

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

TO: California Urban Water Agencies Central Valley Drinking Water Program Work Group

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DATE: August 15, 2007

SUBJECT: Final Technical Memorandum No. 2 – Review Procedures, Policies, and Guidance Used by the U.S. Environmental Protection Agency (EPA)

The objective of this task is to gain an understanding of the methodology used by EPA to establish ambient water quality criteria for the protection of drinking water supplies and the methodology used to establish triggers for additional water treatment.

WATER QUALITY CRITERIA METHODS

The purpose of this subtask is to summarize EPA procedures and guidance on establishing ambient water quality criteria for the protection of drinking water supplies.

The term “water quality criteria” is used in two sections of the Clean Water Act (CWA), Sections 303 (c) (2) and 304 (a) (1). The term has a different definition in each section. Under Section 303 the term is associated with specific water body uses to define the level of a pollutant (or in the case of nutrients, a condition) necessary to protect designated uses in ambient waters. Under Section 304 the term represents a scientific assessment of ecological and human health effects that the EPA recommends to states and tribes for establishing water quality standards that ultimately provide a basis for controlling discharges or releases of pollutants. They also provide guidance to EPA when it promulgates Federal regulations under the CWA. They are not regulations in themselves and do not impose legally binding requirements on EPA, states, authorized tribes or the public.

Human health water quality criteria are numeric values that protect human health from the harmful effects of pollutants in ambient water. A human health criterion is the highest concentration of a pollutant in water that is not expected to pose a significant risk to human health. Under Section 304 (a) of the CWA, water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment.

Regulatory Background

The “Green Book”, published in 1968, provided the first ambient water quality standards. Section 304 (a) (1) of the Clean Water Act (CWA), passed in 1972, requires the EPA to develop criteria for the protection of aquatic life as well as for human health. The water quality criteria must accurately reflect the latest scientific knowledge, therefore they are updated periodically. In 1973 the EPA published updated criteria in the “Blue Book” (Water Quality Criteria 1972) and again in 1976 in the “Red Book” (Quality Criteria for Water).

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

In 1980 the EPA developed the Ambient Water Quality Criteria (AWQC) National Guidelines, which outlined the methodology used by states and tribes to develop human health water quality criteria. Between 1980 and 1984, EPA announced the publication of 65 individual ambient water quality criteria documents for pollutants listed as toxic under Section 307 (a) (1) of the CWA, and provided a methodology for deriving the criteria. These national guidelines addressed three types of endpoints: non-cancer, cancer, and organoleptic (taste and odor) effects. The “Gold Book”, published in 1986, presented a summary of all the criteria developed in the early 1980s.

In 2000 the EPA published a revised methodology for developing water quality criteria, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. This methodology incorporates significant scientific advances made in the 1980s and 1990s, particularly in the areas of cancer and non-cancer risk assessments, exposure assessments, and methodologies to estimate bioaccumulation in fish. The revised methodology provides more flexibility for decision-making at the state, tribal, and EPA regional levels. The methodology is expected to result in more stringent criteria for bioaccumulatives and generally similar values for non-bioaccumulatives.

In 2002 the EPA published revisions to many of the ambient water quality criteria for human health as the National Recommended Water Quality Criteria; 2002 (EPA-822-R-02-047) and then the EPA published an additional 15 revised human health criteria in 2003. Thirteen of the criteria integrate a relative source contribution value from the national primary drinking water standards for the same chemicals.

Revised Methodology for Deriving Health-Based Ambient Water Quality Criteria (2000)

States and tribes must develop water quality standards that include designated uses and water quality criteria necessary to support those uses. The Methodology is the guidance for states and tribes to help them establish water quality criteria and standards to protect human health. It provides detailed means for developing the water quality criteria, including systematic procedures for evaluating cancer risk, non-cancer health effects, human exposure, and bioaccumulation potential in fish.

The Final AWQC Methodology Revisions to the 1980 AWQC National Guidelines were necessitated by the many significant scientific advances made during the 1980s and 1990s in the key areas of cancer and non-cancer assessments, exposure assessments, and bioaccumulation in fish. The major revisions are in four assessment areas: cancer, non-cancer, exposure, and bioaccumulation.

For carcinogen (cancer) risk assessment:

- Recommend more sophisticated methods to comprehensively determine the likely mechanisms of human carcinogenicity.
- Recommend a mode of action (MOA) approach to determine the most appropriate low-dose extrapolation for carcinogenic agents.

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

For non-carcinogens:

- Use EPA guidance on assessing non-carcinogenic effects of chemicals and for the Reference Dose (RfD) derivation.
- Recommend consideration of other issues related to the RfD process including: integrating reproductive/development, immunotoxicity, and neurotoxicity data into the calculation.
- Recommend the use of quantitative dose-response modeling for the derivation of RfDs.
- Provide guidance to states and tribes on the use of an alternative value from the RfD point estimate, within a limited range, to reflect the inherent imprecision of the RfD.

