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Evaluation of the Basis for Drinking-Water Contaminant Level Goals and Maximum Contaminant Levels

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SAF/IEE requested AFIERA's assistance in conducting a historical assessment of environmental standards set by the Environmental Protection Agency (EPA) and the health risk levels indicated by the risk characterizations for contaminants. The objective of this report is to assess the appropriateness of using Maximum Contaminant Levels (MCLs) as groundwater cleanup goals compared to using the results of an actual site-specific risk assessment. AFIERA contracted with Mitretek Systems (MS) for this assessment. MS evaluated the relationships between chemical-specific toxicity values and MCLs for both carcinogens and noncarcinogens. In general, they reached two overall conclusions: first, MCLs are not an acceptable surrogate for site-specific baseline assessments for setting site-specific cleanup goals and for prioritizing site cleanups; second, chemicals that have been detected at AF installations are regulated less stringently by MCLs than chemicals that have not been detected at AF installations.

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EXECUTIVE SUMMARY

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Issue: Maximum Contaminant Levels (MCLs), which are enforceable standards for drinking water, are frequently used to evaluate whether the concentrations of contaminants found in groundwater sampled from hazardous waste site monitoring wells are of concern. MCLs are also often used as convenient cleanup goals for contaminated groundwater, making the major and often inappropriate assumption that the contaminants will reach a drinking-water supply without attenuation. If MCLs are to be used as preliminary benchmarks for evaluation of contaminants in groundwater, it is important to know how consistently MCLs represent human health risk.

Objective: The objective of this study was to assess the appropriateness of using MCLs as groundwater cleanup goals compared to using the results of an actual site-specific risk assessment.

Approach: The relationship between chemical-specific toxicity values and the MCLs was evaluated, together with the consistency of this relationship for both noncarcinogenic and carcinogenic chemicals. For those chemicals that did not demonstrate a consistent relationship, the basis for the MCL was investigated.

Background on setting of MCLs:

Categorization of Chemicals: Chemicals are categorized in three ways for the setting of MCLs.

- Category III Chemicals - Inadequate evidence of carcinogenicity or evidence of non-carcinogenicity via ingestion
- Category II Chemicals - Limited evidence of carcinogenicity via the drinking-water route of exposure
- Category I Chemicals - Known or probable human carcinogens

Methodology of setting MCLs:

- Category III Chemicals
    - o DWEL (mg/L) = [RfD (mg/kg - d) x 70 kg] / [2 L/d]
    - o MCLG (mg/L) = DWEL (mg/L) x RSC (unitless)
    - o Bottom line relationship: MCL = 7 x RfD

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- Category II Chemicals - Same as Category III with a 10-fold safety factor
  - DWEL (mg/L) = [RfD (mg/kg - day) x 70 kg] / [2 L/day]
  - MCLG (mg/L) = [DWEL (mg/L) x RSC (unitless)] / [10 (unitless)]
  - Bottom line relationship: MCL = 0.7 x RfD
- Category I Chemicals - To achieve maximum protection against cancer, MCLs are set at the feasible limit of analytical detection

Evaluation Details:

- Chemicals evaluated by category, separating into two groups based on whether or not they have been detected at Air Force installations
- Calculated the MCL to reference dose (RfD) ratio for categories II and III
- Calculated the MCL to calculated risk-based concentration ratio for category I chemicals

Results:

- Category III Air Force Chemicals
  - 15 of 22 chemicals had the expected MCL to RfD ratio within rounding deviation
  - 5 chemicals had less restrictive MCL to RfD ratios
    - 3 due to large relative source contributions (RSCs)
    - 1 due to analytical detection limit
    - 1 due to MCL being established for a health effect rather than the cosmetic effect which is the basis for the RfD
  - 1 more restrictive due to MCL being established with a now outdated RfD
- Category III non-Air Force chemicals
  - No unexpected MCL to RfD ratios
- Category II Air Force Chemicals
  - 2 Chemicals had less restrictive MCL to RfD ratios
    - 1 due to MCL being established with a now outdated RfD
    - 1 due to analytical limitations
- Category II non-Air Force Chemicals
  - 1 more restrictive MCL to RfD ratio due to MCL being established with a now outdated RfD
- Category I Air Force Chemicals
  - 8 of 15 chemicals are regulated with MCLs that may present a cancer risk greater than 1×10^{-5}
- Category I non-Air Force Chemicals
  - 2 of 7 chemicals are regulated with MCLs that may present a cancer risk greater than 1×10^{-5}

Conclusions:

- MCLs promulgated to date are based on rules and approaches that are readily understood and consistently applied
- MCLs are useful as preliminary benchmarks in evaluating concentrations of contaminants in water as if the sampled water were used directly for drinking
- Chemicals that have been detected at Air Force installations are regulated less restrictively by MCLs than those chemicals that have not been detected at Air Force installations
- MCLs are not acceptable surrogates for site-specific baseline risk assessments in setting site-specific cleanup goals and for prioritizing site cleanup
    - MCLs assume an exposure pathway that may not exist for groundwater at a given site
    - MCLs do not allow for attenuation of contaminant as water migrates to receptor population
    - The default RSC (0.20) generally used to calculate MCLs is not site-specific

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REPORT

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Evaluation of the Basis for Drinking-Water Maximum Contaminant Level Goals and Maximum Contaminant Levels[*]

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INTRODUCTION

Maximum Contaminant Levels (MCLs) are enforceable drinking-water standards set by the Environmental Protection Agency (EPA) as the maximum permissible concentration of contaminants in water delivered to any user of a public water system. The purpose of these standards is to prevent any adverse health effects that could result from chemical contaminants in public water supplies. Because these promulgated values are readily available, they are frequently used to evaluate whether the concentrations of contaminants found in groundwater sampled from hazardous waste site monitoring wells are of concern. Using MCL values in this manner is questionably within the intent of their development, especially since such use often results in their being instituted as the cleanup goals for contaminated groundwater. Such use of drinking-water standards for groundwater makes the major and often inappropriate assumption that the contaminants will reach a drinking-water supply without attenuation.

