Responsiveness Summary
for the
Amendments
to the
Model Toxics Control Act Cleanup Regulation
Chapter 173-340 WAC

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PART A

I. CONCISE EXPLANATORY STATEMENT

Ecology is adopting amendments to the Model Toxics Control Act Cleanup Regulation, Chapter 173-340 WAC. The amendments define procedures for establishing cleanup standards, criteria for selecting cleanup actions to comply with those standards, and requirements for corrective actions at leaking underground storage tanks. The standards apply to sites where hazardous substances have been released into the environment at levels which present a threat to human health and the environment.

RCW 70.105D.030(2)(d) directs Ecology to adopt and enforce "minimum cleanup standards for remedial actions at least as stringent as the federal cleanup standards under Section 121 of the federal cleanup law, 42 U.S.C. 9621 and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law." RCW 70.105D.030 also establishes three basic requirements for remedial actions performed under the Model Toxics Control Act. Cleanup actions shall comply with cleanup standards, utilize permanent solutions to the maximum extent practicable and include adequate monitoring to ensure the effectiveness of the remedial action.

Within this statutory framework, the amendments define a two-step approach for establishing cleanup requirements for individual sites:

> Establishing Cleanup Standards: The standards provide a uniform, statewide approach to cleanup that can be applied on a site-by-site basis. Establishing cleanup standards for individual sites requires specification of (1) hazardous substance concentrations that protect human health and the environment ("cleanup levels"); (2) the location on the site where cleanup levels must be attained ("points of compliance"); and (3) Additional regulatory requirements that apply to a cleanup action because of the type of action and/or the location of the site.
>
> Selecting a Cleanup Action: This step involves evaluating methods that could be used to clean a site before deciding which of those methods would best achieve cleanup standards. Aside from meeting the standards, cleanup actions must also utilize permanent solutions to the maximum extent practicable, achieve cleanup in a reasonable timeframe, and include monitoring to ensure the long-term effectiveness of the cleanup action.

Cleanup levels established under this regulation are based on requirements under other applicable state and federal laws and health risk assessment. Using a health risk approach, cleanup levels for individual carcinogens are generally based upon an excess cancer risk of 1 in 1,000,000 (one-in-one million). The regulation provides the flexibility to utilize a cancer risk level of 1 in 100,000 in limited situations. In both cases, the total site risk cannot exceed 1 in 100,000. For noncarcinogens, cleanup levels are established at levels which are estimated to result in no acute or chronic toxic effects.

Washington State's Underground Storage Tank Act, Chapter 90.76 RCW directs Ecology to establish an underground storage tank program which meets the federal requirements for program delegation. Ecology must adopt rules which

are at least as stringent as the federal underground storage tank regulations (40 CFR Part 280 Subpart F).

Corrective action at petroleum and other hazardous waste sites in Washington State falls within the jurisdiction of the Model Toxics Control Act. Ecology is adopting Section 450 of Chapter 173-340 WAC to address the requirements of Chapter 70.105D RCW, Chapter 90.76 RCW and 40 CFR Part 280 regarding releases from underground storage tanks.

II. INTRODUCTION

A. Statutory Requirements

The Model Toxics Control Act (Initiative 97), Chapter 70.105D RCW, was passed by the voters of the State of Washington in November, 1988. Effective March 1, 1989, the law establishes the basic authorities and requirements for cleaning up contaminated sites in a manner that will protect human health and the environment.

RCW 70.105D.030(2)(d) directs Ecology to adopt and enforce:

> "minimum cleanup standards for remedial actions at least as stringent as the federal cleanup standards under Section 121 of the federal cleanup law, 42 U.S.C. 9621 and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law."

RCW 70.105D.030(1)(b) also establishes three basic requirements for remedial actions performed under the Model Toxics Control Act. Remedial actions shall comply with cleanup standards established under Section 30(2)(d), utilize permanent solutions to the maximum extent practicable and include adequate monitoring to ensure the effectiveness of the remedial action.

The federal cleanup law referenced in RCW 105D.030(2)(d) is the Comprehensive Environmental Response Compensation and Liability Act of 1980 as amended by the Superfund Amendments and Reauthorization Act of 1986 (hereinafter referred to as CERCLA). Section 121 establishes a series of requirements and preferences similar to those under the state law. First, the cleanup action must "attain a degree of cleanup ... which assures protection of human health and the environment...." Protection of human health and the environment is to be achieved, at least in part, by the second element, the identification and compliance with "applicable or relevant and appropriate requirements" (ARARS). Finally, Section 121 specifies that remedial actions must be cost-effective and utilize permanent solutions to the maximum extent practicable.

B. Regulation Development

Chapter 70.105D RCW requires the Department of Ecology to adopt implementing regulations. That regulation, Chapter 173-340 WAC, the "Model Toxics Control Act Cleanup Regulation," has been developed in two phases. The first phase describes the administrative process. It was published in the Washington State Register on January 19, 1990, and became effective on May 4, 1990. The second

phase is the subject of this rulemaking and includes cleanup standards, the selection of cleanup actions, analytical procedures, and leaking underground storage tank corrective actions. This phase is an amendment to the Phase I rules.

Ecology began developing the cleanup standards in early 1989. In March 1989, a committee was formed to advise the Department on the development of the standards. The committee had representatives from businesses, environmental groups, government agencies, and agricultural interests. In addition, the Department formed a five member Science Advisory Board in mid-1989. In consultation with these advisory groups, Ecology developed one draft of the standards which was circulated for informal public review and comment in March 1990. Based on the comments received on that draft, as well as comments received on two earlier work group drafts, the Department developed the Amendments.

The leaking underground storage tank (LUST) amendments were developed with the assistance of another advisory group. The amendments defining the corrective action requirements are based largely on the requirements in the federal underground storage tank rules. Adoption of these rules is necessary for Ecology to continue to be eligible for federal LUST trust fund monies to assure proper cleanup of leaking underground storage tanks.

C. The Public Involvement Process

The proposed rule was published in the August 1 Washington State Register as WSR 90-15-066. The formal comment period continued until September 17, 1990. Documents related to public involvement are located at the end of this summary in Part E.

Informational meetings:

Informational meetings were held in four locations to provide the public with an opportunity to informally discuss the proposed regulations and related issues with Ecology staff.

Printed notice of the public comment period and workshop dates was directly mailed, via the Toxic Cleanup Program's on-going mailing list, to over 1800 interested citizens, environmental organizations, and special interest groups. Notice of the public workshops was published in these newspapers: The Daily Chronicle (Centralia); The Columbian (Vancouver); The Daily Journal of Commerce (Seattle); The Daily News (Longview); Journal-American (Bellevue); The Morning News Tribune (Tacoma); and The Olympian (Olympia).

Four workshops were held:

August 13, 1990 1:00 p.m.	Tacoma	World Trade Center Meeting Room 3600 Port of Tacoma Road
August 14, 1990 7:00 p.m.	Vancouver	Clark Co. P.U.D. Community Room 1200 Fort Vancouver Way

August 15, 1990 Seattle Mountaineers Club Tahoma Room
7:00 p.m. 300 Third Avenue West

August 16, 1990 Lacey Energy Facility Site Evaluation Council
1:00 p.m. Hearing Room
Rowe Six, Building #1
4114 Sixth Avenue South

Public hearings:

Three public hearings were held on the proposed rule. Notice was sent to the Olympia offices of the United Press International and the Associated Press, in addition to the following newspapers: Daily Chronicle (Centralia); The Columbian (Vancouver); The Daily News (Longview), Daily Journal of Commerce (Seattle); Daily Record (Ellensburg); Journal-American (Bellevue); The Morning News Tribune (Tacoma); The Olympian (Olympia); Seattle Times/Seattle Post Intelligencer; Spokesman Review (Spokane); Tri-City Herald (Richland, Pasco and Kennewick); Walla Walla Daily Bulletin; The Wenatchee World; and the Yakima Herald Republic.
Prior to these hearings, staff also informally discussed the proposed regulations and related issues.

