Criteria for Establishing
De Minimis Levels
of Radionuclides and
Hazardous Chemicals
in the Environment

Energy Systems Environmental Restoration Program

Criteria for Establishing *De Minimis* Levels of Radionuclides and Hazardous Chemicals in the Environment

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PREFACE

This white paper dealing with proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment was prepared under Work Breakdown Structure 1.3.12.2.3.04.05.

CONTENTS

ABBREVIATIONS

ALARA	as low as reasonably achievable
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EPA	U.S. Environmental Protection Agency
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
LOAEL	lowest-observed-adverse-effects level
MCL	maximum contaminant level
MCLG	maximum contaminant level goal
NCP	National Contingency Plan
NCRP	National Council on Radiation Protection and Measurements
NOAEL	no-observed-adverse-effects level
RfD	reference dose

EXECUTIVE SUMMARY

This paper develops proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment. The proposed criteria are intended to provide upper bounds on risks that are trivial (negligible). Thus, action to reduce risks at these levels or below generally would not be warranted, regardless of cost-benefit or any other considerations. Furthermore, reduction of risks is not necessarily required whenever risks exceed the upper bounds on *de minimis* levels. Rather, the proper interpretation in this case is that the feasibility of risk reduction generally must be considered, but action to reduce risk would be required only if it is practicable (i.e., if the risks are above levels judged as low as reasonably achievable).

For radionuclides and chemical carcinogens, the proposed *de minimis* criteria include (1) an excess lifetime cancer risk from all exposure pathways less than about 10^4 and (2) concentrations in potential sources of drinking water less than the maximum contaminant levels (MCLs) established by the U.S. Environmental Protection Agency (EPA). For noncarcinogenic hazardous chemicals, the proposed *de minimis* criteria include (1) intakes from all exposure pathways less than the reference doses (RfDs) developed by the EPA and (2) concentrations in potential sources of drinking water less than the MCLs.

The proposed *de minimis* criteria are intended primarily for application to contaminated sites subject to remediation under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and to existing levels of contaminants in environmental media at the present time. However, the criteria and the principles on which they are based are sufficiently general that the criteria should be applicable to any other situations involving exposure to hazardous substances in the environment.

The proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment are consistent with objectives for remediation of contaminated sites under CERCLA, additional regulatory guidance for implementing the CERCLA remediation objectives, and various other regulatory precedents and recommendations. Therefore, the proposed criteria are consistent with the current framework for managing risks to public health for nearly all situations involving potential exposures to hazardous substances in the environment.

This paper does not develop specific recommendations on numerical values for *de minimis* levels of various contaminants in environmental media other than water (e.g., surface soil). Rather, a proposal is discussed suggesting that models for converting the *de minimis* criteria to levels in environmental media should incorporate reasonably likely, but somewhat conservative, assumptions about exposure pathways, rather than very unlikely, worst-case assumptions. Given the other conservative assumptions about the duration and location of exposures that normally are included in health risk assessments, this approach still should provide estimates of *de minimis* levels in the environment that are unlikely to correspond to risks exceeding the proposed criteria.

1. INTRODUCTION

The purpose of this paper is to present proposed criteria that could be used to establish *de minimis* levels of radionuclides and hazardous chemicals in the environment. These criteria are intended primarily for application to existing contamination at sites on the Oak Ridge Reservation that may be subject to remediation under authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). However, the proposed criteria and the principles on which they are based are sufficiently general that the criteria should be applicable to any situation involving potential exposures of the public to hazardous substances in the environment.

The proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment are intended for use by risk managers, risk assessors, and regulators alike. The establishment of such criteria and knowledge of their bases would be particularly useful in setting priorities for remediation of environmental contamination and in communicating with the public and other stakeholder groups the significance of risks to public health associated with contaminated sites.

The term *de minimis* stems from the legal principle *"De minimis non curat lex,"* meaning "The law does not concern itself with trifles." Thus, as applied to radionuclides and hazardous chemicals in the environment, the term *de minimis* refers to levels which are considered <u>trivial</u> or <u>negligible</u>, meaning that the associated risks to public health are so low that action to reduce risks generally is unwarranted.