The preferred approach for determining cleanup requirements for any medium—including groundwater—is to conduct a site-specific baseline risk assessment. The risk assessment incorporates the toxicity of chemicals with a site-specific assessment of the existence of pathways by which the chemicals may reach receptors, thus posing risk. This assessment of site-specific risk is then appropriate for setting cleanup goals for contaminated media at the site.

The toxicity values incorporated into chemical risk assessments are developed by the EPA. These values are among the parameters used to establish the promulgated MCLs. The toxicity values are combined with generalized assumptions about water consumption and the relative contribution of drinking water to overall exposure to a given chemical in order to calculate a safe concentration of chemical in water—the MCL. For some chemicals, analytical feasibility and treatment feasibility are also used to derive MCLs.

Once derived, MCLs are proposed for public comment in the Federal Register and promulgated by the EPA as final rules after consideration of the public comments. Thus, MCLs are based in part on toxicity values combined with exposure assumptions considered appropriate for drinking water, but in some cases may be based on parameters that are unrelated to toxicity, such as analytical feasibility and treatment feasibility.

In an effort to assess the appropriateness of using MCLs as groundwater cleanup goals compared to using the results of an actual site-specific risk assessment, the relationship between the chemical-specific toxicity values and the MCLs was evaluated, together with the consistency of this relationship for both noncarcinogenic and carcinogenic chemicals.

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For those chemicals that did not demonstrate a consistent relationship, the basis for the MCL was investigated.

DEFINITIONS AND TECHNICAL BACKGROUND

The **Maximum Contaminant Level Goal** (MCLG) is the primary value developed by the EPA. It is the concentration of a contaminant in drinking water below which there is no known or expected risk to health. For chemicals that are known or probable human carcinogens (EPA Carcinogen Classification A, B1, and B2), it is EPA's policy to set an MCLG of zero because it is assumed—in the absence of other data—that there is no known threshold dose for carcinogenic effects. For chemicals with health effects other than cancer, the MCLG is derived from the Reference Dose (RfD) for that chemical. The MCLGs allow for a margin of safety and are non-enforceable public health goals.

The **MCL** is the highest concentration of a contaminant that is allowed in drinking water. MCLs are set as close to MCLGs as feasible based on a cost-benefit analysis of the best available treatment technology or based on limitations imposed by analytical feasibility. For most chemicals with health effects other than cancer, the MCL is equal to the MCLG. The MCLs are enforceable standards.

Drinking-water equivalent level (DWEL) is the concentration of a chemical in drinking water that will provide the RfD of that chemical to a 70-kilogram (kg) individual drinking 2 liters of water per day.

The **relative source contribution** (RSC) is a parameter used by the EPA to account for the possibility of human exposure from multiple sources when setting health-based criteria. The purpose of the RSC is to ensure that the concentration of a chemical allowed by a standard or multiple standards—when combined with other identified sources of exposure common to the population of concern—will not result in a total exposure that exceeds the RfD. The EPA has set a ceiling for the drinking-water RSC of 80 percent of the RfD and a floor of 20 percent of the RfD (U.S. EPA, 1991). Thus, the MCLG cannot account for more than 80 percent of the RfD or less than 20 percent of the RfD. EPA applies a default drinking-water RSC value of 20 percent to the RfD when adequate exposure data do not exist. However, there are two exceptions to this general policy: an RSC of 1 was used in setting the MCLG for both barium and fluoride.

RfDs are toxicity values derived primarily for use in risk assessments to estimate the likelihood of non-cancer health effects from exposure to specific chemicals. RfDs are the estimated total daily dose by various routes of individual chemicals to which a person can be chronically exposed without appreciable risk of deleterious non-cancer health effects. For many non-carcinogenic effects, protective biological mechanisms are believed to exist that must be overwhelmed before adverse health effects are manifested. Therefore, a range of doses exists—from zero to some finite threshold dose—that can be tolerated by an organism with essentially no chance of producing adverse effects. RfDs are established in an attempt to define the upper limit of this dose range below which no adverse effects are expected even in the most sensitive populations, such as children and the elderly.

Like RfDs, **Cancer Slope Factors** (CSFs) for chemicals are derived primarily for use in risk assessments. In the case of establishing MCLs for drinking water, only the oral CSF will be considered. For carcinogenic chemicals, it is assumed that only a small number of molecular events are necessary to produce changes in a single cell that can lead to uncontrolled cellular proliferation and cancer. The hypothesized mechanism for carcinogenesis is referred to as "nonthreshold" because it theoretically predicts that any finite dose (even a single molecule) could affect a single cell and thus produce a finite probability, however small, of causing cancer. Therefore, in evaluating cancer risk, an effect threshold cannot be assumed. For carcinogenic effects, a proportionality factor—designated a slope factor—is derived. The CSF defines quantitatively the relationship between the dose and the probability of carcinogenic response. This CSF is used in risk assessments to calculate an estimate of the probability that a carcinogenic response will occur in exposed individuals.

Establishing MCLGs and MCLs

The method used by the EPA to establish MCLGs and thus MCLs depends on the category of chemical under consideration (U.S. EPA, 1991; U.S. EPA, 2002). **Category I** chemicals are known or probable human carcinogens (EPA Carcinogen Classifications A, B1, and B2). **Category II** chemicals are those for which there is limited evidence of carcinogenicity (EPA Carcinogen Classification C) via the drinking-water route of exposure considering available weight of evidence, pharmacokinetic, and exposure information. **Category III** chemicals are those for which there is inadequate evidence of carcinogenicity or evidence of non-carcinogenicity for humans (EPA Carcinogen Classifications D and E) via ingestion. These methods are described below, starting with the noncarcinogenic (Category III) chemicals, followed by the methods for the Category II and Category I chemicals.