September 6, 1990 Seattle Mountaineers Club Skagit Room
7:00 p.m. 300 Third Avenue West

September 10, 1990 Richland Federal Building Auditorium
7:00 p.m. 825 Jawdin Avenue

September 11, 1990 Spokane County Health District Building
7:00 p.m. Conference Room #140
West 1101 College Street

D. Format of the Responsiveness Summary

In addition to the Table of Contents, Explanatory Statement, and this Introduction, this document consists of four other major components. Part B explains the general problems associated with establishing cleanup standards and addresses several general issues that were raised during the rulemaking process.
Part C describes those technical and policy issues that underlie the development of cleanup standards. Part C addresses those issues associated with establishing an acceptable level of protection (Section IV). It also describes the scientific and regulatory procedures that are involved in the methods (and the assumptions on which they are based) for establishing cleanup levels that protect human health (V). Also addressed in this section are methods for assessing ecological health, the role of cost in the cleanup process, and analytical procedures for quantifying trace levels of hazardous substances.

Part D begins Ecology's responses on comments received on specific sections of the proposed rule. Part D also provides a reference list of the scientific and other publications referred to in this document and the concise explanatory statement required under WAC .

Part E contains the concise explanatory statement and the public notice documents.

Part F is bound separately and contains the written comments and public testimony summaries on the proposed rule and the draft environmental impact statement. This document is available from the Department upon request.

This Responsiveness Summary primarily addresses comments on the proposed amendments to the Model Toxics Control Act Cleanup Regulation (Chapter 173-340 WAC). Written comments and responses on the October 16, 1989, December 29, 1989, and March 9, 1990 draft regulations are incorporated where those comments reflect additional opinions or concerns. These comments are available upon request. Comments were reviewed and divided into issue areas which correspond to subsections in the proposed regulation. Where multiple comments were received on a particular issue, an attempt was made to summarize each of the major concerns and provide examples of individual comments. Ecology's response follows each of these comments.

References to written comments are designated by the name of the individual providing the comment, the letter "p", and the page of the written comment (e.g. Johnson, p. 2). References to comments on earlier drafts of the regulation include the date of the draft (e.g. Eaton, p. 3 of comments on October 16, 1989 draft). References to testimony provided at one of the public hearings are designated by the individual's name and the location of the public hearing (e.g. Roberts (Seattle hearing)). Those publications referred to by individual participants or included in the administrative record for this rulemaking are cited by author and date.

PART B

III. GENERAL COMMENTS

A. The Regulatory Dilemma

The amendments attempt to deal with the complex issue of "how clean is clean." Resolution of this issue requires information on (1) hazardous substance levels, (2) the potential for such substances to migrate from the site, and (3) the potential for those hazardous substances, either individually or in combination, to cause adverse health or environmental effects. From a regulatory perspective, the process of collecting and interpreting this information is complicated by the fact that many gaps remain in our scientific understanding of the exact relationships between exposure to hazardous substances and the adverse health or environmental effects resulting from such exposures.

This type of regulatory dilemma is neither new nor unique to the Department of Ecology. Indeed, Ecology and other regulatory agencies face the same difficulties that public officials have faced in the past. Dr. Richard Bates (former Science Director for the Food and Drug Administration) described those similarities in his written comments on the Occupational Safety and Health Administration's cancer policy. He stated:

> A classic episode in the history of disease prevention took place in London in 1854. An epidemic of cholera occurred in the neighborhood around Broad Street. John Snow, the hero of the story, studied the habits of the victims and found that almost all obtained their water from the well on Broad Street. Swift action was taken; the pump was closed down and the epidemic rapidly subsided. This disease was caused by exposure to the bacterium *Vibrio cholerae*. One can imagine the reaction that might occur today if it were proposed to close down the pump on the basis of evidence of the kind obtained by John Snow. Many scientists would point out that it had not been conclusively demonstrated that the water was the cause of the disease. They would be troubled because of the lack of satisfactory theoretical knowledge to explain how the water could have caused the disease. Furthermore, other habits of those who had become ill had not been adequately investigated, so it would not be possible to rule out other causes of the disease. The scientists would have been correct. Others would have pointed out that some members of the community who drank from the Broad Street well had not succumbed to cholera. Thus, even if there were something wrong with the water, there must be other factors involved and if we could control these we would not have to be concerned about the water. The conclusions are also correct. Some who consumed water from the Broad Street well would have objected to closing it because the taste of water from other wells was not as agreeable. Finally, if the pump had been owned by an individual who sold the water, he would certainly have protested against closing down his business on the basis of inconclusive evidence of hazard. (Bates, 1978, pp. 1-2)

Dr. Bates concluded that this story highlights several key concepts that should be kept in mind by government agencies charged with the responsibility of regulating hazardous substances:

- If human disease is to be prevented, it is often necessary to control exposure for which there is some evidence of hazard before that evidence has reached the point that scientists would universally regard as conclusive;

- Development of a disease in any individual is the result of complex interactions of a variety of factors including genetic susceptibility, exposure to other environmental pollutants, age, nutrition, etc.; and

- The incidence of disease in a population can be reduced by reducing exposure to hazardous substances or by measures designed to reduce the susceptibility of individuals.

Ecology finds this advice to be particular relevant to the cleanup of hazardous waste sites. Several sections of the MTCA (RCW 70.105D.010, .030(2)(d), .030(5), and .040) appear to reflect the Initiative drafters' recognition that conclusive medical or scientific evidence may not exist for many hazardous substances. Nevertheless, the law mandates that cleanup standards be developed and used to define cleanup requirements for contaminated sites in the State of Washington. Consequently, Ecology believes it would be inconsistent with its statutory obligations to delay actions in the hope that science will provide definitive answers on the issue of "How Clean is Clean." Although encouraged by the promising developments in the areas of toxicology and risk assessment, the Department is aware that, like other regulatory agencies, it is operating "on the frontiers of scientific knowledge" (IUD vs. Hodgson, 1974), but with a "command to act" (Ethyl Corp vs. EPA, 1975).

In this light, Ecology's rulemaking efforts have been directed towards constructing a rational and efficient regulatory framework that recognizes the fluid and developing nature of scientific knowledge. The Department believes that the standards create a framework for regulatory action which will provide a uniform and reasonable response to site cleanup. We believe the standards will permit Ecology to complete cleanup actions in a timely and efficient manner without imposing unreasonable limits on the consideration of meaningful scientific advances.

The cleanup standards represent a combination of scientific policies and technical procedures for establishing cleanup requirements. The Department recognizes that some issues normally raised and considered on individual sites have been limited or resolved in this rulemaking. It is Ecology's intent to limit the issues in future cleanup actions to those topics and issues specific to a particular hazardous substance or site. The validity of more general policy issues are not to be the subject of individual cleanup actions. We believe this approach will allow Ecology staff to act with greater certainty and efficiency in framing and resolving the critical technical issues associated with individual cleanup sites.

B. Ecology's Regulatory Goals

The development of the amendments involved the consideration and balancing of a number of issues and interests. The proposed amendments were developed to satisfy the following six goals or objectives:

- Remediation of contaminated sites to levels that are protective of human health and the environment. Ecology's foremost goal was to develop standards that are protective of human health and the environment. Protection is defined to include both current and future generations and susceptible subgroups, such as small children, that are particularly sensitive to hazardous substances;

- Scientifically and legally defensible cleanup standards. An important goal was to develop standards that are scientifically and legally defensible. Toward that end, Ecology reviewed the scientific literature and consulted with members of the Science Advisory Board and other individuals experienced in the areas of risk assessment. Where conflicting opinions or recommendations exist, Ecology has attempted to balance the various positions to arrive at a scientifically defensible and workable approach;

- Performance of cleanup actions in a manner that is consistent with existing state and federal regulatory programs. The MTCA requires that minimum cleanup standards be at least as stringent as applicable state and federal laws. In developing the proposed amendments, Ecology has attempted to rely on requirements established under these other authorities and avoid creating duplicate requirements. However, contaminated sites are frequently more complex than situations addressed by existing programs. Consequently, Ecology has attempted to provide an approach that supplements existing requirements to address situations where multi-media contamination and mixtures of hazardous substances are present;

- Efficient cleanup of contaminated sites. An important objective of the proposed amendments is to increase the efficiency of site cleanup. In particular, the proposed amendments represent an attempt to reduce the amount of flexibility in the present system which serves to heighten uncertainty rather than predictability by resolving fundamental policy issues. In doing so, Ecology hopes to create a system which focuses available funds on site cleanup and minimizes cleanup standard negotiation or litigation;

- Use of a consistent approach for assessing and managing health risks. In the past, there has been considerable variability in both the quality and methodologies used to develop cleanup levels. Through the development of the proposed amendments, Ecology hopes to ensure that consistent procedures are used to assess and manage health risks; and

- Provide some flexibility to address individual site characteristics. In developing the proposed amendments, Ecology has tried to balance the goals of regulatory consistency and efficiency with the need to provide some flexibility to address individual site characteristics.