For exposure assessment:

- Encourage states and tribes to use local studies on fish consumption that better reflect local intake patterns and choices.
- Recommend default fish consumption values for the general population, recreational fishers, and subsistence fishers.
- Account for other sources of exposure, such as food and air, when deriving AWQC for non-carcinogens and nonlinear carcinogens.

For bioaccumulation:

- Focus on the use of bioaccumulation factors instead of bioconcentration factors for estimating potential human exposure to contaminants via the consumption of contaminated fish and shellfish.
- Use high quality field data over laboratory or model-derived estimates for deriving bioaccumulation factors, since field data best reflect factors that can affect the extent of bioaccumulation (e.g., chemical metabolism, food web structure).

The EPA has not, and does not plan to, completely revise all of the criteria developed, but partial updates of all criteria may be necessary. The EPA will continue to develop and update toxicology and exposure data needed in the derivation of AWQC that may be impractical for the states and regions to obtain.

Methodology Revisions Implementation by EPA/States

The EPA's future role in developing AWQC for the protection of human health will include:

- The development of revised criteria for chemicals of high priority and national importance (including, but not limited to, chemicals that bioaccumulate, such as PCBs, dioxin, and mercury).
- The development or revision of AWQC for some additional priority chemicals.
- Technical assistance to states and tribes on the toxicology, exposure and bioaccumulation methods, and review of state/tribal water quality standards.

The EPA encourages states and tribes to use the revised methodology to develop or revise AWQC to reflect local conditions appropriately. The EPA believes that AWQC

TECHNICAL MEMORANDUM Evaluation of Drinking Water Quality Goals

inherently require several risk management decisions that are, in many cases, better made at the state and regional level (e.g., fish consumption rates, target risk levels).

National Recommended Water Quality Criteria

Only seven of the constituents of concern for the Drinking Water Program have water quality criteria developed for them. Here are the current criteria set by the EPA in either the “Gold Book” or subsequent updates.

Ammonia

Data used in deriving criteria was predominantly from flow through tests in which concentrations were measured. All tests were fish and invertebrate toxicology tests, no human parameter was examined. Criteria have been developed for both freshwater and saltwater. The freshwater criteria are pH, temperature and life-stage dependent. The formulas used to develop site-specific criteria for one-hour and four-day are provided in **Attachment 1**. The EPA has also generated summary tables.

Bacteria

Criteria for bacteria have been set for freshwater, assuming primary contact recreation, based on a sufficient number of samples (not less than five spaced equally over 30 days) the geometric mean of densities should not exceed one or the other as follows:

- *E. coli* – 126 per 100 mL
- *Enterococci* – 33 per 100 mL

These values are based on specific levels of risk of acute gastrointestinal illness. The levels of risk used by EPA correlating to these values are not more than eight illnesses per 1,000 swimmers for fresh waters. The illness rates are the EPA’s best estimates of the accepted illness rates for areas that had previously applied the fecal coliform criterion. The EPA determined that when implemented in a conservative manner, these water quality criteria are protective of gastrointestinal illness resulting from primary contact recreation.

Although EPA recommends the use of *E. coli* and *Enterococci*, some states/tribes continue to use the older criteria for fecal coliform. This criteria is a geometric mean less than 200 colony forming units (CFU) per 100 mL (based on not less than five samples equally spaced over a 30 day period) and no more than 10 percent of the samples exceeding 400 CFU per 100 mL during the same period.

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

Nitrates/Nitrites

Major point sources of nitrogen entry into water bodies are from municipal/industrial wastewaters, septic tanks, and feedlot discharges. Diffuse sources are from farm site fertilizer, animal wastes, lawn fertilizers and leachate from waste disposal at dumps and sanitary landfills, atmospheric fallout, discharges from auto exhaust and other combustion processes, and losses from natural sources such as mineralization of soil organic matter. High intake of nitrates is a hazard to warm blooded animals under conditions that are favorable to reduction to nitrate. It reacts with hemoglobin to produce methemoglobin, which impairs transport and can be hazardous in infants under three months of age. The basis of this criterion is due to the potential risk to bottle fed infants and the absence of substantiated physiological effects at concentrations less than 10 mg/L. This criterion is set for domestic water supplies.

- 10 mg/L (as N) nitrate for domestic water supply (health)

Nutrients (Total Phosphorous and Nitrogen)

Nutrients, including total phosphorous and total nitrogen, are listed for aquatic life and recreation but do not have discreet levels, rather reference to the EPA Ecoregional Nutrient Criteria for Lakes/Reservoirs and Streams/Rivers. These are technical guidance manuals that describe a process that states/tribes can implement to adopt appropriate water quality standards for varying nutrient conditions in different waterbody types.