Establishing MCLs for Category III Chemicals

For Category III chemicals, those for which there is inadequate evidence of carcinogenicity or evidence of noncarcinogenicity, the MCLGs are generally derived from the RfD in a two-step process. First, the DWEL is calculated from the RfD based on the assumption that a 70 kg individual drinks 2 liters of water per day. The DWEL is the concentration of a chemical in drinking water that will provide such an individual with the RfD on a daily basis.

$$\text{DWEL (mg/L)} = [\text{RfD (mg/kg - d)} \times 70 \text{ kg}] / [2 \text{ L/d}]$$

The second step develops the MCLG (rounded to one significant figure) by multiplying the DWEL by the RSC (see above).

$$\text{MCLG (mg/L)} = \text{DWEL (mg/L)} \times \text{RSC (unitless)}$$

For Category III chemicals, the MCL is set equal to the MCLG (U.S. EPA, 1992). However, there is one exception to this general rule. The MCL for thallium is higher than the MCLG because of the limitation of analytical feasibility.

Establishing MCLs for Category II Chemicals

For Category II chemicals, those for which there is limited evidence of carcinogenicity by ingestion, there are two methods available to establish the MCL. The first approach described has been used for *all* Category II chemicals for which MCLs have been published. However, the second approach is available for any future situations where valid noncarcinogenicity data are not available and adequate experimental data are available to quantify the cancer risk.

For those Category II chemicals for which an RfD has been established (all Category II chemicals for which MCL have been promulgated to date), the MCLG (rounded to one significant figure) is derived by the same equations as for the Category III chemicals, with the exception that a tenfold safety factor is incorporated (U.S. EPA, 1992). Thus the two equations for establishing the MCLGs for these chemicals are as follows:

$$\text{DWEL (mg/L)} = [\text{RfD (mg/kg - day)} \times 70\text{ kg}] / [2\text{ L/day}]$$

$$\text{MCLG (mg/L)} = [\text{DWEL (mg/L)} \times \text{RSC (unitless)}] / [10\text{ (unitless)}]$$

In these cases, the MCL is set equal to the MCLG. However, there is one exception to this general rule: the MCL for 1,1,2-trichloroethane is higher than the MCLG because of the limitation of analytical feasibility.

If an RfD had not been established for a Category II chemical, an MCLG would be derived using a conservative calculation such that the ingestion of contaminated water would result in a calculated nominal lifetime cancer risk in the range of 10^{-5} to 10^{-6} (U.S. EPA, 1992). The MCL is then set equal to the MCLG or a feasible analytical concentration. For the MCL, the EPA sets a maximum excess individual cancer risk range of 10^{-4} to 10^{-6} (U.S. EPA, 1992).

Establishing MCLs for Category I Chemicals

For Category I chemicals, the known or probable human carcinogens, it is EPA's policy to set the MCLGs at zero. The MCL for each of these chemicals is set as close as possible to the MCLG based on the limitation of analytical feasibility. As with the MCL for Category II chemicals, the EPA sets a maximum excess individual cancer risk range of 10^{-4} to 10^{-6} for the Category I chemicals (U.S. EPA, 1992).

EVALUATION APPROACH

For each of the three categories of chemicals for which the EPA has established MCLs, there should be a different but relatively consistent mathematical relationship to the toxicity values. In the case of the Category III and many of the Category II chemicals, this correlation will be directly dependent on the RfD. In the case of Category I chemicals, a relationship is more likely to exist with a contaminant concentration derived using the CSF, depending on the degree of limitation by analytical feasibility. This evaluation addressed all organic chemicals for which MCLs have been developed and for all inorganic chemicals, with the exception of asbestos.

To evaluate the consistency of these mathematical relationships for Category III chemicals, the ratio of the MCL and the RfD was calculated and tabulated. Inconsistent values were readily recognized; the bases for these MCLs were further investigated and are described in the Evaluation Results section.

The MCLG, and thus MCLs, for Category II chemicals could be developed by two methods. Because the method based on the RfD is the only approach used in the Category II MCLs promulgated to date, the MCL to RfD ratio was calculated and tabulated. This approach again permitted identification of inconsistent ratio values; the basis for those MCLs were further investigated and are described in the Evaluation Results section.

Although the MCLs for Category I chemicals are established based on limitations imposed by the analytical detection of each chemical, these concentrations are intended by the EPA to ensure that the risk posed by the contaminant does not exceed a targeted maximum excess individual cancer risk range of 10^{-4} to 10^{-6}. Therefore, the MCL for each of these chemicals was compared to the risk-based concentration (RBC) that would result in an excess cancer risk of 10^{-6}. The RBC was calculated for a conservative exposure scenario. The ratio of the MCL of Category I chemicals to these RBCs provides a measure of the effectiveness of the MCL at limiting risk.

EVALUATION RESULTS

The results of the evaluation of numerical relationships between MCLs and toxicity values (RfDs or concentrations derived using CSFs) for the three chemical categories for which MCLs are derived are provided in Tables 1 through 3. This presentation allows a comparison of the chemicals within each category with respect to the consistency of the relationship between the MCL and a risk-based value for each chemical. For each category, the chemicals are separated into two groups based on whether or not they have been detected at Air Force installations. Within each group, the chemicals are ordered by the ratio between the MCL and the risk-based value, from lowest to highest.

Category III Chemicals

Table 1 presents a comparison of the MCL to RfD ratios among Category III chemicals. For these chemicals, the equations used to calculate the MCL from the RfD are relatively straightforward, as described above. These equations predict a MCL to RfD ratio of 7 for Category III chemicals if the default RSC value of 0.2 is used. All of the chemicals that have not been detected at Air Force installations have the expected MCL to RfD ratio. The variation observed in the ratios for these chemicals—between 5 and 10—is a result of the rounding to a single significant figure.

Of the chemicals that have been detected at Air Force installations, 14 of the 22 chemicals had the expected MCL to RfD ratio within rounding deviation. Three of the remaining chemicals—antimony, chromium, and barium—have greater-than-predicted MCL-to-RfD ratios of 15, 20, and 28.6, respectively, because RSC values of 0.4, 0.7, and 1, respectively, were used to derive their MCLs.