The primary impetus for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment is the recognition that efforts at reducing risk generally are not cost-free. Rather, efforts at risk reduction for any exposure situation entail a direct monetary cost, and decisions thus are required about whether it is worth allocating resources to reduce risk. In addition, for remediation of contaminated sites, there may be other, more indirect costs including, for example, increased exposures of workers to the contaminants, damage to ecosystems and the environment, transfer of risks to other locations and populations, and a decrease in resources available for other beneficial purposes. The concept of *de minimis* levels of hazardous substances in the environment then embodies the notion that, at sufficiently low levels of risk, it simply is not worth the cost of attempting to achieve further risk reduction, even if the required direct expenditures and other associated costs would not be large.

In discussing levels of risk that might be considered *de minimis*, it is important to distinguish between risks that are accepted voluntarily (e.g., from recreational activities) and risks that are imposed without knowledge or consent, primarily because voluntary risks that are readily accepted often are well above readily accepted imposed risks. This paper is concerned only with imposed risks, particularly those due to the presence of radionuclides and hazardous chemicals in the environment.

A useful concept that often has been applied in protecting public health is the following: Imposed risks often are considered trivial if they are much less than other risks which are routinely experienced in everyday life, especially those imposed risks that are largely unavoidable. For example, risks due to hazardous substances at contaminated sites may be considered trivial if they

are much less than the largely unavoidable risks due to the ubiquitous background of naturally occurring radionuclides or hazardous chemicals in the environment.

The concept of *de minimis* levels of radionuclides and hazardous chemicals in the environment is best understood within the context of the general framework for the management of risks to public health for any hazardous substances. This framework is described in the following section. The remainder of this paper then presents and discusses the proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment.

2. GENERAL FRAMEWORK FOR RISK MANAGEMENT

For any hazardous substances in the environment, current approaches to risk management generally recognize, either explicitly or implicitly, that risks to public health can be grouped into three broad categories (Travis *et al.* 1987; Kocher and Hoffman 1991). These categories are summarized in Table 1 and are described below.

The first of these categories, which is the subject of this paper, includes any risks that are considered *de minimis*, which again means that the risks are so trivial that action to reduce risk generally would be unwarranted. It should be noted that *de minimis* risks may be non-zero, particularly for radionuclides and chemical carcinogens for which a linear, no-threshold dose-response relationship generally is assumed at low doses.

A second category, which is at the opposite end of the risk spectrum from *de minimis* levels, includes any risks that are considered *de manifestis*, which means that the risks are so high that they are manifestly intolerable. For risks in this category, action to reduce risk generally would be required under any circumstances (e.g., regardless of cost).
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The third category includes any risks intermediate between *de minimis* and *de manifestis* levels. This category thus includes risks which are neither so low that they can be neglected nor so high that risk reduction would be required regardless of any other circumstances. For risks in this intermediate category, risk reduction generally must be <u>considered</u> because the risks are too high to be neglected out-of-hand, but risk reduction would be <u>required</u> only if it is feasible (e.g., cost-effective) because the risks are not so high that they are manifestly intolerable.

An important characteristic of risks in the intermediate category is that judgments are required on a case-by-case basis about the extent to which risks should be reduced. A general principle that is widely applied in controlling exposures to radionuclides and hazardous chemicals in the environment is that risks should be as low as reasonably achievable (ALARA), taking into account economic factors (i.e., cost-benefit) and other societal concerns. However, it must be emphasized that achieving a *de minimis* risk is not the goal of ALARA because risks that are ALARA may be well above *de minimis* levels. On the other hand, the ALARA principle generally would not be applied for risks at *de minimis* levels, even if risk reduction would be cost-effective, again because *de minimis* risks generally are too low to be of concern.

Particularly in current approaches to risk management for hazardous chemicals, risks at *de minimis* levels often are referred to as "acceptable." However, the three categories of risk described above and summarized in Table 1 serve to emphasize that risks above *de minimis* levels also can be

acceptable under certain conditions—namely, if the risks are not so high that they are manifestly intolerable <u>and</u> they are ALARA. Thus, it is improper to characterize all risks above *de minimis* levels as "unacceptable," because such risks are unacceptable only if they are manifestly intolerable <u>or</u> they are below manifestly intolerable levels but are not ALARA.

Table 1. General framework for categorizing risks from exposure to radionuclides and hazardous chemicals in the environment

Severity of risk[a]	Characterization of risk	Approach to risk reduction
De minimis	Risks are so low that they are considered trivial or negligible.	Action to reduce risk generally is unwarranted.
Intermediate	Risks are between *de minimis* and *de manifestis* levels.	Feasibility of risk reduction generally must be considered, but action to reduce risk is required only if risks are above levels judged as low as reasonably achievable (ALARA).
De manifestis	Risks are so high that they are considered manifestly intolerable.	Action to reduce risk generally is required, regardless of cost or any other considerations.