There are two ecoregions within the Central Valley Regional Water Quality Control Board jurisdiction; Ecoregion I - Willamette and Inland Valleys and Ecoregion II – Western Forested Mountains. These guidance manuals provide information to support the development of nutrient criteria in the specific regions. Currently, there is only guidance available for Lakes/Reservoirs in Ecoregion II and Streams/Rivers in Ecoregions I and II.

EPA has provided aggregate nutrient criteria for each Ecoregion, based on waterbody type see **Table 1**.

Table 1
Aggregate Ecoregional Nutrient Criteria

Nutrient	Lakes/Reservoirs		Streams/Rivers	
	Ecoregion I	Ecoregion II	Ecoregion I	Ecoregion II
Total P, µg/L	NA	8.75	47	10
Total N, mg/L	NA	0.1	0.31	0.12

*No guidance manual is available for Lakes/Reservoirs in Ecoregion I

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

Elemental Phosphorous

Elemental phosphorus is a key element required by plants, and it can lead to eutrophication of water. This form of phosphorus enters the waterways from various sources, including human excretions, detergents and industrial wastes. Diffuse sources into drainage to waterways include crop, forest, idle and urban lands, effluent from tile lines, return flows from irrigation, cattle feed lots, concentrated duck populations tree leaves and atmospheric fallout. The criterion is based on lethal levels to marine organisms and level that have been found to result in significant bioaccumulation.

- 0.10 µg/L for marine/estuarine waters

Phosphate Phosphorous

Concentrations greater than 100 µg/L may interfere with coagulation in water treatment plants. Concentrations greater than 25 µg/L at the time of spring turnover may stimulate excessive/nuisance growth of algae/aquatic plants, causing aesthetic unpleasantness. It also imparts an undesirable taste and odor to the water and alters the chemistry of a water supply.

- Phosphates as P should not exceed 50 µg/L in any stream at the point it enters any lake/reservoir, nor exceed 25 µg/L within a lake/reservoir.
- 100 µg/L in streams not discharging to lakes is the goal for prevention of plant nuisance.

Dissolved Solids (TDS)

TDS consists of inorganic salts, small amounts of organic matter and dissolved materials such as carbonates, chlorides, sulfates, nitrates, sodium, potassium, calcium and magnesium. These solids are known as “filterable residue.” TDS are objectionable in drinking water due to possible physiological effects, unpalatable mineral tastes and higher costs due to corrosion or the necessity for additional treatment. They can have a laxative effect on humans and some humans have an adverse reaction to sodium. Specific sodium levels for the entire water supply are not recommended but various restricted sodium intakes are recommended. Levels of 270 mg/L may be aesthetically unacceptable, however, many domestic water supplies exceed this amount. A level of 250 mg/L of chlorides is a reasonable maximum to set to protect consumers of drinking water based on taste panels conducted. Hazards for irrigation water are much higher, 500 mg/L had no effect on crops and 500 to 1000 mg/L affected sensitive crops.

- 250 mg/L for chlorides and sulfates in domestic water supplies for basic welfare

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

Strategy for Future Water Quality Standards and Criteria

Water quality standards and criteria are the foundation for a wide range of programs under the CWA. In 2003 the EPA published a strategy for water quality standards and criteria; *Setting Priorities to Strengthen the Foundation for Protecting and Restoring the Nation's Waters*. The strategy contains priority strategic actions that the EPA will undertake in collaboration with states and authorized tribes over the next six years to strengthen and improve this foundation. The strategy is the product of a review of the existing water quality standards and criteria program within the context of all clean water programs. The review focused on clean water goals, mandates and authorities, and the EPA's current strategic goals for clean water and other strategic planning efforts. The review also focused on major needs of the current water quality standards and criteria program and key programs linked to it. These include water quality monitoring, total maximum daily loads (TMDLs), National Pollutant Discharge Elimination System (NPDES) permits, non-point source programs, oceans and wetland programs, and source water protection.

The actions in the strategy are designed to fill major program gaps that the EPA has identified to achieve critical environmental results. They include:

- Help states strengthen water quality criteria for three pollutants (sedimentation, pathogens, and nutrients);
- Strengthen and maintain the scientific foundation of water quality programs, including targeting criteria development for specific pollutants of highest importance;
- Clarify for states how to implement key scientific and technical components of standards and criteria when regulating discharges;
- Establish important technical and policy linkages between the water quality standards and criteria program and other programs such as those that protect drinking water, and,
- Broaden participation in the water quality standards and criteria program with states and other stakeholders.

The strategy also presents ten strategic actions of highest priority. In February 2007, the EPA published an update on these highest priority strategic actions (see **Attachment 2**). Provided below are the actions as well as the current status of activities.