The greater-than-predicted MCL-to-RfD ratio for thallium is the result of current analytical detection limits that are greater than the MCLG. The MCLG for thallium is 0.0005 mg/L, almost exactly seven times the RfD of 0.00007 mg/kg-d, indicating that the approach for deriving an MCLG from the RfD was consistent with the described methodology. However, analytical detection limitations required the MCL to be established at 0.0002 mg/L.

The fluoride MCL-to-RfD ratio of 66.7 is an outlier because the RfD (0.06 mg/kg-d) in Table 1 is derived from a cosmetic effect, dental fluorosis. The MCL was developed using an RfD based on a different effect, crippling skeletal fluorosis. Continuous oral exposure of humans to fluoride for 20 years or longer resulted in a lowest observable adverse effect level (LOAEL) of 20 mg/kg/day. The LOAEL was divided by an uncertainty factor of 2.5 and a

Table 1. Comparison of Drinking-Water Maximum Contaminant Limits for Category III Chemicals to Their Oral Reference Dose Toxicity Values

CHEMICAL	US EPA MCLG[a] (mg/L)	US EPA MCL[a] (mg/L)	RfD[b] (mg/kg-d)	MCL / RfD (unitless)
Detected at Air Force Installations[c]				
1,1,1-Trichloroethane	2.0E-01	2.0E-01	2.0E-01	1.0
Xylenes (total)	1.0E+01	1.0E+01	2.0E+00	5.0
Toluene	1.0E+00	1.0E+00	2.0E-01	5.0
trans-1,2-Dichloroethylene	1.0E-01	1.0E-01	2.0E-02	5.0
Chlorobenzene	1.0E-01	1.0E-01	2.0E-02	5.0
2,4,5-TP (Silvex)	5.0E-02	5.0E-02	8.0E-03	6.3
Mercury (inorganic)	2.0E-03	2.0E-03	3.0E-04[d]	6.7
o-Dichlorobenzene	6.0E-01	6.0E-01	9.0E-02	6.7
Endrin	2.0E-03	2.0E-03	3.0E-04	6.7
Ethylbenzene	7.0E-01	7.0E-01	1.0E-01	7.0
cis-1,2-Dichloroethylene	7.0E-02	7.0E-02	1.0E-02	7.0
1,2,4-Trichlorobenzene	7.0E-02	7.0E-02	1.0E-02	7.0
Methoxychlor	4.0E-02	4.0E-02	5.0E-03	8.0
Cadmium	5.0E-03	5.0E-03	5.0E-04	10.0
Selenium	5.0E-02	5.0E-02	5.0E-03	10.0
Cyanide (as free cyanide)	2.0E-01	2.0E-01	2.0E-02	10.0
Antimony	6.0E-03	6.0E-03	4.0E-04	15.0
Chromium (total)	1.0E-01	1.0E-01	5.0E-03	20.0
Barium	2.0E+00	2.0E+00	7.0E-02	28.6
Thallium	5.0E-04	2.0E-03	7.0E-05	28.6
Fluoride	4.0E+00	4.0E+00	6.0E-02	66.7
Copper	1.3E+00	e		
Not Detected at Air Force Installations[c]				
Endothall	1.0E-01	1.0E-01	2.0E-02	5.0
Nitrate (measured as Nitrogen)	1.0E+01	1.0E+01	1.6E+00	6.3
Dalapon	2.0E-01	2.0E-01	3.0E-02	6.7
Glyphosate	7.0E-01	7.0E-01	1.0E-01	7.0
Dinoseb	7.0E-03	7.0E-03	1.0E-03	7.0
2,4-D	7.0E-02	7.0E-02	1.0E-02	7.0
Picloram	5.0E-01	5.0E-01	7.0E-02	7.1
Carbofuran	4.0E-02	4.0E-02	5.0E-03	8.0
Oxamyl (Vydate)	2.0E-01	2.0E-01	2.5E-02	8.0
Hexachlorocyclopentadiene	5.0E-02	5.0E-02	6.0E-03	8.3
Diquat	2.0E-02	2.0E-02	2.2E-03	9.1
Nitrite (measured as Nitrogen)	1.0E+00	1.0E+00	1.0E-01	10.0

a. U.S. EPA, 2002a.
b. ORNL, 2002, except for mercury (see footnote d)
c. Hunter (2002) personal communication.
d. U.S. EPA, 1997b.
e. Regulated by treatment technology to control corrosiveness

drinking-water intake of 2 liters per day to obtain the MCLG, then the MCL was set equal to the MCLG. Drinking water was considered to be the only source of fluoride exposure for the calculation (RSC=1) (U.S. EPA, 1986). Interestingly, at about the same time, EPA published a secondary maximum contaminant level (SMCL) for fluoride of 2.0 mg/L to protect against dental fluorosis, which is considered to be an adverse cosmetic effect (U.S. EPA, 1986). This SMCL is equal to the 0.06 mg/kg-d RfD presented in Table 1, multiplied by 70 kg, divided by 2 liters, and multiplied by a RSC of 1.

The MCL-to-RfD ratio of 1 for 1,1,1-trichloroethane is an additional outlier for Category III chemicals detected at Air Force installations. This is because the RfD of 0.035 mg/kg-d used to derive the MCLG for 1,1,1-trichlorethane has been withdrawn (U.S. EPA, 2002b) and has been replaced with a provisionary value of 0.2 mg/kg-d (ORNL, 2002). The ratio of the 0.2 mg/L MCL to the outdated RfD of 0.035 mg/kg-d is 5.7, which reflects consistent application of the approach for Category III chemicals. The health effects resulting from exposure to 1,1,1-trichloroethane are being reassessed, and the MCL could be modified as a result of this assessment (U.S. EPA, 2002).