C. Ecology's Proposal

The amendments to the Model Toxics Control Act Cleanup Regulation (Chapter 173-340 WAC) define numerical cleanup levels for relatively straightforward cleanup actions and provide a process for establishing site-specific cleanup levels at more complex sites. These rules will be applied to hazardous substances in ground water, surface water, marine water, soil, air, and sediments. The

amendments also include provisions for selecting cleanup actions and performing leaking underground storage tank (LUST) corrective actions.

The amendments would apply to owners and operators of facilities (commonly referred to as hazardous waste sites) where there has been a release or threatened release of hazardous substances that may pose a threat to human health or the environment. These facilities include locations where hazardous substances have entered ground water, fresh and marine surface water, soils, air, sediments, or combinations of these media.

The proposed amendments (WSR 90-15-066) included a number of key provisions which are summarized below.

General Requirements:

Four sections within the proposed amendments included provisions applying to hazardous substances in all media. These include:

General Procedures - WAC 173-340-700 introduced the concepts of compliance cleanup levels and conditional cleanup levels and defined how the cleanup levels sections related to other portions of the regulation. Compliance cleanup levels are defined as concentrations that are protective of human health and the environment under unrestricted site use conditions. Contitional cleanup levels are defined as concentrations that are protective under limited site use conditions (for example, industrial site use). In both cases, cleanup levels would be based on reasonable maximum exposure scenarios and the highest beneficial use of a particular state resources such as surface water. The reasonable maximum exposure is defined as the highest exposure that is reasonably expected to occur at the cleaup site taking into account both currrent and potential furture site use.

General Principles - WAC 173-340-705 defined the policies and procedures that Ecology will utilize to ensure that cleanup levels are established and implemented in a scientific and technically sound manner.

Applicable State and Federal Laws - WAC 173-340-710 defines the criteria for determining what requirements are applicable state and federal laws. Ecology has proposed to define this term to include both "legally applicable" and "relevant and appropriate" requirements. The proposed definitions for these terms and criteria for judging individual laws and regulations are virtually identical to provisions included in the National Contingency Plan (EPA, 1990).

Definitions - WAC 173-340-200 has been amended to incorporate those terms that are unique to cleanup standards and LUST portions of the regulation.

Cleanup Standards:

There are six sections that provide more detailed procedures for establishing cleanup standards in the various environmental media. Each section defines the reasonable maximum exposure for that media, applicable state and federal laws, risk assessment procedures for hazardous substances, and points of compliance. The six sections include:

- Ground Water Cleanup Standards - WAC 173-340-720
- Surface Water Cleanup Standards - WAC 173-340-730

- Soil Cleanup Standards - WAC 173-340-740
- Industrial Soil Cleanup Standards - WAC 173-340-745
- Cleanup Standards to Protect Air Quality - WAC 173-340-750
- Sediments Cleanup Standards - WAC 173-340-760

The sediment cleanup standards section has been reserved. Ecology's Sediment Management Unit has developed regulations that will define a comprehensive approach for managing sediments (Chapter 173-204 WAC). The sections of that rule dealing with cleanup standards will be applicable to cleanup actions performed under this rule.

Selection of Cleanup Actions:

There are five sections that specify requirements for selecting and implementing cleanup actions. These include:

Selection of Cleanup Actions - WAC 173-340-360 defines the basic requirements for cleanup actions under this chapter and the procedures for documenting cleanup decisions. Under the amendments, cleanup actions must be protective of human health and the environment (including compliance with cleanup standards), comply with applicable state and federal laws, and provide for monitoring to assure the effectiveness of the cleanup. When selecting from among several alternatives which fulfill these basic requirements, the cleanup action must use permanent solutions to the maximum extent practicable, be implemented in a cost-effective manner, provide for a reasonable restoration time frame, and consider public concerns.

Periodic Review - WAC 173-340-420 defines the requirements for periodically reviewing cleanup actions. The amendments specify that in situations where residual hazardous substances exceed Method A or Method B cleanup levels or if conditional points of compliance are approved, the Department shall review the cleanup action at least once every five years to assure that human health and the environment is being protected.

Institutional Controls - WAC 173-340-440 defines the general requirements for restricting site use where hazardous substances are left on-site as part of the cleanup action. The amendments require the use of institutional controls when residual levels of hazardous substances exceed Method A or Method B cleanup levels or a conditional point of compliance is established. The institutional controls shall generally be described in a restrictive covenant which, at a minimum, shall specify appropriate site use restrictions to protect human health and the environment and maintain the integrity of cleanup measures.

Releases From Underground Storage Tanks - WAC 173-340-450 responds to the need to address the corrective action requirements outlined in the federal Underground Storage Tank (UST) rules. The amendments specify additional requirements for UST owners and operators regulated under Chapter 90.76 RCW. These include reporting of confirmed releases within 24 hours, follow-up investigations, free product removal and immediate assessment and reduction of the threat to human health and the environment at the site. A written report describing the site and remedial actions must be submitted within 90 days of

release confirmation. If appropriate, UST owners and operators must also conduct and report any additional cleanup actions.

Analytical Procedures - WAC 173-340-830 defines standard analytical methods for use in the investigation and cleanup of hazardous waste sites.

Final Rule

In the final regulation, Sections 700 and 705 were reorganized to provide a more concise overview of the cleanup standards portion of the rule. This change was made in response to public comment and is intended to improve the readability of the rule. The original language is located in Sections 700, 704, 705, 706, 707, and 708 of the final rule. Refer to Issue #3 in Section III and Issue #1 in Section XIV for an expanded discussion of format changes.

D. Areas of Confusion

Ecology received thirty seven (37) written comments and ten oral testimonies addressing a wide range of regulatory issues. Some statements expressed general support for Ecology's proposal; other statements reflected opposition to specific provisions or provided reasons why the proposal should not apply in certain situations. However, some of the statements appear to reflect some confusion over certain key terms or concepts. Ecology believes it is important to clarify the use of these basic terms before analyzing and responding to specific comments on the proposed rule.

Distinction between cleanup levels, cleanup standards, and cleanup actions

The law requires the Department to "[p]ublish and periodically update minimum cleanup standards for remedial actions at least as stringent as the cleanup standards under Section 121 of the federal law ... and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law." In reviewing the public comments, there appears to be three different interpretations of what is actually meant by the term "cleanup standards." These include the following:

(1) Cleanup Standards Include Cleanup Levels: Several individuals appeared to equate the term "cleanup standards" with "cleanup levels" [See comments from Tabbutt, p. 3; Wishart, p. 3). This interpretation is consistent with the approach utilized in Ecology's 1984 *How Clean is Clean* policy (Ecology, 1984).

(2) Cleanup Standards Include Cleanup Levels and Points of Compliance:The proposed amendments defined a two-step approach for establishing cleanup requirements: (1) Establising cleanup standards and (2) Selecting Cleanup Actions. Establishing cleanup standards involved specifying cleanup levels, points of compliance, and other requirements under applicable state and federal laws.