1. Issue implementation guidance for the 1986 bacteria criteria for recreation. EPA has promulgated analytical methods for ambient water and wastewater as well as issued the Beach Rule for coastal recreation waters. Currently, the EPA is working on an implementation guidance for inland waters.
2. Produce and implement a strategy for the development of pathogen criteria for drinking water and recreational use. Since 2003, the EPA has changed program priorities and this effort now only focuses on recreational use. Studies are on-

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

going that will provide the scientific foundation for new recreational criteria. These are expected to be issued in about five years (2012).

3. Produce and implement a strategy for the development of suspended and bedded sediment criteria. EPA has published a framework document and conducted a workshop.
4. Provide technical support to states and tribes for developing and adopting nutrient criteria and biological criteria. EPA has assisted states in developing nutrient criteria development plans as well as established a nutrient technical support website. EPA leadership developed a policy memo to support remaining state managers in establishing numeric nutrient criteria.
5. Develop and apply a systematic selection process to produce new and revised water quality criteria for chemicals to address emerging needs. Criteria have been developed for numerous constituents, including nutrients, and more will be coming. No other constituents of interest for the drinking water policy are listed at this time.
6. Complete the national Endangered Species Act consultation with the federal services on existing aquatic life criteria. A methodology has been agreed upon and was implemented for cyanide. Negotiations on next steps are in process.
7. Provide technical support, outreach, training and workshops to assist states and tribes with designated uses, include use attainability analyses (UAAs) and tiered aquatic life uses (TALUs). EPA conducted workshops in 2005 and 2006. A policy memo on the importance of UAAs was issued to regions and a clearinghouse of designated use case studies and examples was developed. EPA provided the regions with a draft method for TALUs to share with states and develop pilot applications. EPA is now focused on designated uses questions and answers, as well as a strategy/action plan for designated uses expected in 2007/2008.
8. Provide implementation support concerning technical issues affecting permits and TMDLs, beginning with technical support and outreach concerning the duration and frequency components of existing water quality criteria. EPA issued the Integrated Report Guidance for 2008 305(b) assessments and 303(d) listings, completed a compilation on regulations for mixing zones, and established a new branch for standards support. Currently, the EPA is focused on criteria implementation support documents for selected constituents, including nutrients.
9. Identify any drinking water source waters whose water quality standards do not protect the use, and work with EPA regions, states and tribes to correct any deficient standards as soon as possible. Investigation showed that 85 percent of designated uses were protected. EPA is encouraging states to increase coordination between source water protection programs and standards programs.
10. Develop a web-based clearinghouse for exchanging information on critical water quality standards issues, beginning with anti-degradation. A pilot site for anti-degradation was established for state review and a designated uses site with case studies was also established. EPA plans to provide public access to the anti-degradation site and add more use case studies.

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

DRINKING WATER SOURCE WATER REGULATORY LIMITS

The EPA established source water concentrations of organic carbon in the Stage 1 Disinfectants/Disinfection Byproduct Rule (D/DBR) and *Cryptosporidium* in the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that trigger additional treatment at water treatment plants. The purpose of this subtask is to present the methodology used to establish these limits.

Organic Carbon

The EPA developed the Stage 1 D/DBR to protect the public from potentially harmful disinfection byproducts (DBPs). The disinfectant reacts with natural organics, represented by total organic carbon (TOC), in the water to form disinfection byproducts. Many of these byproducts have a suggested association with being carcinogenic or causing reproductive and developmental issues, although there is no causal link.

The rule states the maximum residual disinfectant levels (MRDLs), maximum contaminant levels (MCLs) and variances thereof are based on the best available technology. The process to develop the rule was negotiated rulemaking. All stakeholders were involved in setting the proposed standards, including state and local health and regulatory agency staff, elected officials, consumer and environmental groups, and representatives of the public water systems (PWSs). All stakeholders agreed that there was a lack of information needed to understand the issue at hand; therefore they agreed to use what little information there was to propose the rule. They came up with the following four goals:

- Reduce the current total trihalomethane (TTHM) MCL,
- Regulate additional DBPs,
- Set limits on use of disinfectants, and
- Reduce the level of compounds that may react with disinfectants to form DBPs.

In drinking water systems, treatment techniques for DPB precursors include conventional filtration treatment required to remove a specific percentage of organic materials, such as organic carbon (OC). Removal of OC is done by a treatment technique; either enhanced coagulation or enhanced softening, unless the system meets the following alternative criteria:

- The system's source water TOC is less than 2.0 mg/L
- The system's treated water TOC is less than 2.0 mg/L
- The system's source water TOC less than 4.0 mg/L, its source water alkalinity is greater than 60 mg/L (as CaCO₃), and the system is achieving TTHM less than 40µg/L and HAA5 less than 30 µg/L (or the system has made a clear and irrevocable financial commitment to technologies that will meet the TTHM and HAA level)