[a]Severity of risk increases from top to bottom of table.

The general framework for risk management described above represents an integration of many factors including information on biological effects from exposure to hazardous substances, an evolving regulatory philosophy, experience in enforcing existing regulations, decisions by courts of law, and the feasibility of reducing risk with available technology. It must be emphasized that the establishment of this framework, including not only the concepts of *de minimis* and *de manifestis* risks but also the particular levels of risk that may be considered *de minimis* or *de manifestis*, is not a purely objective exercise. Rather, decisions about risk management in general, and levels of risk that are considered *de minimis* in particular, although supported by scientific information, necessarily involve societal values and judgments that are largely subjective and can change over time. For example, as noted in Section 1, *de minimis* voluntary risks may be well above *de minimis* imposed risks of the kind addressed in this paper.

3. PROPOSED *DE MINIMIS* CRITERIA

With the discussions in Sect. 2 on the general framework for categorizing risks to public health according to their severity as background, the proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment are presented in this section. Separate criteria are developed for carcinogens, including radionuclides and chemical carcinogens, and noncarcinogenic hazardous chemicals because these two types of substances generally are assumed to have different dose-response relationships—specifically, linear, no-threshold for carcinogens but threshold for noncarcinogens.

3.1 *DE MINIMIS* CRITERIA FOR CARCINOGENS

The proposed criteria for establishing *de minimis* levels of radionuclides and chemical carcinogens in the environment are stated as follows.

Levels of radionuclides or chemical carcinogens in the environment should be considered *de minimis* if

1. the excess lifetime cancer risk from all exposure pathways would be less than about 10^{-4}; and

2. concentrations in potential sources of drinking water are less than the maximum contaminant levels (MCLs) for public drinking water supplies specified by the U.S. Environmental Protection Agency (EPA) in 40 CFR Part 141.

These two criteria are discussed in the following sections.

3.1.1 Excess Lifetime Cancer Risk

The first proposed criterion that excess lifetime cancer risks from all exposure pathways less than about 10^{-4} should be considered *de minimis* is based primarily on regulations implementing CERCLA and additional EPA guidance on their interpretation. These regulations are directly applicable to contaminated sites on the Oak Ridge Reservation that are subject to remediation under CERCLA.

The National Contingency Plan (NCP) implementing CERCLA (EPA 1990) specifies certain objectives for remediation of contaminated sites. Among these is the objective of achieving an excess lifetime cancer risk of 10^{-4}–10^{-6} from all hazardous substances and all exposure pathways at a given site.

The lifetime cancer risk and other objectives for remediation specified in the NCP are properly interpreted as goals, rather than limits that must be met, because CERCLA and the NCP also specify many conditions for waiving compliance with a lifetime cancer risk of 10^{-4}–10^{-6} or any other remediation goals—for example, if meeting the goals would not be cost-effective—thus clearly indicating that they are not limits. Rather, what is required under CERCLA and the NCP is that consideration must be given to reducing any lifetime cancer risks above 10^{-4}–10^{-6}, but risk reduction then is to be carried out only if it is feasible. This certainly is not the same as requiring action to reduce any risks above these levels regardless of any other circumstances.

Further EPA guidance on the remediation goals in the NCP (Clay 1991) states that action to reduce risk generally is not warranted if the excess lifetime cancer risk is less than about 10^{-4}. Thus, it is no longer EPA policy that risks less than about 10^{-4}, and as low as 10^{-6}, require consideration of the feasibility of risk reduction.

The current EPA policy that lifetime cancer risks at contaminated sites less than about 10^{-4} do not warrant any action to reduce risks is based in part on an assumption that the size of the population at greatest risk would be small. For example, the type of resident homesteader scenario often assumed in baseline risk assessments at CERCLA sites (EPA 1989) involves only a few individuals. Then, if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be zero.

The following, more general arguments can be used to support the proposal that excess lifetime cancer risks less than about 10^{-4} should be considered *de minimis*.