(3) Cleanup Standards Includes All Cleanup Requirements: In contrast to the first two definitions, several commentors viewed the issue of "Cleanup Standards" to include cleanup levels, points of compliance, and requirements for selecting and conducting cleanup actions (Science Advisory Board, pp. 3-4). This approach is embodied in Section 121 of the CERCLA and represents an expansion

of earlier views. This expansion was summarized by Ms. Linda Greer of the Environmental Defense Fund at a recent conference on ground water remediation:

> Since 1982, the "How Clean is Clean?" question has expanded to include not only the question of the level of cleanup appropriate at dump sites but also the technology to be selected in undertaking a cleanup and the point of compliance at which the cleanup goals will be attained. These three issues have been addressed by environmental and citizens groups at particular sites as well as in lobbying efforts on the 1986 reauthorized Superfund bill. (Greer, 1988, p. 110)
>
> Section 121 of CERCLA (entitled "Cleanup Standards"), reflects this broader definition. It addresses cleanup levels or "degree of protection" (Section 121(d)) and points of compliance, and contains criteria and requirements for remedy selection. Several individuals noted the cross reference to Section 121 and urged Ecology to define cleanup standards to include all three elements (See Thomson, p. 4)

The regulatory framework established by the adoption of the Model Toxics Control Act (MTCA) Cleanup Regulations in May 1990 is based on Option 2. It differs from the CERCLA approach in that it provides a more explicit separation between cleanup levels and cleanup actions. In the first step, "cleanup standards" are established using the procedures in Sections 700 through 760. This includes the first two elements described by Ms. Greer: cleanup levels and points of compliance. This also includes specifying other action- or location-specific requirements in applicable state and federal laws. In the second step, "cleanup actions" (or remedies in the federal terminology) to achieve the cleanup standards are evaluated and selected using the procedures in Section 360. This approach is consistent with recommendations from several expert review panels charged with reviewing the federal cleanup program (Office of Technology Assessment, 1989; Clean Sites Inc, 1990).

Ecology has sought to clarify the distinctions between these two steps in the final rule by incorporating the following new language in WAC 173-340-700(2):

> Establishing cleanup standards for individual sites requires the specification of the following:
>
> (i) Hazardous substance concentrations that protect human health and the environment ("cleanup levels");
>
> (ii) The location on the site where those cleanup levels must be attained ("points of compliance"); and
>
> (iii) Additional regulatory requirements that apply to a cleanup action because of the type of action and/or the location of the site. These requirements are specified in applicable state and federal laws and are generally established in conjunction with the selection of a specific cleanup action.
>
> (b) For most sites, there are several cleanup technologies or combinations of cleanup technologies ("cleanup action alternatives") that may be used to comply with cleanup standards at individual sites. Other parts of this rule govern the process for planning and deciding on the cleanup action to be taken at a site.

> For example, WAC 173-340-350 (state remedial investigation and feasibility study (RI/FS)) specifies the studies that are prepared to define the nature and extent of contamination ("RI") and to identify and evaluate cleanup action alternatives("FS"). WAC 173-340-360 (selection of cleanup action) specifies the criteria for selecting the preferred alternative. WAC 173-340-410 specifies the monitoring required to assure that the remedy is effective.

Ecology recognizes that there is not always a complete separation between these two steps. For example, in evaluating whether it is appropriate to utilize Method C (conditional cleanup levels), one considers the net environmental impacts. To evaluate such impacts, one must consider the types of cleanup actions that will be used at the site.

Distinctions between scientific and policy issues in standard setting

There appeared to be some confusion on whether Ecology's regulatory choices were based on science, public policy, or a combination of both. This is not surprising given that the approach used to establish cleanup standards, quantitative risk assessment, has been described by former EPA Administrator William Ruckelshaus as the product of "a shotgun wedding between science and the law" (Ruckelshaus, 1983, p. 1026). It is a method which attempts to utilize scientific evidence and techniques in the context of regulatory decision-making. As a result, it often fails to fully satisfy either the people who advocate, draft, and administer environmental laws or members of the scientific community.

Given this context, it is not surprising that there is frequently some confusion on the interplay between science and public policy in regulatory decision-making. Ms. Elizabeth Tabbutt (WEC) highlighted this issue in her comments:

> There are very few environmental decisions which are thoroughly based on science. Uncertainty surrounds the assessments even when those assessments are expressed in numbers which imply accuracy. We cannot wait for science to give us certainty but we must make decisions based on our limited knowledge and the concerns of the public. It is misleading to characterize what are really policy decisions as "scientific" or "scientifically defensible. (Tabbutt, p. 1)

The Conservation Foundation, in the report State of the Environment: An Assessment at Mid-Decade, highlighted the need for regulatory agencies to distinguish between scientific and policy choices when utilizing the risk assessment process:

> A key to understanding and improving the risk assessment process is to distinguish between those aspects of the process that are scientific and those that are matters of policy or personal values, and to appreciate their complex interrelationships...A risk assessment process that is defensible from both a scientific and a policy standpoint must accurately identify which aspects of assessment are policy and which are science. The difficulty is that both scientists and policy makers tend to define their realms in the broadest terms. (Conservation Foundation, 1984, p. 310)

Unfortunately, there is no natural "bright line" between scientific matters and policy considerations in the risk assessment process. Indeed, in the course of conducting a risk assessment, a number of choices must be made. Those choices can be viewed as a series of decision points. In many cases, the decisionmaker has enough information to make a choice solely on the basis of scientific facts. For example, in estimating exposure to hazardous substances, it is necessary to obtain measurements of the concentrations present in air, water, or soils. The answer to the question of what level of cadmium is present in ground water can be determined on the basis of laboratory data.

However, there are also a number of situations where available data or scientific knowledge does not provide a definitive basis for selecting from among several plausible approaches. These situations can be divided into two categories. The first type of uncertainty problem, those associated with insufficient data ("if we only ran more tests we could solve this problem"), can often resolved through the collection of additional data. In the context of establishing cleanup requirements for individual sites, the question becomes one of whether there is sufficient time or money to collect the additional data. Lacking such data, one generally utilizes standard "guidelines" or "default" values.

The second type of uncertainty, that resulting from gaps in scientific knowledge, are much more resistent to brute force data collection efforts. The National Academy of Sciences (1983) has noted that "when scientific uncertainties are encountered in the risk assessment process, inferential bridges are needed to allow the process to continue...." These "inference bridges" represent policy decisions about which of several plausible approaches to use. These choices are largely driven by an overall policy decision of how conservative to be in estimating risk. This dilemma was highlighted by the Conservation Foundation:

> Using worst-case assumptions is a general decision rule. There are a number of specific steps in quantitative risk assessment in which a policy decision has to be made about how to do the assessment. For example, in extrapolating the risks from the results of animal studies to human exposure, the analyst can use either the ratio of the animal's weight to the average human weight or the ratio of skin surface area. There is no scientific basis for choosing between the two. Federal regulatory agencies generally use the surface-area method which, for tests conducted on mice, increases the risk estimate by a factor of 13 over using the weight method.[108] Like the worst-case rule, the choice of the surface-area method is a policy decision about how conservative to be in estimating risk. It is not a scientific decision, because at present scientific knowledge is not adequate to choose between methods. (Conservation Foundation, 1984, p. 311)

The amendments represent a mechanism for provisionally "resolving" from a public policy perspective, certain of these scientific controversies in order for Ecology to make the decisions required by the mandates of the MTCA. In making those choices, Ecology has considered available scientific data, the uncertainties associated with that data, approaches by other regulatory agencies, and the mandates of the Toxics Control Act. The Department recognizes that some policy issues normally raised and considered on individual sites have been limited or resolved in this rulemaking.

The resolution of these public policy issues does not foreclose the use of new scientific information. Indeed, Ecology will continue to encourage the

development and use of new scientific information. The rule is subject to change when new scientific knowledge warrants such changes and Ecology has provided several avenues for incorporating those changes in an efficient and open manner. (See Section V)

Distinctions between various measures of risk

The concept of risk can be very confusing and people often differ in the ways in which they measure and interpret risk. This was highlighted by Lyndon (1989) who observed that "risk is a slippery concept; it has no simple meaning, but varies in content according to circumstances."

Ecology proposed to define "excess cancer risk of one in 1,00,000" as "the upper 95th confidence limit on the estimated risk of one additional cancer above the background cancer rate per 1,000,000 individuals." The "slippery" nature of risk was evident from the manner in which various participants used the term. For example, some commentors suggested that Ecology focus on "population" risks as opposed to "individual" risks. Other participants expressed the opinion that regulatory decisions should be based upon "best" or "average" estimates instead of "upper bound" estimates. Finally, a few individuals suggested that Ecology base cleanup decisions on estimates of "actual" or "real" risks as opposed to "theoretical" or "hypothetical" risks.