Copper is another Category III chemical detected at Air Force installations. It is regulated on the basis of a required treatment technology to control corrosiveness rather than an enforceable concentration standard. The EPA has not developed an RfD for copper, because data are not available to do so (U.S. EPA, 1987).

Category II Chemicals

Table 2 presents a comparison of the MCL-to-RfD ratios among Category II chemicals. For these chemicals, the equations used to calculate the MCL from the RfD are the same as the equations for Category III chemicals, with the addition of a safety factor—generally 10—as described above. These equations predict a MCL-to-RfD ratio of 0.7 for these chemicals if the default RSC is used.

Six of the nine MCL-to-RfD ratios for Category II chemicals are in the range of 0.5 to 0.8, within rounding variation of the expected 0.7 value. Of the six Category II chemicals detected at Air Force installations, the MCL-to-RfD ratios of two chemicals—1,1,2-trichloroethane and beryllium—have greater-than-predicted ratios.

The greater-than-predicted MCL-to-RfD ratio for 1,1,2-trichloroethane is the result of current analytical detection limits. The MCLG for 1,1,2-trichloroethane is 0.003, which is 0.75 times the RfD of 0.004, indicating that the approach to deriving the MCLG was consistent with the methodology described for Category II chemicals. However, analytical detection limitations required the MCL to be established at 0.005 mg/L.

Beryllium has the highest MCL-to-RfD ratio among the Category II chemicals detected at Air Force installations. This different-than-expected ratio resulted because the MCLG for beryllium was based on an RfD of 0.005 mg/kg-d, which has since been updated to 0.002 mg/kg-d. The ratio of the beryllium MCL and the dated RfD used to derive it is 0.8; this demonstrates a consistent application of the described approach for deriving MCLGs for Category II chemicals.

Beryllium is a somewhat unique compound in that it is classified as a Group B1 carcinogen yet is treated as a Category II chemical for setting the MCL. This is because the evidence

Table 2. Comparison of Drinking-Water Maximum Contaminant Limits for Category II Chemicals to Their Oral Reference Dose Toxicity Values

CHEMICAL	US EPA MCLG[a] (mg/L)	US EPA MCL[a] (mg/L)	RfD[b] (mg/kg-d)	MCL / RfD (unitless)
Detected at Air Force Installations [c]				
Styrene	1.0E-01	1.0E-01	2.0E-01	0.5
Lindane	2.0E-04	2.0E-04	3.0E-04	0.7
p-Dichlorobenzene	7.5E-02	7.5E-02	1.0E-01	0.8
1,1-Dichloroethylene	7.0E-03	7.0E-03	9.0E-03	0.8
1,1,2-Trichloroethane	3.0E-03	5.0E-03	4.0E-03	1.3
Beryllium	4.0E-03	4.0E-03	2.0E-03	2.0
Not Detected at Air Force Installations [c]				
Atrazine	3.0E-03	3.0E-03	3.5E-02	0.1
Di(2-ethylhexyl) adipate	4.0E-01	4.0E-01	6.0E-01	0.7
Simazine	4.0E-03	4.0E-03	5.0E-03	0.8

a. US EPA. 2002a
b. ORNL 2002
c. Hunter (2002) personal communication

for the carcinogenicity of beryllium is derived from inhalation studies. Studies using oral exposure do not provide adequate information for the assessment of carcinogenicity via this exposure route.

The beryllium RfD used to derive the MCLG was based on a study of the effects of lifetime oral exposure to beryllium in drinking water (Schroeder and Mitchener, 1975). The current RfD (0.002 mg/kg-d) was derived from a later study (Morgareidge et al., 1976) in which animals were exposed to beryllium in the diet. As recognized by the EPA, the RfDs derived from these two studies are not significantly different (U.S. EPA, 1998).

Among the three Category II chemicals that have not been detected at Air Force installations, atrazine is the only one for which the MCL-to-RfD ratio is not the predicted value. This anomaly results from a difference in the RfD presently listed for atrazine (0.035 mg/kg-d) and the RfD (0.005 mg/kg-d) used by to derive the MCLG (U.S. EPA, 1991). The ratio of the atrazine MCL to the RfD used to derive it is 0.6, showing a consistent application of the described approach for deriving MCLGs for Category II chemicals.

The lower RfD used to develop the atrazine MCLG was based on an earlier interpretation of a dog study (Ciba-Geigy, 1987). Subsequent interpretation of this study based on additional information from the study (Ciba-Geigy, 1989) and a rat study showing a higher LOAEL (Ciba-Geigy, 1987a) resulted in raising the RfD by a factor of seven to 0.035. The MCL remains unchanged because a reassessment of the health effects of atrazine is ongoing (U.S. EPA, 2002).

Category I Chemicals

Table 3 presents a comparison among the ratios of the MCL to the RBC of Category I chemicals. For Category I chemicals, which are known or probable human carcinogens, the MCLG is set at zero and the MCL is set as low as analytical technology will permit. The RBC of each Category I chemical that would result in an estimated excess individual cancer risk to 1×10^{-6} was calculated for a 70 kg person consuming 2 liters of water per day 350 days per year over a 30-year period of a 70-year lifetime. Therefore, the risks delineated below would only be realized if water containing the chemical at the MCL was consumed under the described exposure scenario.

The MCL-to-RBC ratios in Table 3 provide the numerical relationships between the MCLs, which are limited by analytical feasibility, and the cancer risk. A ratio between 1 and 10 means that the MCL limits excess cancer risk to the range of 1×10^{-6} and 1×10^{-5}, a risk that is generally considered acceptable and is frequently the starting point for cleanup decisions. Ratios greater than this range indicate a proportionately greater risk resulting from the analytically limited MCLs.

Of the 16 Category I chemicals that have been detected at Air Force installations, 7 have MCL-to-RBC ratios less than 10, within the range of cancer risk that is generally considered acceptable. The next 7 chemicals have MCL-to-RBC ratios ranging from 10 to 100, or excess cancer risk between 1×10^{-5} and 1×10^{-4}.