First, an analysis of EPA regulatory decisions under several laws (Travis *et al.* 1987)showed that, in all cases, the EPA declined to require risk reduction if the lifetime cancer risk was less than about 10^{-4}–10^{-6}. Furthermore, whenever the size of the population at greatest risk was relatively small, risk reduction was never required when the lifetime cancer risk was less than about 10^{-4}. As described above, the assumption of a small population at greatest risk usually is appropriate for contaminated sites.

Second, the National Council on Radiation Protection and Measurements (NCRP 1993) and the International Atomic Energy Agency (IAEA 1988) have developed recommendations on exemption principles for exposures of the public to radionuclides and other radiation sources. These recommendations include a provision that radiation doses to individuals less than about 10 μSv (1 mrem) per year generally can be exempted from regulatory control (i.e., such doses are *de minimis)*. For an assumed risk of fatal cancers of 5×10^{-2} per Sv (5×10^{-4} per rem), as recommended by the NCRP (1993) and the International Commission on Radiological Protection (ICRP 1991), exposure at the recommended *de minimis* dose over an average lifetime of 70 years corresponds to a lifetime risk of fatal cancers of about 4×10^{-5}. If cancer induction, rather than fatal cancers, is the desired health-effects endpoint, then the corresponding lifetime risk would be increased to about 5×10^{-5} (EPA 1994).These risks are consistent with the upper bound on *de minimis* risk of about 10^{-4} proposed in this paper.

Third, as mentioned in Sect. 1, it can be argued that *de minimis* risks from exposure to man-made radionuclides and chemical carcinogens in the environment reasonably can be set at a small fraction of the largely unavoidable background risks from exposure to naturally occurring radionuclides and chemical carcinogens. The essence of the argument is that individuals generally do not take into account the magnitude of such background risks, particularly the variability in background risks with geographical location, in deciding where to live, which indicates that it is not reasonable to require action to reduce risks that are only a small fraction of the unavoidable background risks of the same kind.

The estimated average lifetime risk in the U.S. population from exposure to natural background radiation is about 10^{-2} (NCRP 1993; ICRP 1991), and the lifetime risk from exposure to certain naturally occurring chemical carcinogens has been estimated to be greater than 10^{-3} (Travis and Hester 1990) and may well be on the order of 10^{-2} if all naturally occurring chemical carcinogens were accounted for. Therefore, a *de minimis* risk of about 10^{-4} appears to be a small fraction of the unavoidable background risk from radionuclides or chemical carcinogens.

3.1.2 Maximum Contaminant Levels in Drinking Water

The second proposed criterion is that *de minimis* levels of radionuclides and chemical carcinogens in potential sources of drinking water, either groundwater or surface water, should be defined in terms of the MCLs in public drinking water supplies, as specified by the EPA in 40 CFR Part 141. Inclusion of a separate criterion for potential sources of drinking water and its specific form are based on CERCLA requirements and regulatory guidance and, in addition, on the requirements for determining MCLs under authority of the Safe Drinking Water Act.

CERCLA explicitly states that remediation goals for groundwater at contaminated sites include federal drinking water standards, and further EPA guidance on interpreting the remediation goals (Clay 1991) states that action to reduce levels of carcinogens in contaminated groundwater should be considered only if MCLs are exceeded. Thus, the CERCLA remediation goals and further EPA guidance indicate that MCLs provide upper bounds on *de minimis* levels of carcinogens in potential

sources of drinking water at contaminated sites because action to reduce levels of contamination below the MCLs generally is unwarranted.

The approach specified in the Safe Drinking Water Act for determining MCLs is as follows. First, for any contaminant of concern, the EPA establishes maximum contaminant level goals (MCLGs), which are non-enforceable health goals. The Safe Drinking Water Act specifies that MCLGs must correspond to levels at which <u>no</u> known or anticipated adverse health effects would occur and which allow an adequate margin of safety. For radionuclides and hazardous chemicals that are known or probable human carcinogens, the MCLGs thus must be <u>zero,</u> based on the usual assumption of a linear, no-threshold dose-response relationship for cancer induction. For any naturally occurring carcinogens in drinking water (e.g., radium, arsenic), the MCLGs clearly are not attainable at any cost. For chemical carcinogens with lesser evidence of carcinogenicity in humans, the MCLGs can be non-zero.