Based upon the range of definitions presented during the public comment period, it should not be surprising that there are numerous ways to characterize the amount of risk in an exposed population. The selection of one or more these ways of characterizing risk involves an number of critical policy choices, and, consequently can have a substantial impact on the overall regulatory strategy.

Individual Risk versus Population Risk

Regulatory agencies have routinely considered three measures of health risks when making decisions on carcinogens. These include:

Individual Risk: Individual risk is expressed as an estimated probability (e.g. 1 in 100,000). Therefore, a 1 in 100,000 individual risk is an added "chance" of 1 in 100,000 of developing cancer sometime in a person's lifetime.

Risk Distribution: A risk distribution estimates how many persons within a certain distance of a site are at what level of individual risk. Typically, the distribution is given for 10-fold increments of individual risk.

Incidence (Population Risk): Incidence is an estimate of population, rather than individual, risk. It is derived by multiplying individual risk by the estimate of the number of persons at that level of risk and summing the results over all risk levels.

Cleanup levels under the MTCA regulation are based on risks to the reasonable maximum exposed individual(s). The choice of this measure was based upon the following considerations:

Statutory Mandate: This decision is consistent with the policy stated in RCW 70.105D.010 that "[e]ach person has a fundamental and

unalienable right to a healthful environment." Given this policy statement, Ecology would find it difficult to justify an approach where an individual's right to protection from hazardous substances is dependent upon how many neighbors are similarly situated. Indeed, given the rapid population growth in certain areas of the state it is unclear whether today's sparsely-populated areas will remain unchanged in the future. (This is discussed in Section IV, Issue #5)

Regulatory Consistency: This approach is also consistent with requirements under other regulatory programs. For example, a similar approach is used in the EPA Superfund Program (EPA, 1989a). EPA's proposed requirements for emissions from hazardous waste incinerators are also based on exposure to the maximum exposed individual (EPA, 1990f).

Ecology recognizes that the use of individual risk is not without problems. Indeed, some of the tradeoffs on this issue were summarized by Finkel (1990):

> "Another familiar difference between risk measures concerns whether the risk manager considers individual probabilities of harm or population expectations of harm. If all risks were controlled in isolation, and if individual risks did not vary, then the difference between the two measures would be one of scale alone (the semantic distinction between "a 10-6 risk' and "one death expected per million people"). But because risks must often be compared and prioritized, and because the sizes of affected populations vary, the distinction between individual and population risk is in fact pivotal and controversial. Milvy (1986) has shown that any decision rule that is based solely on minimizing one measure or the other can lead to profound contradictions and inefficencies. Saying that any number M represents a cutoff between an "acceptable" and an "unacceptable" number of expected deaths will lead to very high individual risks when the affected population is small. On the other hand, setting an "acceptable" level of individual risk R could lead to unworkably stringent standards in cases where exposures and risks are confined to small occupational (or other) groups." (Finkel, 1990, p. 17)

Ecology believes that the overall process for site cleanup actually incorporates both of these concepts. Specifically, Ecology considers the size of the potentially affected population when establishing priorities for cleanup using the Hazard Ranking System. By considering population size at this stage of the process, the Department hopes to maximize the rate at which health protection is actually achieved.

Averages versus Upper-Bound Estimates

Risk assessment involves the use and integration of a large amount of information relating to the toxicity of hazardous substances and the potential for exposure to such substances. At some point in a regulatory decisionmaking process, available information on risk is generally compressed into one or more "summary statistics" (Finkel, 1990). As with the choice of risk measure, the selection of a summary statistic represents a fundamental policy choice.

Several summary statistics have been considered by regulatory agencies. The main difference between the various approaches is the manner in which

they balance the probability of error and social costs. This was discussed by Finkel (1990):

> It may be helpful to characterize the properties of the different summary measures in terms of their influence on the probability and magnitude of errors in estimating, and hence in efficiently controlling risk. Some summary statistics involve only the probability of error. For example, a decisionmaker may choose to characterize risk via the mode of it's possible values - the single value that is deemed most likely to be correct. Such a choice implies that the decision maker wishes to minimize the probability of incorrectly estimating risk, without regard to whether the unknown true value is above or below the summary measure, or to how large a divergence there may be in either direction.
>
> Another choice is the median of the possible risk estimates, such that there is an equal (50 percent) chance the true value lies above or below the summary measure. This choice carries with it the assessment that an error of overestimation is no more or less adverse than one of underestimation, again without regard to the absolute size of either error. The median is really just a special case of a general percentile estimator. For example, the 90th percentile upper confidence limit (90 UCL) is the summary value designed to make it nine times more likely that the decision-maker is overestimating the true value than underestimating it. Choosing the 90 UCL as the basis for regulation therefore suggests (though the choice may not be so conscious) that the decision-maker regards a case where the true risk turns out to be higher than the chosen value as roughly nine times as "bad" an outcome as a case where the true risk is lower." (Finkel, 1990, pp. 17-18)

Cleanup levels under the MTCA regulation are generally based on estimates of the "95th percentile upper confidence limit" on risk. The choice of this summary statistic was based on the following considerations:

> Regulatory Consistency: This approach is similar to approaches taken by a number of other state and federal regulatory programs (EPA, 1989a; EPA, 1990f; EPA, 1989d).
>
> Uncertainty is Risk Estimates: There are large uncertainties associated with various aspects of quantitative risk assessment. The use of the "95th percentile confidence limit" reflects Ecology's decision to "err on the side of safety". In making this choice, Ecology considers that an error of underestimating risk to be worse than overestimating risk.
>
> Wide Variations in Susceptibility: The use of the "95th percentile upper confidence limit" also reflects the fact that within a given population, there is a wide range of susceptibility to disease.

Total Risk versus Attributable Risk

In the United States, it is estimated that 25-30 percent of the population will develop cancer. Because cancer is a complex disease which characteristically progresses through a number of stages of development, a variety of different factors can initiate or accelerate

it's development at each stage. These factors include pollution, personal habits (i.e. smoking), diet, etc. A person's total risk results from the sum total of all of these factors.

Under the MTCA, the problem is not how to estimate an individual's total cancer risk, but how to estimate the incremental or excess contribution resulting from exposure to hazardous substances. This is the risk that is attributable to the cleanup site. It does not include risks that can be attributable to other factors such as diet or natural background levels.

In conclusion, Ecology believes that the concepts embodied in the proposed definition of cancer risk are consistent with the statutory mandate under the MTCA and are similar to definitions used by other regulatory programs. However, Ecology has slightly modified the proposed language in order to more clearly convey the above concepts. For example, the rule now refers to term, "upper bound on the estimated excess cancer risk", instead of "excess cancer risk".

Distinctions between "technically feasible" and "technically practicable":

Several individuals expressed the opinion that the use of the terms "technically feasible" and "technically practicable" was very confusing. This confusion and the impacts on completing cleanup actions were summarized by Mr. Weiner:

> As we discussed in our public hearing testimony, the terms "technically feasible" and "technically practicable" are inconsistent with common English usage. Not only are these synonymous, but is inconsistent with case law, where the modifier "technical" generally excludes cost. Equally important, the confusion reflects some basic conceptual problems in the statement of the balancing criteria in Section 360.
>
> There are two basic concepts that need definition in order to be applied in the currently proposed rule; (1) methods or alternatives that can actually be done, regardless of whether they are easy, hard, affordable or desirable - in other words, is something "technically possible"; and (2) methods or alternatives that can be done and should be done - in other words, is something "reasonable" or "feasible." Since the latter term is already used to evaluate options (remedial investigation/*feasibility* study), it seemed to be an appropriate term. (Weiner, p. 4-5)

Ecology agrees with Mr. Weiner and others that a clearer distinction is needed between what is "possible" and what is "feasible/practicable." Toward that end, the term "technically possible" has replaced "technically feasible" in the final rule. This change is designed to better convey the concept that a cleanup action can actually be performed using available technologies. This contrasts with "technically practicable" which takes into account how much the action will cost, what the community thinks about the action and potential adverse impacts.