Only one chemical—arsenic—presents a risk in excess of 1×10^{-4} at the MCL. The ratio of its MCL to the RBC is 176, which indicates a risk of 1.76×10^{-4}. Because arsenic is a naturally occurring chemical, the cost of compliance for a lower enforceable concentration could be substantial for public water systems. The present MCL of 0.01 mg/L was published in January 2001. Compliance with this new standard is required by 2006. This new standard represents a change in the value of 0.05 mg/L, which has been in place since 1975. It will require the development of new technologies to allow public water suppliers to comply. The change in this standard was the subject of long and controversial deliberations, requiring consideration of the cost of compliance against the risk indicated by certain studies of health effects (U.S. EPA, 2002c).

The remaining chemical detected at Air Force installations—lead—is regulated on the basis of a required treatment technology, rather than an enforceable concentration standard. In addition, there is no CSF for lead. According to the EPA, "[Q]uantifying lead's cancer risk involves many uncertainties, some of which may be unique to lead. Age, health, nutritional state, body burden, and exposure duration influence the absorption, release, and excretion of lead. In addition, current knowledge of lead pharmacokinetics indicates that an estimate derived by standard procedures would not truly describe the potential risk. Thus, the EPA Carcinogen Assessment Group recommends that a numerical estimate not be used" (U.S. EPA, 1997a).

For the nine Category I chemicals that have not been detected at Air Force installations, five chemicals have ratios of less than 10, within the range of cancer risk that is generally considered acceptable. Two chemicals—hexachlorobenzene and toxaphene—have ratios of 18.8 and 38.7, respectively, indicating excess cancer risks of 1.88×10^{-5} and 3.87×10^{-5}, respectively, at the MCL. Two chemicals on this list—acrylamide and epichlorohydrin—

Table 3. Comparison of Drinking-Water Maximum Contaminant Limits for Category I Chemicals to Concentrations Derived using the Oral Cancer Slope Factor and Conservative Values for Risk Characterization Parameters

CHEMICAL	US EPA MCLG[a] (mg/L)	US EPA MCL[a] (mg/L)	RfD[b] (mg/kg-d)	CSF[b] (mg/kg-d) $^{-1}$	RBC[c] (mg/L)	MCL / RBC (unitless)
Detected at Air Force Installations [d]						
Trichloroethylene	zero	5.0E-03	6.0E-03	1.1E-02	7.7E-03	0.6
Pentachlorophenol	zero	1.0E-03	3.0E-02	1.2E-01	7.1E-04	1.4
Tetrachloroethylene	zero	5.0E-03	1.0E-02	5.2E-02	1.6E-03	3.1
Benzene	zero	5.0E-03		5.5E-02	1.5E-03	3.2
1,2-Dichloropropane	zero	5.0E-03		6.8E-02	1.3E-03	4.0
1,2-Dichloroethane	zero	5.0E-03		9.1E-02	9.4E-04	5.3
Chlordane	zero	2.0E-03	5.0E-04	3.5E-01	2.4E-04	8.2
Polychlorinated Biphenyls	zero	5.0E-04		2.0E+00	4.3E-05	11.7
Benzo(a)pyrene (PAHs)	zero	2.0E-04		7.3E+00	1.2E-05	17.1
Heptachlor	zero	4.0E-04	5.0E-04	4.5E+00	1.9E-05	21.1
Heptachlor Epoxide	zero	2.0E-04	1.3E-05	9.1E+00	9.4E-06	21.4
Vinyl Chloride	zero	2.0E-03	3.0E-03	1.4E+00	6.1E-05	32.9
Ethylene Dibromide	zero	5.0E-05		8.5E+01	1.0E-06	49.9
2,3,7,8-Tetrachlorodibenzo-P-Dioxin	zero	3.0E-08		1.5E+05	5.7E-10	52.8
Arsenic	zero	1.0E-02	3.0E-04	1.5E+00	5.7E-05	176.1
Lead	zero	e	f			
Not Detected at Air Force Installations [d]						
Dichloromethane	zero	5.0E-03	6.0E-02	7.5E-03	1.1E-02	0.4
Di(2-ethylhexyl) phthalate	zero	6.0E-03	2.0E-02	1.4E-02	6.1E-03	1.0
Alachlor	zero	2.0E-03	1.0E-02	8.0E-02	1.1E-03	1.9
1,2-Dibromo-3-Chloropropane	zero	2.0E-04		1.4E+00	6.1E-05	3.3
Carbon Tetrachloride	zero	5.0E-03	7.0E-04	1.3E-01	6.6E-04	7.6
Hexachlorobenzene	zero	1.0E-03	8.0E-04	1.6E+00	5.3E-05	18.8
Toxaphene	zero	3.0E-03		1.1E+00	7.7E-05	38.7
Acrylamide	zero	g	2.0E-04	4.5E+00	1.9E-05	
Epichlorohydrin	zero	g	2.0E-03	9.9E-03	8.6E-03	

a. US EPA. 2002a

b. ORNL. 2002

c. Calculated based on a cancer risk of 10^{-6} for a 70 kg individual drinking 2 L of water per day 350 days per year for 30 years and a 70 yr lifetime

d. Hunter (2002) personal communication

e. Regulated by treatment technology to control corrosiveness

f. EPA RfD Work Group considers it inappropriate to develop an RfD for lead http://www.epa.gov/iris/test/subst/0277.htm

g. Regulated by treatment technology for water clarification are regulated on the basis of a required treatment technology rather than an enforceable concentration standard.

CONCLUSIONS AND DISCUSSION

This study has examined the basis for the MCLs that have been promulgated to date, as a means of evaluating consistency in the use of the stated rules for establishing MCLs and the relevance of the MCLs to quantifiable risk. The EPA uses three approaches to establish MCLs for three different categories of chemicals. For Categories II and III, the approaches are similar; the only difference is the application of a tenfold safety factor to Category II chemicals. For Category I chemicals, known or probable human carcinogens, the MCLG is set at zero, representing an intention to provide maximum protection and a belief that these chemicals cause cancer by a non-threshold mechanism. For these chemicals, the enforceable concentration, MCL, is set as close to zero as possible, limited by analytical detection.