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

- The system's TTHM is less than 40 μ g/L and HAA5 less than 30 μ g/L, and chlorine is used for primary disinfection and maintenance of a distribution system residual
- The system's source water specific ultraviolet absorbance (SUVA) prior to any treatment is less than or equal to 2.0 L/mg-m
- The system's treated water SUVA is less than or equal to 2.0 L/mg-m

The treatment technique requirement for TOC removal to reduce the formation of DBPs, via the methods above, has two steps of application. First, the rule specifies the percent of influent TOC that must be removed based on raw water TOC and alkalinity levels. If it is technically infeasible for systems to meet step one requirements, the rule sets alternative percent removal of raw TOC, which is determined by jar tests on at least a quarterly basis for a year. This percentage is determined after alum (or another ferric coagulant) is added in 10 mg/L increments until pH is lowered to a target pH level, which is based on alkalinity ranges. TOC removal is then plotted against the coagulant dose (both in mg/L) and the alternative TOC removal percentage is set a point of diminishing returns (PODR). This is the point on the plot where the slope changes from greater than 0.3/10 to less than 0.3/10 and remains less than that. If the system can't meet the PODR definition the water is considered "not amendable to enhanced coagulation" and TOC removal is not required if the PWS requests and is granted a waiver from the requirement by the state.

The major goal of the TOC removal treatment technique requirement was to minimize transactional costs to the states by limiting the number of systems seeking alternative performance criteria and in providing relatively simple methodologies for determining alternative performance criteria. The proposed TOC removal percentages and data supporting changes were developed with limited data and set with the intent that 90 percent of affected systems would be able to achieve them.

The EPA cites the following data supporting the use of SUVA as an exemption from treatment. SUVA (the UV-254 measured in m^{-1} divided by the DOC concentration measured as mg/L) is an indicator of how much DBP precursor material enhanced coagulation is able to remove. The humic matter significantly affects DBP formation upon chlorination. Coagulation primarily removes the humic portion of the natural organic matter in water. SUVA can indicate the amount of humic matter present in the water; therefore, this method is a logical indicator of enhanced coagulation's ability to remove humic substances. The final rule suggests a SUVA value of less than or equal to 2.0 L/mg-m as an exemption from the treatment technique.

Studies examining the relationship between increased coagulation dose and TOC removal for enhanced softening show some improvement in TOC removal with small doses of iron salts but no additional TOC removal during softening occurred with increased coagulation addition.

For softening plants the EPA has specified alternative compliance criteria. They are required to meet one of the three following alternative performance criteria:

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

- Produce a finished water with a SUVA of less than or equal to 2.0 L/mg-m
- Remove a minimum of 10 mg/L magnesium hardness (as CaCO₃)
- Lower alkalinity to less than 60 mg/L (as CaCO₃)

If any system is still unable to meet these criteria, they may apply to the state for a waiver from treatment technique requirements.

The EPA believes that enhanced coagulation would reduce the number of systems switching to alternative disinfectants, which is a goal of the regulatory committee. Even if the plants are meeting the required MCLs, they still must practice enhanced coagulation to decrease the risks posed by DBPs in general.

The EPA used the following studies to help determine these requirements. Singer et al., (1995) raised concerns that a significant number of waters, especially those low in TOC and high in alkalinity would not be able to meet required percentages and would need to use step 2 of the protocol to set alternative performance criteria. Malcolm Pirnie Inc. and Colorado University developed a nationally representative database on 127 source waters and used this data to develop a model to predict enhanced coagulation ability to remove TOC. This database was used to analyze the percent of TOC removal that is operationally feasible to achieve for the boxes of the TOC removal matrix. Nine predictive equations were developed for TOC removal to select the percent that could be reasonably obtained by 90 percent of the systems implementing enhanced coagulation.

Randtke et al., (1994) and Singer et al., (1995) studied data on full scale TOC removal obtained from 76 treatment plants of the American Water Works Service Co. The data were one time sampling events at each plant under their current operating conditions when enhanced coagulation was not practiced. The treatment of moderate TOC/low alkalinity water removed a greater percentage of the TOC than required by the removal matrix in 83 percent of the plants. Another 14 percent of plants treating low TOC/high alkalinity water met the TOC removal requirements. This data prompted lowering the TOC removal requirement in the first row of the matrix by 5 percent to enable 90 percent of plants to comply without going to step 2 requirements.

Cryptosporidium

Existing rules for microbial pathogens in drinking water include the Surface Water Treatment Rule (SWTR), the Total Coliform Rule, the Interim Enhanced Surface Water Treatment Rule (IESWTR), the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR), and the Filter Backwash Recycle Rule (FBRR). The EPA has established a maximum level contaminant level goal (MCLG) of zero for microbial pathogens in drinking water; including *Giardia*, viruses and legionella, as well as coliform bacteria.

Treatment technique requirements under these rules include the following aspects.