E. The Public's Response

Ecology received a number of comments which presented general concerns with the proposed rule. Several broad issues were raised which are discussed below:

Issue #1: **Is there a potential risk that these cleanup standards may be used for purposes that they were not intended?**

Issue #2: **Is the regulation overly complex and difficult to understand?**

Issue #3: **Does the proposed rule provide an sufficient amount of flexibility to address unique characteristics of individual sites or hazardous substances?**

Issue #4: **Is the proposed rule consistent with other state and federal requirements?**

Issue #5: **Does the proposed rule duplicate existing state or federal requirements?**

Issue #6: **Should the detailed requirements of the proposed rule be placed in guidance documents?**

Issue #7: **Does the proposed rule provide a disincentive for PLP-initiated cleanup actions?**

Issue #8: **Are the proposed amendments consistent with other parts of the regulation?**

Issue #9: **Does the proposed rule place too much emphasis on interim cleanup actions?**

Issue #10: **Will exceedances of the cleanup standards result in the automatic listing of a hazardous substance site?**

In analyzing these issues, Ecology has placed primary weight on comments from participants who documented their concerns, and who, from their participation in the rulemaking process or their experience in site cleanup activities, possess considerable experience in this field.

F. Ecology's Evaluation and Response

Issue #1: Is there a potential risk that these cleanup standards may be used for purposes for which they were not intended?

Several individuals expressed concern that the proposed standards may be used for purposes other than defining requirements for cleanup sites. They urged the Department to carefully define how and where these standards were to be used. For example:

> The regulations should state explicitly that they are to be used only for site cleanups under the Model Toxics Control Act. As has been the case with cleanup standards published in the past by other agencies, these cleanup standards may be inappropriately used for many purposes for which they are not intended. Examples of inappropriate use include evaluation of data gathered during property transfer studies, additional conditions to permits regulating hazardous waste management and disposal, and standards

for RCRA corrective action. (Fisher, p. 1 comments on March 9, 1990 draft)

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The potential for community leaders, lenders and buyers and sellers of real estate to focus on the numbers in method A is of concern. The great reliance that could be placed on these levels, used out of their context in the regulation, could threaten business transactions. We suggest including a statement that use of the tables is expressly limited to method A clean ups and shall not be used for decisions relating to the listing or the potential need for remedial actions. (von Gohren, p. 2)

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While the purpose for establishing tables setting forth Method A compliance cleanup levels is presumably to provide consistent and clear levels at which routine cleanups can occur, these tables also present problems regarding the potential use by entities such as lenders, regulators and potential purchasers. If the tables are to remain, there should be a clear explanation of their intended use and the fact that they do not, of themselves, constitute ARARs or establish cleanup levels for a site. Instead, it should be explained they are designated cleanup levels that will be approved but may not be necessary at any given site. (Syrdal, p. 12)

Weiner, p. 2, expressed a similar opinion.

Ecology's Response: Ecology agrees that the regulation should clearly state where and when cleanup standards apply. WAC 173-340-110 (Applicability) provides a general description of the types of situations that may lead to the application of this chapter. The above comments reflect more specific concerns and can be divided into the following three areas:

Property Transactions. The Department has attempted to address concerns regarding the automatic use of the Method A tables in evaluating property transactions or similar purposes by incorporating precautionary language into WAC 173-340-704 (Use of Method A) and the footnotes to Tables 1, 2, and 3. This clarifies that Methods B or C may be more appropriate for a site.

The Department recognizes that the addition of precautionary language may not provide the level of certainty some would like. For example, in the case of property transfers, the decision to purchase property involves consideration of a number of factors including the level of contamination and the potential for future regulatory action. However, since purchasers will inevitably seek out readily available levels to provide some measure of future liability, it is doubtful that explicit language will completely eliminate this particular use of the standards.

RCRA Corrective Action. In the case of hazardous waste corrective actions, the Department currently utilizes the MTCA as the statutory basis for state corrective action authority. In this and other situations where the MTCA provides the statutory basis for Departmental action, the cleanup standards would be applicable. Indeed, the use of

different standards would be inconsistent with many participants' (including Chemical Processors) recommendations for consistency among Ecology programs (See Discussion on Regulatory Consistency).

Site Identification. See issue #10.

Issue #2: Is the proposed regulation overly complex and difficult to understand?

A number of participants expressed concerns that the regulation was overly complex and difficult to understand. For example:

> Reading the regulation is difficult. Perhaps such difficulty is inherent in such a complex document; however some improvements may be possible. For example, the many citations back and forth within the regulation make following an idea through to its regulatory answer very difficult. Repeating some of the text in full, in place of citations may be a case where longer equals better. (von Gohren, p. 1)

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> One of the comments that has been made by many individual ports as they have reviewed this rule is that it is far too complex and difficult to understand. Several experienced port environmental planners and analysts have great difficulty understanding this rule as it is written. There are too many internal citation references, and too many complicated concepts with subtle shades of meaning (such as practicable vs. technically practicable). (Johnson, p. 1)

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> [T]he complexity of the rules threatens their workability. Unless appropriate administrative principles are expressed in the rules, application of the rules will be a cumbersome and confusing process. We sense broad support for such a rule addition. Specific language amendments are desirable in a number of areas for clarity and to prevent application of standards inconsistent with MTCA goals and unnecessary conflict with established areas of the federal Superfund program. (Thomson, p. 1)

Other individuals presenting similar views included the following: Fortier, p. 2; Stefani, p. 1; Tamblyn, p. 1; and Sacha, p. 1.

However, other individuals stated that they found the regulation to be easily understood. For example, Mr. Patmont and Ms. Wineman stated:

> Overall, we feel the proposed amendments are a positive step towards the identification and selection of appropriate remedial actions at hazardous waste sites. The proposed regulations appear to be consistent with similar programs underway at the federal level, and this consistency will provide for a minimum of confusion at sites where both state and federal involvement occurs. The generally clear application of risk assessment methodology in the proposed cleanup standards also provides an easily understandable

> technical foundation upon which to base future cleanup actions. (Patmont and Wineman, p. 1)

Ecology received several recommendations on ways to improve the proposal. For example, Mr. Johnson stated:

> The rule would be immeasurably improved by the addition of a clear section of administrative principles, which puts forth in simple language the general administrative cleanup policies of the Department. This section could clear up some of the current confusion about concepts such as the role of cost, the permanence of cleanups, acceptable risks, etc. (Johnson, p. 1)

Similar recommendations were provided by Mr. Weiner, Mr. von Gohren, Mr. Ryan and Mr. Thomson.

Mr. Fortier and Mr. Stefani recommended that Ecology develop flow charts to more clearly outline the decision pathways. A similar recommendation was provided by Mr. Ryan who suggested that Ecology prepare an appropriate guidance manual or preamble to the rule to clarify how the process should work (p. 1). Mr. Tamblyn recommended the use of shorter sentences and the addition of examples. Finally, Mr. von Gohren suggested that Ecology reduce the number of cross-references in the regulation.

Ecology's Response: Ecology recognizes that the regulation is fairly complex and shares some of the concerns summarized above. The regulation has grown in size and complexity over the last eighteen months as the Department has attempted to address comments from the Cleanup Standards Work Group, the Science Advisory Board, and the general public. This complexity also stems from the fact that the regulations will be applied to a wide variety of sites in a wide variety of settings.

In preparing the final rule, Ecology has worked to clarify the regulations so that a first-time reader can more easily understand the basic procedures for establishing cleanup standards and selecting cleanup actions. The detailed comments submitted by Mr. Weiner provided the overall framework for those changes. Specifically, Ecology has:

- Reduced the number of cross-references used in the document;
- Divided sections 700 and 705 into a series of smaller sections addressing common topics;
- Increased the use of examples to illustrate key concepts; and
- Added a short section which provides an overview of the cleanup standards and defines the administrative principles for cleanup standards (WAC 173-340-700).

For further expansion of this issue, refer to XIV - Issue #1.

Issue #3: Does the proposed rule provide a sufficient amount of flexibility to address unique

characteristics of individual sites or hazardous substances?