For Categories II and III, this evaluation demonstrated a consistent use of the rules defined for the establishment of MCLs. A few chemicals were identified as outliers on the basis of a ratio of MCL to RfD that did not fall within the expected range. These outliers were explained on the basis of the use of RSC values that differed from the default value of 0.2, or the use of an RfD different than the one currently used in baseline risk assessments.

For Category III chemicals that have not been detected at Air Force installations, there were no outliers from the expected MCL-to-RfD ratio. For Category III chemicals that have been detected at Air Force installations, five outliers could be identified with MCLs that were higher (less stringent) than predicted by the expected MCL-to-RfD ratio. Three of these anomalies—for antimony, chromium, and barium—were due to the use of RSC values greater than the 0.2 default value. Thallium was an outlier because of analytical limitations on the MCLG. Fluoride was an outlier because the listed RfD was derived for a cosmetic effect, while the MCL was developed to protect against crippling skeletal fluorosis, which occurs only at a higher dose.

One of the Air Force chemicals—1,1,1-trichloroethane—was an outlier in the more stringent direction, with a lower than expected MCL-to-RfD ratio. This was due to using a RfD that has since been withdrawn and replaced by a provisional RfD that is nearly sixfold greater. The health effects resulting from exposure to 1,1,1-trichloroethane are being reassessed, and the MCL could be modified in the future as a result of this assessment (U.S. EPA, 2002).

Of the three Category II chemicals that have not been detected at Air Force installations, one—atrazine—is an outlier because the MCL was developed using a RfD that has since been revised.

Among the six Category II chemicals that have been detected at Air Force installations, beryllium was the only one for which the MCL-to-RfD comparison fell outside the expected ratio; this was due to the use of a slightly less restrictive RfD than the one that is presently used. The EPA has stated that the difference between the two RfDs is not significant.

For Category I chemicals, 2 of 7 chemicals classified as known or probable carcinogens that have not been detected at Air Force installations are regulated by MCLs that may present a cancer risk slightly greater than 1×10^{-5}. For Category I chemicals that have been detected at Air Force installations, 8 of 15 chemicals are regulated with MCLs that may present a cancer risk greater than 1 x 10^{-5}; the cancer risk for one of these—arsenic—may exceed 1 x 10^{-4}.

On the whole, the chemicals that have been detected at Air Force installations are regulated less stringently by MCLs than those chemicals that have not been detected at Air Force installations.

In considering the applicability of MCLs to cleanup decisions at hazardous waste sites, the consistency in MCL development and the relative consistency of their relationship to risk based concentrations create confidence in their use as a preliminary benchmark in evaluating concentrations of contaminants in water as if the sampled water were used directly for drinking. However, for setting actual site-specific cleanup goals and for prioritizing site cleanup, MCLs are not an acceptable surrogate for site-specific baseline risk assessments for a number of reasons.

The MCL assumes that the sampled water will be consumed by a population of humans at a rate of 2 liters per day. A site-specific risk assessment should evaluate the existence of pathways of migration of the contaminated water into the drinking-water supply of an actual human-receptor population, as well as the attenuation of the contaminant over the course of any such migration. If no such pathway or population exists, the risk is essentially zero. If a pathway exists but the contaminant will experience attenuation in the migration process, the risk could be considerably less, depending on the magnitude of the diminution in contaminant concentration. If a pathway exists and the water represents the only source of the contaminant, then the default value of 0.2 used for RSC for 90 percent of MCLs developed for Category II and III chemicals is invalid. In such cases, the concentration of a chemical up to five times the MCL would be expected to have no adverse health effects.

In summary, the MCLs promulgated to date are based on rules and approaches that are readily understandable and consistently applied. The MCLs should be effective in preventing any occurrence of non-carcinogenic health effects and keeping cancer risk at or below a ceiling of 10^{-4}. The MCL may serve as a preliminary benchmark in the evaluation of concentrations of contaminants in water *as if* the sampled water were to be used directly for drinking. They are not, however, acceptable surrogates for a properly executed site-specific baseline risk assessment when establishing cleanup goals and priorities.

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CORRESPONDENCE

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STAFF SUMMARY SHEET

	TO	ACTION	SIGNATURE (*Surname*), GRADE AND DATE		TO	ACTION	SIGNATURE (*Surname*), GRADE AND DATE
1	AFIERA/ CA	Coord	Hossain, Col, 3 Sep 02	6			
2	311HSW/ CCEA	Process	T. Dehy E-7 9/4/02	7			
3	311 HSW/ CV	Coord	Stuart R Lowder, O-6, 13SEP02	8			
4	311 HSW/ CD	Coord	[illegible] 12 [illegible]	9			
5	311 HSW/ CC	Sign	Dodd, Brig Gen, 20 Sep	10	AFIERA/ CD Sec		Phelt, GS-08, 29 Aug 02

SURNAME OF ACTION OFFICER AND GRADE	SYMBOL	PHONE	TYPIST'S INITIALS	SUSPENSE DATE
John Hinz, GS-13	AFIERA/RSRE	4-6136	jh	

SUBJECT
Evaluation of the Basis for Drinking Water Maximum Contaminant Levels (MCLs)

DATE
29 Aug 02

SUMMARY

1. The proposed memorandum at Tab 1 is for 311 HSW/CC approval and signature. It is written in reply to SAF/IEE's memorandum to Brig Gen Dodd dated 2 May 02 (Tab 2).