TECHNICAL MEMORANDUM Evaluation of Drinking Water Quality Goals

- Filtration of the source water unless specific avoidance criteria are met.
- Maintenance of a disinfectant residual in the distribution system, removal or inactivation of 3-log (99.9 percent) of *Giardia*, 4-log (99.99 percent) of viruses, and 2-log (99 percent) of *Cryptosporidium*.
- The maximum allowable turbidity in combined filter effluent is 1 NTU and the 95th percentile of 0.3 NTU or less.
- Return of recycled water upstream of point of primary coagulation.
- And watershed protection and source water quality requirements for unfiltered PWSs.

The purpose of the LT2ESWTR is to protect public health from illnesses caused by *Cryptosporidium* and other microbial pathogens in drinking water and to address risk and risk tradeoffs with the control of disinfection byproducts (DBPs). This new rule supplements existing microbial treatment regulations and targets PWSs with higher potential risks from *Cryptosporidium*. The existing regulations require filtering of water to remove at least 99 percent (2-log) of the *Cryptosporidium*, which is sufficient for most PWSs. However, there are some source waters that require additional treatment. Source water monitoring is now required to determine the average *Cryptosporidium* levels in source waters and then determine the extent of treatment those levels require.

Based on the results of the source water monitoring, systems will be classified in one of four risk categories (bins). The system's bin classification will determine the extent and type of additional *Cryptosporidium* treatment required beyond current regulations. A compliance value will be determined for each source water, either the mean of all samples (bi-weekly monitoring) or a maximum running annual average (monthly monitoring) to determine bin classification. **Table 2** provides a summary of bin classification for filtered systems.

Table 2
Bin Classification for Filtered Systems

<i>Cryptosporidium</i> Compliance Value	Bin Classification
<0.075 oocysts/L	Bin 1
$0.075 \leq x < 1.0$ oocysts/L	Bin 2
$1.0 \leq x < 3.0$ oocysts/L	Bin 3
≥ 3.0 oocysts/L	Bin 4

New information on *Cryptosporidium* risk management was utilized for development of the LT2ESWTR. The probability of infection related to the number of *Cryptosporidium* oocysts a person ingests is used to predict disease burden associated with a particular level in drinking water. This is derived from dose response studies of healthy human volunteers. The EPA analyzed two new studies along with the one older study to assess this association. Using two different dose-response models the analyses suggested that overall infectivity is greater than was estimated for the IESWTR. The mean probability of infection from one infectious oocyst is between 7 and 10 percent. This is 20 times higher than the 0.4 percent reported in the IESWTR. This information

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

was reanalyzed after evaluating three more studies and recommendations from the Science Advisory Board (SAB) to use a wider range of models. The EPA re-estimated *Cryptosporidium* infectivity data using the new data and six different dose-response models, which included the two used previously. The results estimated the probability of infection from 1 oocyst to range from 4 to 16 percent. There is still uncertainty about the infectivity of *Cryptosporidium*. There are variables, such as host susceptibility response at low oocyst doses typical of drinking water, and relative occurrence or infectivity in the environment. The EPA used a representative range of model results to address this uncertainty. All the models suggested the risk associated with a given concentration of *Cryptosporidium* is most likely higher than the EPA estimated for the IESWTR. This supports the need for increased treatment as required in the LT2ESWTR.

Information on the occurrence of *Cryptosporidium* oocysts in drinking water sources is a critical parameter for risk assessment and the need for additional treatment. Data was obtained from two national surveys, the Information Collection Rule (ICR) and the ICR Supplemental Surveys (ICRSS). This rule was designed to provide improved estimates of the oocyst occurrence on a national basis. The ICR included monthly samples from the sources of approximately 350 large PWSs over a span of 18 months. The ICRSS included twice monthly samples from sources of a simple random sample of 40 large and 40 medium PWSs over the span of 12 months using enhanced analytical and sample preparation methods. The results of these studies demonstrated two main differences for filtered PWSs in comparison to *Cryptosporidium* occurrence data used for the IESWTR. First, the occurrence is lower in many sources than was indicated by data used for the IESWTR. The median ICR and ICRSS levels are nearly 50 times lower than IESWTR estimates, although a subset of PWSs contain levels considerably greater than the median. Second, the occurrence is more variable from location to location than was shown by the data considered for the IESWTR. These findings supported a risk-targeted approach for the LT2ESWTR. This includes the additional *Cryptosporidium* treatment required only for filtered PWSs with the highest source water pathogen levels, and the requirement for unfiltered PWSs to take additional steps to obtain public health protection equivalent to filtered PWSs in regards to *Cryptosporidium* treatment.