For contaminants for which MCLGs are established, the EPA then establishes MCLs, which are the legally enforceable standards for drinking water. The Safe Drinking Water Act specifies that MCLs must be set as close to the MCLGs as possible, taking into account technical feasibility and cost. Thus, particularly for carcinogens, the MCLs are <u>not</u> based primarily on considerations of limitation of health risk (i.e., a need to achieve a certain level of risk in order to protect public health). Rather, the MCLs are based primarily on the capabilities of available technologies for removing contaminants from drinking water. Indeed, the EPA may periodically revise the MCLs based on reconsideration of the costs of water treatment and the associated benefits in reduced health risks, and the MCLs for carcinogens may be increased (EPA 1991) if the previously existing values are no longer judged to be reasonably achievable.

The proper interpretation of MCLs as defining upper bounds on *de minimis* levels of carcinogens in drinking water is indicated by two considerations. The first, as discussed above, is that the MCLs generally are judged by the EPA to be ALARA. The second is that at levels of contaminants in drinking water below the MCLs, there is no requirement to reduce the levels further, even if the reductions would be cost-effective.

Current MCLs for radionuclides and known or probable chemical carcinogens correspond to excess lifetime cancer risks of about 10^{-4}–10^{-6}. Thus, MCLs toward the upper end of this range (e.g., MCLs for radionuclides) are consistent with the proposed *de minimis* criterion for all exposure pathways. The use of MCLs that correspond to risks toward the lower end of this range as *de minimis* levels also is appropriate when one considers that exposure pathways other than drinking water may be important.

3.1.3 Summary of Criteria for Carcinogens

Based on the discussions in Sects. 3.1.1 and 3.1.2, an excess lifetime cancer risk from all exposure pathways of about 10^{-4} or concentrations of carcinogens in potential sources of drinking water equal to the MCLs for public drinking water supplies established by the EPA in 40 CFR Part 141 clearly define levels at contaminated sites subject to remediation under CERCLA below which action to reduce risk generally is not warranted. Conversely, cancer risks above about 10^{-4} or concentrations of carcinogens in potential sources of drinking water above MCLs generally require consideration of the feasibility of reducing risk, although risk reduction generally is not required unless it is practicable. Therefore, based on the general risk categories discussed in Sect. 2 and summarized in Table 1, the proposed criteria clearly can be used to define *de minimis* levels of radionuclides and chemical carcinogens at CERCLA sites.

3.2 *DE MINIMIS* CRITERIA FOR NONCARCINOGENIC HAZARDOUS CHEMICALS

Because of the assumed threshold dose-response relationship for noncarcinogens, the basic objective of risk management is somewhat different than it is for carcinogens. In the latter case, any exposure is assumed to entail some risk, and the objective is to limit the probability of occurrence of health effects. For noncarcinogens, however, the objective is to prevent health effects by limiting exposures to levels below any threshold. If exposures are below any threshold, then the risk presumably is zero.

The establishment of *de minimis* criteria for noncarcinogens is of concern only for hazardous chemicals. Although ionizing radiation can induce noncarcinogenic effects in humans, the thresholds for these effects occur only at doses of about 0.5 Sv (50 rem) or higher, and any dose limits for the public that are intended to limit the risk of cancer induction [i.e., annual doses of 1 mSv (100 mrem) or less]
are sufficiently low to preclude the occurrence of noncarcinogenic effects (NCRP 1993; ICRP 1991).

The proposed criteria for establishing *de minimis* levels of noncarcinogenic hazardous chemicals are stated as follows.

Levels of noncarcinogenic hazardous chemicals in the environment should be considered *de minimis* if

1. the intakes from all exposure pathways would be less than the reference doses (RfDs) specified by the EPA; and

2. concentrations in potential sources of drinking water are less than the MCLs for public drinking water supplies specified by the EPA in 40 CFR Part 141.

These two criteria are discussed in the following sections.

3.2.1 Reference Doses

The first proposed criterion that intakes from all exposure pathways less than RfDs should be considered *de minimis* is based on the approach generally used by the EPA in establishing the RfD for any noncarcinogenic hazardous chemical (EPA 1989), as described below.

The EPA's approach to establishing the RfD for any noncarcinogen usually starts with an estimate of the no-observed-adverse-effects level (NOAEL), which is the highest dose delivered to humans or test animals for which there are no statistically or biologically significant increases in the frequency or severity of adverse health effects. With only a few exceptions (e.g., arsenic), the estimated NOAEL is based on animal data. As an alternative, if the NOAEL has not been established, the EPA starts with an estimate of the lowest-observed-adverse-effects level (LOAEL), which generally is higher than the NOAEL and is the lowest dose delivered at which significant health effects are induced. Thus, for any noncarcinogen, either the NOAEL or the LOAEL is used to define an assumed threshold for adverse health effects.