Several participants expressed concerns that various drafts of the cleanup standards contained too much detail which considerably reduced the flexibility to establish site-specific requirements. For example:

> The basic structure of the cleanup standards is appropriate to the extent that it calls for risk assessments, allows conditional cleanup levels and anticipates the completion of routine cleanups. However, inadequate flexibility has been built into the use of those standards so that the claimed objectives are unlikely to be met. (von Gohren, p. 1 of comments on March 9, 1990 draft)

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> Another goal shared by all concerned is cleanup standards which are workable and facilitate rapid response as necessary to protect human health and the environment. This will likely not occur if the standards are so burdensome as to require responses which are neither cost effective nor constitute a reasoned response in light of the true risks presented at or from a facility. For this reason, we believe the regulations should contain a great deal of flexibility to adjust to the actual environmental risks presented at each facility and to provide a more cost effective response that appropriately deals with those risks.
>
> Because of the provisions of the MTCA requiring cleanup actions to comply with the cleanup standards adopted by regulations, this flexibility must, of necessity, be found within the cleanup standards themselves. It is, therefore, extremely difficult to develop a regulatory program that provides the necessary flexibility at only the implementation stage. Any such attempt will be subject to continual challenge of the Department's discretion in making remedial actions selection decisions regarding such things as how long before a cleanup standard must be met, what types of techniques may be used to meet the cleanup standard, where the cleanup standard must be met, etc. While flexibility in the remedial action selection phase is an important adjunct to flexibility in the standards themselves, it cannot remove many of the inequities and inconsistencies associated with developing nearly uniform cleanup standards to apply in all of the dramatically different situations to which these regulations will apply.
>
> For this reason, our most serious concern regarding these proposed cleanup standards is the lack of flexibility within the cleanup standards themselves (emphasis added). There are many noteworthy examples of this failing, most of which will be more thoroughly discussed in the specific comments below. Some of the more important failures in this regard include the regulations' failure to provide an alternative cleanup level where greater risk to human health or the environment would occur by meeting the risk based on ARAR standard than by setting a lower standard for the cleanup. (Syrdal, p. 2)

Mr. Meyer (Seattle hearing) expressed similar concerns.

A differing opinion was expressed at the Seattle Hearing by Mr. Roberts who suggested that the regulation provides too much flexibility and he said that there will be no deterrent force in the Inititative if industry perceives that the Department will bend its way.

Ecology's Response: The mission of the Department of Ecology is to protect, preserve, and enhance Washington's environment and promote the wise management of our air, land, and water for the benefit of current and future generations (Department of Ecology, 1989). The development of cleanup standards under the MTCA has been guided in part by the Department's perception that this mission has been undermined by the excessive flexibility in the cleanup process. This view is shared by the Office of Technology Assessment which concluded in a recent report (OTA 1989) that "reducing excessive flexibility in the superfund implementation is critical to reducing the constant confrontation among nearly everyone affected by and working in the program...." OTA concluded that excessive flexibility, in combination with opposing views of risks to human health and the environment, have resulted in a system in which competing interests find too many opportunities to achieve their objectives at too great an expense to their adversaries. A similar conclusion was reached by Clean Sites Inc., a non-profit organization which organizes/mediates superfund cleanup efforts involving large numbers of responsible parties (Clean Sites, 1990).

In developing the cleanup regulations, Ecology has attempted to balance the competing goals of flexibility and predictability. The tradeoffs between these two characteristics have been discussed by Hodge and Roman (1990). They noted that "[f]lexible regulation is an oxymoron. The notion that broad discretion granted to bureaucrats will automatically be converted into the "best" social/technical solutions and limited politically motivated interference is simply wrong. The real world is full of tradeoffs. The less rigidity there is in rules and the greater discretion that is allowed, the more opportunity there is for both of the evils Freeze and Cherry decry: political interference and legal adversarial proceedings. When the rules are clear and rigid, there is no room for lawyers or politicians to interfere. The lawyer's ability to laugh all the way to the bank is created by ambiguity, broad discretion in regulation, and any other flexibility in which effective advocacy can encourage the regulator to flex in the direction of the client's interest...." (Hodge & Roman 1990)

However, Ecology agrees that a certain amount of flexibility is needed to implement an environmental program. Indeed, we believe the regulation currently contains flexibility in a number of areas. These include:

- Selection of Indicator Hazardous Substances
- Definition of Reasonable Maximum Exposure Scenarios
- Toxicological Parameters
- Method C Cleanup Levels
- Conditional Points of Compliance

- Selection of Cleanup Actions

In each of these areas, either a set of factors to be considered on a site-by-site basis or a range of values is provided. The Department recognizes that the flexibility in the regulations is somewhat less than that in the federal program. However, as noted above, we are concerned that the present system provides an excessive amount of flexibility which hinders, rather than facilitates, site cleanup. We believe the statutory mandate to protect human health and the environment will continue to be frustrated if we continue to handle each site as a completely unique situation. Consequently, Ecology has attempted to establish a regulatory framework which constrains flexibility, but does not eliminate it.

Issue #4: Is the proposed rule consistent with other state and federal requirements?

A number of participants expressed concerns during the rule development process over the perceived lack of consistency between the draft cleanup standards and other state and federal environmental regulations and guidelines. However, not all individuals providing comments on the proposed rule shared this opinion. For example, Mr. Patmont and Ms. Wineman concluded that:

> The proposed regulations appear to be consistent with similar programs underway at the federal level, and this consistency will provide for a minimum of confusion at sites where both state and federal involvement occurs. (Patmont and Wineman, p. 1)

Ecology's Response: In preparing the amendments, Ecology has reviewed regulations, guidance documents, and risk assessment procedures utilized by other programs, agencies, and expert organizations. In addition, Ecology has received numerous comments on risk assessment procedures from members of the Science Advisory Board and other individuals experienced in the field of risk assessment. In situations where conflicting recommendations exist, Ecology has attempted to balance the various recommendations to arrive at a scientifically and legally defensible approach.

One objective of the cleanup standards is to preserve the integrity of existing regulatory programs and avoid major inconsistencies with those programs. However, given the often wide variations in the requirements of these programs, the demands for absolute consistency are unrealistic and in many cases unachievable. For example, various commentors have urged the Department to utilize the risk assessment procedures in the Interim Final Risk Assessment Guidance for Superfund (EPA, 1989a) and the Exposure Factors Handbook (EPA, 1989b). In each document, EPA outlines procedures for estimating exposures resulting from the consumption of contaminated seafood. In EPA (1989a), the standard exposure assumptions incorporate a fish consumption rate of 6.5 g/day (daily intake factor to be used in conjunction with an exposure frequency of 365 days/year). The value of 6.5 g/day was also used to develop the Ambient Water Quality Criteria. However, EPA (1989b) and EPA (1989a) specify an average intake of 30 g/day and an upper bound intake of 140 g/day with the reasonable maximum exposure being defined as 140 g/day. More recent draft EPA guidance (HWCRI, 1990) recommends the use of 54 g/day.

With respect to current and evolving Ecology regulations, the potential for interprogram inconsistencies in risk assessment and management approaches was identified as a concern during the early stages of rule development. Initial concerns centered around the definition of acceptable cancer risk levels. A subsequent, informal review of regulations being developed revealed that a one-in-a-million cancer risk level is being utilized by the programs charged with establishing regulatory requirements for toxic air pollutants, ground water, surface water, sediments, and hazardous waste cleanup. The regulations requiring remediation of past contamination (as opposed to the prevention of future problems) are being designed to allow more flexibility in modifying this level, based on technical feasibility and net environmental impacts. Consequently, Ecology has achieved a high degree of internal consistency on this issue.

Issue #5. Does the proposed rule duplicate existing state or federal requirements?

A few individuals recommended that Ecology not duplicate existing regulatory programs. For example:

> The most important flaw in Section 750 is that it ignores Ecology's proposed rules for toxic air pollutants. Ecology's air program has released draft air toxics rules for new sources, and is working on draft rules for existing sources.... The new source rules expressly apply to sites undergoing cleanup under the MTCA. (Syrdal, p. 19)

Ecology's Response: Ecology agrees with the comments and has made every effort to incorporate existing requirements by reference. For example, RCW 173-340-720 references state and federal drinking water standards, RCW 173-340-730 references the ambient water quality criteria and water quality standards, and RCW 173-340-750 references the state's new source regulations. In each case, concentrations specified in these regulations would be utilized to establish minimum cleanup levels for individual hazardous substances. However, as with cleanup levels based on other applicable state and federal laws, the cleanup levels based on these regulations may need to be modified on a site-specific basis to ensure that the total site cancer risk and Hazard Index do not exceed 10-5 and one (1), respectively. This approach is similar to that utilized by EPA and other state cleanup programs.