When the EPA developed the IESWTR the best method to measure *Cryptosporidium* was the ICR method (ICR Protozoan Method). This method provided a quantitative measurement of oocysts, but it typically undercounted actual occurrence due to low method recovery. The EPA concluded the method was adequate for making national occurrence estimates in ICR surveys, but it would not suffice for making estimates of levels at specific sites. Subsequently the EPA developed the EPA Method 1622 (and later 1623), which improved *Cryptosporidium* methods to achieve higher recovery rates and lower inter and intra laboratory variability. These methods incorporate improvements in the concentration, separation, staining and microscope examination procedures. The ICRSS required this method.

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

The EPA concluded that the monitoring program using Methods 1622/1623 can be effective in characterizing PWSs source water *Cryptosporidium* levels for purposes of determining the need for additional treatment requirements. This supports the feasibility of risk targeted treatment requirements under the LT2ESWTR.

E. coli

The Advisory Committee for the LT2ESWTR recommended that small filtered PWSs initially monitor source water for *E. coli* for one year as a screening analysis. Biweekly sampling (i.e., 1 sample every two weeks) for *E. coli* is required to achieve high confidence in the results, since no additional monitoring is required if the *E. coli* level is less than the trigger value. Mean *E. coli* concentrations above 10 and 50 MPN/100 mL trigger *Cryptosporidium* monitoring in PWSs using reservoir/lake and flowing stream sources, respectively.

Data from the ICR and ICRSS were used in the investigation of indicators. *E. coli* performed the best in identifying sources with low *Cryptosporidium* levels. In addition, different relationships were identified between *E. coli* and *Cryptosporidium* in reservoir/lake sources compared to flowing stream sources.

The analysis of *E. coli* concentrations that could trigger *Cryptosporidium* monitoring was based on false negative and false positive rates. False negatives were defined as sources that do not exceed the *E. coli* trigger value but exceed a *Cryptosporidium* level of 0.075 oocysts/L. False positives were defined as sources that exceed the *E. coli* trigger value but do not exceed a *Cryptosporidium* level of 0.075 oocysts/L. The false negative rate characterizes the ability of the indicator to identify plants with higher *Cryptosporidium* levels that should conduct *Cryptosporidium* monitoring to determine if additional treatment is needed.

For plants with flowing stream sources, a mean *E. coli* trigger concentration of 50 MPN/100 mL produced zero false negatives for both ICR and ICRSS data sets. The false positive rate for this trigger concentration was near 50 percent, meaning it was not highly specific in targeting only those plants with high *Cryptosporidium* levels. For plants with lake or reservoir sources, a mean *E. coli* trigger of 10 MPN/100 mL resulted in a false negative rate of 20 percent with ICR data and 67 percent with ICRSS data. After evaluating these results, the Advisory Committee recommended that all large PWSs monitor for *Cryptosporidium*, rather than using *E. coli* in a screening analysis. The EPA concurred with this recommendation because it achieves the highest certainty that these PWSs will be classified in the correct *Cryptosporidium* treatment bin and provide the appropriate level of public health protection. In addition, the rule requires that large filtered PWSs collect *E. coli* and turbidity samples along with *Cryptosporidium*. The EPA will use these data to confirm or, if necessary, further refine the use of *E. coli* and possibly turbidity as indicators for monitoring by small filtered PWSs.

ATTACHMENT 1

Calculation of Freshwater Ammonia Criterion

1. The one-hour average concentration of total ammonia nitrogen (in mg N/L) does not exceed, more than once every three years on the average, the CMC (acute criterion) calculated using the following equations.

Where salmonid fish are present:

$$\text{CMC} = \frac{0.275}{1 + 10^{7.204-\text{pH}}} + \frac{39.0}{1 + 10^{\text{pH}-7.204}}$$

Or where salmonid fish are not present:

$$\text{CMC} = \frac{0.411}{1 + 10^{7.204-\text{pH}}} + \frac{58.4}{1 + 10^{\text{pH}-7.204}}$$

2A. The thirty-day average concentration of total ammonia nitrogen (in mg N/L) does not exceed, more than once every three years on the average, the CCC (chronic criterion) calculated using the following equations.

When fish early life stages are present:

$$\text{CCC} = \% \frac{0.0577}{1 + 10^{7.688-\text{pH}}} + \frac{2.487}{1 + 10^{\text{pH}-7.688}} \quad \square \quad \text{C MIN (2.85, 1.45 @ } 10^{0.028 \times (25-T)})$$

When fish early life stages are absent:

$$\text{CCC} = \% \frac{0.0577}{1 + 10^{7.688-\text{pH}}} + \frac{2.487}{1 + 10^{\text{pH}-7.688}} \quad \square \quad \text{C 1.45 @ } 10^{0.028 \times (25-\text{MAX}(T,7))}$$

2B. In addition, the highest four-day average within the 30-day period should not exceed 2.5 times the CCC.