The EPA then establishes the RfD as a dose intended to be adequately protective of public health by applying several safety and uncertainty factors to the observed NOAEL or LOAEL, which take into account various sources of uncertainty in the data used to derive the NOAEL or LOAEL and in extrapolating the data from animals to humans. These safety and uncertainty factors generally

include (1) a factor of 10 to account for the variability in susceptibility in the general population, with the intent of protecting especially sensitive subpopulations (e.g., children and the elderly); (2) a factor of 10 when extrapolating from animals to humans to account for the possible interspecies variability in susceptibility; (3) a factor of 10 when a NOAEL is derived from a study involving subchronic exposures, rather than longer-term chronic exposures; and (4) a factor of 10 when using a LOAEL rather than a NOAEL to account for the uncertainty in extrapolating from LOAELs to NOAELs. In addition, the EPA may apply a modifying factor to account for any other uncertainties and judgmental factors not addressed in the safety and uncertainty factors described above.

Thus, the RfD generally is intended to be well below any threshold for adverse health effects. In particular, when the RfD is based on animal studies, which usually is the case, its value generally is set at least a factor 100 and sometimes more than a factor of 1000 below the threshold, as represented by the NOAEL or LOAEL (EPA 1993).

There are two considerations indicating that RfDs are properly interpreted as upper bounds on *de minimis* doses for noncarcinogenic hazardous chemicals. The first is the use of large safety and uncertainty factors in deriving RfDs from observed thresholds for adverse health effects, as described above, which again are intended to ensure that doses to individual members of the public would be well below any thresholds. Indeed, because of the way RfDs are derived, there should be no evidence that doses somewhat above an RfD would cause any adverse health effects.

The second consideration is that RfDs are presumed to be sufficiently far below any thresholds for adverse health effects that action to reduce doses at levels below RfDs generally is not required by the EPA. That is, RfDs are used to distinguish between doses that are trivial and, thus, require no further consideration and doses that are sufficiently high that consideration must be given to the feasibility of dose reduction. However, as is the case with the upper bound on *de minimis* risk for carcinogens discussed in Sect. 3.1.1, reduction of doses above RfDs generally is required only to the extent practicable.

3.2.2 Maximum Contaminant Levels in Drinking Water

The second proposed criterion is that *de minimis* levels of noncarcinogenic hazardous chemicals in potential sources of drinking water, either groundwater or surface water, should be defined in terms of MCLs in public drinking water supplies, as specified by the EPA in 40 CFR Part 141. As in the case of carcinogens discussed in Sect. 3.1.2, inclusion of a separate criterion for potential sources of drinking water and its specific form are based on existing CERCLA requirements and regulatory guidance and, in addition, on the requirements for determining MCLs under authority of the Safe Drinking Water Act.

As noted in Sect. 3.1.2, CERCLA explicitly states that remediation goals for groundwater at contaminated sites include federal drinking water standards, and further EPA guidance on interpreting the remediation goals (Clay 1991) states that action to reduce levels of contamination in groundwater should be considered only if MCLs are exceeded. These remediation goals apply to noncarcinogenic hazardous chemicals as well as carcinogens. Thus, MCLs for noncarcinogens provide upper bounds on *de minimis* levels in potential sources of drinking water because action to reduce levels of contamination below the MCLs generally is unwarranted.

The general approach specified in the Safe Drinking Water Act for determining MCLs for any hazardous substances is described in Sect. 3.1.2. However, as discussed in the following, the general

approach to determining MCLs is implemented somewhat differently for noncarcinogens than it is for carcinogens.

First, although the MCLGs for all known or probable human carcinogens, which again are non-enforceable health goals, must be zero, the MCLGs for noncarcinogens can be non-zero, provided they allow an adequate margin of safety below any threshold for adverse health effects. Indeed, except for lead, all MCLGs for noncarcinogens established by the EPA are non-zero.

The non-zero MCLGs established by the EPA generally are based on (1) the observed threshold for adverse health effects, as represented by the NOAEL or LOAEL discussed in Sect. 3.2.1; (2) a safety and uncertainty factor of 10–1000, based on the quality of the data including, for example, whether the data are obtained from human or animal studies and whether the threshold is represented by the NOAEL or the LOAEL; and (3) further reduction below the threshold by a factor of 5 for organic substances or a factor of 10 for inorganic substances to account for potential routes of intake other than drinking water. Thus, MCLGs for noncarcinogens in drinking water essentially are equivalent to RfDs for all exposure pathways.