2. SAF/IEE is requesting AFIERA's assistance in conducting a historical assessment of environmental standards set by the Environmental Protection Agency (EPA) and the health risk levels indicated by the risk characterizations for contaminants. The objective of this effort is to assess the appropriateness of using Maximum Contaminant Levels (MCLs) as groundwater cleanup goals compared to using the results of an actual site-specific risk assessment. AFIERA contracted Mitretek Systems for this assessment. Mitretek Systems evaluated the relationships between chemical-specific toxicity values and MCLs for both carcinogens and noncarcinogens. In general, they reached two overall conclusions: first, MCLs are not an acceptable surrogate for site-specific baseline risk assessments for setting site-specific cleanup goals and for prioritizing site cleanups; second, chemicals that have been detected at AF installations are regulated less stringently by MCLs than chemicals that have not been detected at AF installations. A summary of Mitretek Systems' report is at Attachment 1 to Tab 1; the full report is at Attachment 2 to Tab 1.

3. RECOMMENDATION. 311 HSW/CC sign the proposed memorandum at Tab 1.

ERIC L. STEPHENS, SES
Director, AFIERA

2 Tabs
1. Proposed Memorandum w/2 Atch
2. SAF/IEE Memorandum, 2 May 02

DEPARTMENT OF DEFENSE UNITED STATES OF AMERICA

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS 311TH HUMAN SYSTEMS WING (AFMC)
BROOKS AIR FORCE BASE TEXAS

20 SEP 2002

MEMORANDUM FOR SAF/IEE

FROM: 311 HSW/CC
2510 Kennedy Circle
Brooks AFB TX 78235-5115

SUBJECT: Evaluation of the Basis For Drinking Water Maximum Contaminant Levels (MCLs) (Your Memo, 2 May 02)

1. In your memorandum of 2 May 02, you requested that the Air Force Institute for Environment, Safety and Occupational Health Risk Analysis (AFIERA) conduct a historical assessment of environmental standards set by the Environmental Protection Agency and the health risk levels indicated by the risk characterizations for contaminants.

2. AFIERA and its contractor, Mitretek Systems, addressed this assignment through an examination of the relationships between chemical-specific toxicity values and MCLs for both carcinogens and noncarcinogens. The objective of this effort was to evaluate the appropriateness of using Maximum Contaminant Levels (MCLs) as groundwater cleanup goals compared to using the results of an actual site-specific risk assessment. Their research into and findings about this matter are summarized in the attached documents. In summary, AFIERA and Mitretek concluded that for setting site-specific cleanup goals and for prioritizing site cleanups, MCLs are not acceptable surrogates for site-specific baseline risk assessments. It also seems that the Air Force is not necessarily being treated unfairly, since chemicals detected at Air Force installations appear to be less stringently regulated by MCLs than chemicals detected elsewhere.

3. My POC at AFIERA for the details of this assessment is Mr. John P. Hinz, DSN 240-6136, e-mail john.hinz@brooks.af.mil.

Lloyd Dodd

LLOYD E. DODD, JR.
Brigadier General, USAF, MC, CFS
Commander

Attachments:
1. Summary Report
2. Full Report

DEPARTMENT OF THE AIR FORCE
WASHINGTON, DC

Office Of The Assistant Secretary

2 MAY 2002

MEMORANDUM FOR 311 HSW/CC
2510 Kennedy Cir Ste,116
Brooks AFB TX 78235-5120

FROM: SAF/IEE
1665 Air Force Pentagon
Washington DC 20330-1665

SUBJECT: Air Force Institute for Environment, Safety, and Occupational Health Risk Analysis

I had the pleasure of visiting Brooks AFB for the first time in February. During the visit, Mr. Stephens presented the various capabilities of the Air Force Institute for Environment, Safety, and Occupational Health Risk Analysis (AFIERA). I am requesting assistance from AFIERA to conduct a historical assessment of environmental standards set by the Environmental Protection Agency (EPA) and the health risk levels indicated by the risk characterizations for those contaminants. AFIERA has the unique mix of environmental health and health risk expertise to complete such an analysis.

I recently met with the EPA Assistant Administrator for the Office of Research and Development. Part of our discussion focused on the role of health risk in the process of standard setting, which is some of the work done by AFIERA on trichloroethylene and perchlorate. Health information is not the sole basis for a standard, however it appears there are few exceptions. A better understanding of the process will benefit the Air Force as we move forward with environmental cleanup of contaminants, which will have a standard set relatively soon. My POC for specific details of the assessment is Lt Col Barbara Larcom, DSN 227-1019. I appreciate your support and look forward to hearing from Mr. Stephens.

Maureen T. Koetz

MAUREEN T. KOETZ
Deputy Assistant Secretary
of the Air Force
(Environment, Safety, and
Occupational Health)

MTS™
Mitretek Systems

10 July 2002
H050-L-447KK

Mr. John Hinz
AFIERA/RSRE
2513 Kennedy Circle
Brooks AFB, TX 78235-5116

Subject: Evaluation of the Basis for Drinking-Water Maximum Contaminant Level Goals and Maximum Contaminant Levels

Reference: Independent Systems Engineering and Acquisitions Support to the Air Force Center for Environmental Excellence, Contract F41624-00-D-8520, Task Order 29

Dear Mr. Hinz:

Mitretek Systems evaluated the basis for the enforceable drinking-water Maximum Contamination Levels (MCLs) promulgated by the Environmental Protection Agency to evaluate consistency in the use of the stated rules for establishing MCLs, as well as the relevance of the MCLs to quantifiable risk. This evaluation was conducted in part to assess the technical validity of using MCLs as cleanup goals and to determine whether the rules for establishing MCLs were followed consistently both for chemicals that are of concern to the Air Force Environmental Restoration Program and those that are not.

Two overall conclusions were reached: (1) for setting site-specific cleanup goals and for prioritizing site cleanups, MCLs are not an acceptable surrogate for site-specific baseline risk assessments, and (2) the chemicals that have been detected at Air Force installations are regulated less stringently by MCLs than chemicals that have not been detected at Air Force installations.

If you have any questions regarding the enclosed report, please call me at (210) 479-0476.

Sincerely,

Raymond S. Kutzman, Ph.D., DABT
Principal Scientist
Center for Science and Technology

RSK/lem

Enclosure

cc: B. Howard, AFIERA

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Attachment 2