ATTACHMENT 2

**STRATEGY FOR
WATER QUALITY STANDARDS AND CRITERIA¹**

Highest Priority Strategic Actions
Update – 2003 through February 2007

1. Issue implementation guidance for the 1986 bacteria criteria for recreation.

- Promulgated analytical methods for ambient water and wastewater
- Issued Beach Rule for coastal recreation waters, and related fact sheets that address some implementation issues for waters covered by the beach act
- **Current emphasis: implementation guidance for inland waters: answering a few key questions**

2. Produce and implement a strategy for the development of pathogen criteria for drinking water and recreational use.

- Per change of program priorities, focused primarily on criteria to protect recreational use.
- **Current emphasis: completing studies that will provide the scientific foundation for new recreational criteria that would be issued in about 5 years (this includes epidemiological studies for recreational waters); Pellston-style experts workshop (March 2007) to develop science plan for needed research to support new recreational criteria.**

3. Produce and implement a strategy for the development of suspended and bedded sediment criteria.

- Issued framework document
- Conducted workshop

4. Provide technical support to states and tribes for developing and adopting –
a. Nutrient criteria

- Assisted states/territories to develop nutrient criteria development plans; 45 are on target with implementation.
- Established nutrient technical support website (N-STEPS)
- **Current emphasis: developing a new Policy memo from senior EPA leadership to State and Regional managers emphasizing the need for State action to establish numeric nutrient criteria; implementing an expanded, targeted support strategy; issuing wetlands methods manual; developing demonstration project manuals for coastal waters, three estuaries.**

b. Biological criteria

¹ EPA Office of Science and Technology, August 2003, <http://www.epa.gov/ost/standards/strategy>

TECHNICAL MEMORANDUM

Evaluation of Drinking Water Quality Goals

- Assisted 25 states/territories to incorporate quantitative biological criteria into assessment process
- Issued large river method, ORD paper on statistical analysis
- **Current emphasis: management primer, continued support, coral reefs rapid assessment methodology, linkage paper defining relationships between biocriteria and other types of criteria**

5. Develop and apply a systematic selection process to produce new and revised water quality criteria for chemicals to address emerging needs.

- Issued criteria for nutrients, tributyl tin, nonylphenol, diazinon, 15 human health criteria (updates).
- **Current emphasis: developing criteria for selenium, copper, atrazine, endocrine disruptors; CTR selenium and PCP criteria; also, working with Office of Pesticide Programs on issue of how to best use OPP science and build on commonalities**

6. Complete the national consultation with the federal Services on existing aquatic life criteria.

- Reached agreement on BE methodology to use to pilot first national consultations on 304(a) criteria
- Developed biological evaluation for cyanide (first national consultation)
- **Current emphasis: Initiated negotiations with Senior Services management concerning major policy issues and next steps (these issues are also relevant to regional consultations on State standards)**

7. Provide technical support, outreach, training and workshops to assist states and tribes with designated uses, including use attainability analyses and tiered aquatic life uses.

- Conducted four co-regulator and three multi-stakeholder workshops in 2005-2006;
- Issued policy memo with case studies to regions on importance of UAAs and getting uses right
- Developed the Designated Uses Clearinghouse of documents and case studies and examples
- Issued draft methods for Tiered Aquatic Life Uses (TALU) to Regions to share with states and develop pilot applications
- **Current emphasis: Q&As on Designated Uses; Arid West-related designated uses Qs and As, Pacific Northwest Federal Dams Workshop; development of 2007/2008 Designated Uses Strategy/Action Plan, TALU implementation in water quality standards**

8. Provide implementation support concerning technical issues affecting permits and TMDLs, beginning with technical support and outreach concerning the duration and frequency component of existing water quality criteria.

- Issued Integrated Report Guidance for 2008 305(b) assessments and 303(d) listings addressing some duration/frequency issues.

TECHNICAL MEMORANDUM Evaluation of Drinking Water Quality Goals

- Completed compilation of EPA regulations, policy, guidance available on mixing zones.
- Established a new OST branch for Regional, State, and Tribal Standards Support.
- **Current emphasis: criteria implementation support documents for copper, mercury, selenium, atrazine, nutrients, saltwater dissolved oxygen; new framework for duration/ frequency;**

9. Identify any drinking-water source waters whose water quality standards do not protect the use, and work with regions, states, and tribes to correct any deficient standards as soon as possible.

- Letters sent to states concerning review of source waters and water quality standards.
- Conducted pilot evaluation of data linkages between intakes and designated uses.
- **Current emphasis: because review of WQS at sample of intake locations nationally showed designated uses were correct in about 85% of the cases, EPA response is to encourage states to increase coordination between state drinking water source water protection programs and state WQS programs.**

10. Develop a web-based clearinghouse for exchanging information on critical water quality standards issues, beginning with antidegradation.

- Established pilot antidegradation site for state review and ongoing state access.
- Established designated uses site with case studies, key guidance
- **Current emphasis: public access to antidegradation site; additional Uses case studies**

TECHNICAL MEMORANDUM Evaluation of Drinking Water Quality Goals

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