Second, although the MCLs for all known or probable human carcinogens, which again are the legally enforceable standards for drinking water, are higher than the MCLGs, the MCL for most noncarcinogens is the same as the MCLG, particularly in cases where the MCLG is non-zero and the EPA judged that the MCLG is reasonably achievable using existing technology for water treatment. In the unusual exceptions (e.g., lead and thallium), the MCL is higher than the MCLG only because the latter cannot be achieved using existing technology.

As described in Sect. 3.1.2, the proper interpretation of MCLs as defining upper bounds on *de minimis* levels of noncarcinogenic hazardous chemicals in drinking water is indicated by the considerations that, first, MCLs are judged by the EPA to be ALARA; and, second, for levels in drinking water at MCLs or below, there is no requirement to reduce the contaminant levels further, even if the reductions would be cost-effective.

3.2.3 Summary of Criteria for Noncarcinogens

Based on the discussions in Sects. 3.2.1 and 3.2.2, intakes of noncarcinogenic hazardous chemicals from all exposure pathways equal to RfDs or concentrations of noncarcinogens in potential sources of drinking water equal to the MCLs for public drinking water supplies established by the EPA in 40 CFR Part 141 clearly define levels at contaminated sites subject to remediation under CERCLA below which action to reduce risk generally is not warranted. Conversely, intakes above RfDs or concentrations of noncarcinogens in potential sources of drinking water above MCLs generally require consideration of the feasibility of reducing risk, although risk reduction generally is not required unless it is practicable. Therefore, based on the general risk categories discussed in Sect. 2 and summarized in Table 1, these criteria clearly can be used to define *de minimis* levels of noncarcinogenic hazardous chemicals at CERCLA sites.

Approaches to implementing the proposed *de minimis* criteria for carcinogens and noncarcinogens are discussed in the following section.

4. IMPLEMENTATION OF PROPOSED *DE MINIMIS* CRITERIA

The proposed *de minimis* criteria for carcinogens and noncarcinogens presented in Sects. 3.1 and 3.2 include upper bounds on risk or intakes from all exposure pathways and upper bounds on concentrations of contaminants in potential sources of drinking water. This section discusses approaches to implementing the proposed *de minimis* criteria for the purpose of establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment. However, it is not the purpose of this paper to develop specific values of *de minimis* levels of contaminants in environmental media other than groundwater or surface water (e.g., in surface soil).

The proposed *de minimis* criteria for carcinogens and noncarcinogens presented in this paper are intended for application to existing levels of radionuclides and hazardous chemicals in environmental media at the present time. Therefore, in implementing the proposed criteria, it is not intended that modeling of transport of contaminants from their present locations in the environment, especially over long time periods in the future, would be required. However, potential exposure pathways for the existing contamination in various environmental media would need to be considered.

For existing contamination of groundwater or surface water which is a potential source of drinking water, implementation of the proposed criteria in the form of MCLs is straightforward because determinations of *de minimis* levels normally would be based on direct measurement of contaminant concentrations in water. However, implementation of the proposed criteria in the form of upper bounds on risk or intakes from all exposure pathways generally would require assumptions about the relationship between levels of contaminants in environmental media (e.g., surface soil) and exposures of individuals.

Modeling of exposure pathways for contaminants in the environment generally involves considerable uncertainty. A common approach to dealing with this uncertainty is to develop exposure pathway models which provide point (deterministic) estimates of exposures using presumably conservative (i.e., pessimistic) assumptions (EPA 1989).

The use of conservative assumptions for exposure pathway modeling in determining *de minimis* levels of contaminants in the environment can be justified to some extent because the intent is to determine levels that generally would entail a negligible risk for most conceivable exposure situations. However, we believe that the use of extreme, worst-case assumptions for exposure pathways in determining *de minimis* levels is unwarranted due to the conservative nature of other assumptions embodied in the usual approaches to estimating health risks or intakes.

