomness of radioactive decay, the counting uncertainty. Because the uncertainty is characterized by the Poisson Distribution, repeatability could be compared to the expected, computed uncertainty when randomness dominated, (3 to 5 times background). Reproducibility was the index of data quality used to determine the limits of data quality and the feasibility of resolving differences between nuclide concentrations. With the externalization of the PE program, data quality monitoring and control is no longer possible. Future performance of methods and data quality can only be estimated from historical performance.

As opposed to chemical analytes, the determination of measurement feasibility for radionuclides do not rely on a PQL convention. Because of the aforementioned factors that contribute to measurement feasibility for radionuclides, EPA-LV determined that a different, statistically valid and scientifically defensible approach was necessary for determining measurement reliability for radiochemicals. In determining measurement reliability for radionuclides, the grand average of the means and reproducibility (total error) of the study population are computed. The distribution of laboratory averages reflected both random uncertainty and bias introduced by the laboratory and represented an empirical yard stick of the reliability or feasibility of laboratories to measure a nuclide, all factors considered. This distribution around the known value was the reproducibility (data quality) of the population for the nuclide in water, the focus here. The goal of determining the reproducibility for the population of laboratories was to provide an upper limit on accuracy for any result provided by a certified laboratory. The reproducibility of a population of laboratories (i.e., the measurement feasibility) is not obtainable except by multiple laboratory testing.

Reference:

Kafadar, Karen. "A biweight approach to the one-sample problem." *Journal of the American Statistical Association*. 77 416-424. 1982.