For example, standard exposure scenarios used in health risk assessments for contaminated sites generally assume that individuals are exposed for long periods of time (e.g., 30–70 years) and at the locations where the concentrations of contaminants are the highest, but neither assumption is a likely occurrence in real populations. In addition, the slope factors used by the EPA (1993) to estimate risk per unit intake for carcinogens generally are intended to provide upper bounds on cancer risk, rather than best estimates; and, as discussed in Sect. 3.2.1, RfDs and MCLs in drinking water for noncarcinogens generally include large safety and uncertainty factors intended to ensure that all exposures would be well below any thresholds for adverse health effects. Therefore, even if reasonably realistic models and parameter values for estimating exposures were used, the resulting estimates of cancer risk or intakes of noncarcinogens relative to observed thresholds presumably should still be conservative and, thus, appropriate for determining *de minimis* levels in the environment.

As described in Sect. 2, *de minimis* levels of contaminants in the environment not only define levels too low to be of concern, but they also define levels above which the feasibility of reducing contamination should be considered. Therefore, although action to reduce contaminant levels above *de minimis* values is required only to the extent practicable, unreasonably conservative assumptions about exposure pathways should be avoided in order not to obtain unreasonable conclusions about low contaminant levels at which action to reduce risks should be undertaken.

5. SUMMARY

This paper has developed proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment. The proposed criteria for carcinogens and noncarcinogens, which include consideration of all potential exposure pathways and exposures to potential sources of drinking water only, are summarized in Table 2. These criteria are intended for application to existing levels of contaminants in environmental media at the present time.

As indicated in Table 1, these criteria are intended to be interpreted as providing upper bounds on risks that are trivial (negligible) and, thus, would generally not warrant action to reduce risk. However, levels of environmental contamination that are only somewhat in excess of the upper bounds on *de minimis* levels do not necessarily indicate that the levels must be reduced. Rather, the proper interpretation in this case is that the feasibility of risk reduction generally must be considered, but action to reduce risk then would be required only if it is practicable (i.e., if the risks are above levels judged ALARA).

The criteria developed in this paper are intended primarily for application to contaminated sites subject to remediation under CERCLA. However, the criteria and the principles on which they are based are sufficiently general that the criteria should be applicable to other situations involving exposure to hazardous substances in the environment. An additional consideration that might be needed for other situations is the size of the exposed population because the *de minimis* criterion for lifetime cancer risk of about 10^{-4} was based in part on an assumption that only a small population would be at greatest risk. However, for exposure situations that might involve large populations at risk, a value for the upper bound on *de minimis* lifetime cancer risk substantially less than 10^{-4} might be justified (Kocher and Hoffman 1991). On the other hand, when large populations are at risk, it often is the case that the average risk in the population is considerably less than the risk to maximally exposed individuals.

The proposed criteria for establishing *de minimis* levels of radionuclides and hazardous chemicals in the environment are consistent with objectives for remediation of contaminated sites under CERCLA, additional regulatory guidance for implementing the CERCLA remediation objectives, and various other regulatory precedents and recommendations. Therefore, the proposed criteria are consistent with the current framework for managing risks to public health for nearly all situations involving potential exposures to hazardous substances in the environment.

For the criteria involving all exposure pathways in Table 2, this paper does not develop specific recommendations on numerical values for *de minimis* levels of various contaminants in different environmental media (e.g., surface soil). Rather, a proposal was discussed that models for converting the *de minimis* criteria on risk for carcinogens or intakes for noncarcinogens to levels in environmental media should incorporate reasonably likely, but somewhat conservative, assumptions about exposure pathways, rather than very unlikely, worst-case assumptions. Given the other conservative assumptions normally included in health risk assessments, this approach still should provide estimates of *de minimis* levels in the environment that are unlikely to correspond to risks or intakes exceeding the proposed criteria.

**Table 2. Proposed criteria for establishing *de minimis* levels of
radionuclides and hazardous chemicals in the environment**

Type of contaminant	Proposed *de minimis* criteria
Radionuclides and chemical carcinogens	Excess lifetime cancer risk from all exposure pathways would be less than about 10^{-4}; and
	Concentrations in potential sources of drinking water are less than maximum contaminant levels (MCLs).[a]
Noncarcinogenic hazardous chemicals	Intakes from all exposure pathways would be less than reference doses (RfDs);[b] and
	Concentrations in potential sources of drinking water are less than MCLs.[a]

[a]MCLs apply to public drinking water supplies and are established by the EPA in 40 CFR Part 141.
[b]RfDs are based on observed thresholds for induction of adverse health effects and application
of several safety and uncertainty factors [EPA 1989].

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