With respect to the "proposed" rules for toxic air pollutants, it is important to understand that Ecology is unable to cross reference rules that do not exist. Ecology is scheduled to published the proposed rules for air toxics. Adoption is scheduled to take place several months after the MTCA amendments become effective.

Issue #6: Should the detailed requirements of the proposed rule be placed in guidance documents?

Several participants suggested that the regulation be limited to a general framework for establishing cleanup standards with the detailed exposure assumptions and risk equations included in an accompanying set of guidelines which could be easily modified as new scientific information is obtained. For example:

> We believe it inappropriate to place the equations and assumptions which implement the standards, such as the ones presented here, directly into a regulation. It would be far better to place such information by reference, than to codify it. In a field evolving as rapidly as risk assessment, this would help everyone avoid the inevitable pitfalls of attempting to modify what are already rigid, outdated and extraordinarily conservative assumptions. (Coenen, p. 1 of comments on March 9, 1990 draft)
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> **********
>
> In our program [federal Superfund program] we have some flexibility to balance conflicting concerns in arriving at a remedy. Your guidelines as they are presently written do not appear to provide that flexibility. The Superfund program is constantly being updated with respect to science, policy, and technology. We believe it is important to be able to incorporate these changes into our decision-making in order to achieve adequate remedies. (Cirone and Schwartz, p. 1 of comments on October 16, 1989)
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> **********
>
> "Utilizing this approach, the Department may be able to `have it both ways.' The specific values in the guidelines could be changed as the science progresses without the problems and effort associated with changes in the regulation." (Eaton, p. 1 of comments on October 29, 1989 draft)

Similar comments were provided by Butler, p. 1.

Ecology's Response: The Department believes that the detailed requirements for establishing cleanup standards must be incorporated into the regulation. Although the use of guidelines may provide some additional flexibility for the Department to modify the health-based assumptions as new scientific information becomes available, the marginal improvements resulting from the placement of the substantive requirements into a series of guidelines would create several potential legal and implementation problems. These include:

> Statutory Considerations: The MTCA specifies that the minimum cleanup standards required by Section 70.105.030(2)(d) must be promulgated as regulations under Chapter 34.04 RCW, the Administrative Procedures Act. The Department has been advised by the Office of the Attorney General that rules which include evaluation procedures that are "fairly objective, understandable, and actually resulted in a cleanup for sites ..." would probably fulfill the statutory requirement for standards. Ecology believes that an approach which involved (1) publication of rules which include the general framework for establishing cleanup standards and (2) guidelines which contained the substantive requirements would not meet this requirement.
>
> Historical Concerns: Even if an approach relying on guidelines and policies could be devised in a manner that withstood legal challenges, it is important to recognize that the Department has been criticized in the

past for having too many "desk drawer rules" (i.e. guidelines) that are developed and modified with little or no public review.

Relationship to Federal Program: Under the federal cleanup law, guidelines are not considered to be ARARs. Consequently, the Department would be faced with arguing the applicability of the guidelines on a site-by-site basis.

Consistency: The use of an ever-changing guidance document would increase the potential for inconsistencies among various programs and agencies. It would also create additional uncertainties for potentially liable persons (PLP) who are making good faith efforts to determine cleanup requirements for individual sites.

Ecology agrees that cleanup decisions need to be made on the basis of current and up-to-date scientific information. Toward that end, the regulation includes a number of provisions which encourage the development and use of new scientific information. These are discussed under Issue #15 in Section V.

Issue #7: Does the proposed rule provide a disincentive for potentially liable person-initiated cleanup actions?

Throughout the rulemaking process, individuals have expressed concerns that stringent cleanup standards may serve as a disincentive for PLP-initiated cleanup actions. For example:

> Cleanup standards will have a direct impact on the willingness of potentially liable parties to step forward to cleanup their own sites. As a result, these standards will in large part determine the workability of the entire implementation plan for the Model Toxics Control Act. A cleanup standards section which discourages PLP-initiated cleanups will jeopardize an overall cleanup process which was crafted, using a broad consensus of interest groups, with the goal of accomplishing cleanups. (Johnson, p.1 of comments on October 16, 1989 draft)

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> "Excessively conservative cleanup levels are also likely to discourage voluntary actions because of the projected high cost, the uncertainty of the cost projection, and the uncertainty that the cleanup level can be achieved." (Landau, p.3 of comments on December 29, 1989 draft)

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> Cleanup of contaminated sites to protect human health and the environment is the objective of these regulations. To the extent that the cleanup standards discourage private parties to clean up sites they will reduce the number of sites which are cleaned up. To encourage private parties to negotiate with Ecology or to clean up their sites independently, the cleanup standards must be achievable, understandable, reasonable, and appropriate. The

> regulations, including Appendix A, as they are presently drafted are not. (Thomson, p.1 of comments on December 29, 1989 draft)
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> **********
>
> Frankly, the proposed regulation will not only discourage voluntary cleanups, but it is likely many willing parties will be unable to ever conclude a cleanup. Standards are overly conservative, criteria for technical decisions are confusing and arbitrary, choice of reasonable cleanup options is overly restricted, and too frequently the responsible party is required to pursue studies and attempt answers to questions that no one has ever satisfactorily answered. Proceeding through the proposed "how clean is clean" decision process can in itself be extremely costly and time consuming. Hidden costs are the cost of proving and attaining negligible risk levels and the cost of responding to the inevitable challenge that data is inadequate. (Sacha, p. 1)

Mr. Stefani and Mr. Meyer (Seattle hearing) expressed similar concerns.

Ecology's Response: Ecology finds itself in basic agreement with some of these comments and has attempted to address these concerns in the final rule. First, Ecology agrees that cleanup standards which serve as a disincentive for PLP-initiated cleanups have the potential for undermining the success of the cleanup program. However, the Department faces a basic conflict of interest with respect to providing incentives for PLP initiated cleanups. On the one hand, the Department is striving to fulfill the statutory requirement to protect human health and the environment while at the same time pursuing a strategy which encourages settlements (thereby minimizing the amount of Toxic Account monies used at individual sites). One of the Department's objectives in developing these cleanup standards is to reduce some of that basic conflict by providing a well-defined process for establishing cleanup standards for individual sites.

We believe that a well-defined process for defining cleanup standards will reduce the uncertainty for PLPs faced with the prospect of cleaning up a contaminated site. We also believe that such an approach will reduce the transaction costs associated with site cleanup and enable PLPs to focus funds for site cleanup rather than unnecessary studies and extra attorney fees.

Finally, Ecology is confident that the many groups involved in developing the cleanup process rule did not envision a process that encouraged PLP cleanups at the expense of human health and environmental protection. Nonetheless, Ecology shares the concern expressed by the Washington Environmental Council (see Issue #9 below) that site-specific negotiations on cleanup levels may jeopardize the goal of protecting human health and the environment. Some groups perceive this to be a problem with the implementation of the Federal Superfund program by EPA and the states. For example, OTA (1989) has concluded that cleanup decisions under the federal Superfund have been affected by the desire for settlement with responsible parties. In support of this conclusion, OTA referenced a study of EPA Record of Decisions (RODs) that noted how closely a cleanup approaches legal mandates can be influenced by responsible parties. The study, prepared by the Oak Ridge National Laboratory (Baes and Marland, 1989), concluded "when the PRP [potentially responsible party] plays an active role (provided that public acceptance is possible), the EPA may be willing to negotiate and accommodate. Negotiation allows the EPA to gain PRP

participation and financial resources where the alternative would likely be litigation... 'clean' becomes whatever can be done at a reasonable cost with the technology available and that will be accepted by the public.

Issue #8: Are the proposed amendments consistent with other parts of the regulations?

Two participants expressed concerns that the proposed approach for establishing cleanup standards was inconsistent with the approach used in the Washington Ranking Method. For example, Dr. David Eaton in his comments on the October 16, 1989 draft stated:

> Use of 1 in one million risk level as stated allows no consideration of population size at risk. As written, this and other parts of the regulation would require this level of cleanup even if the opportunity for human exposure is very low. These are quite explicit in the Hazard Ranking System. (Eaton, p.16 of comments on October 29, 1989 draft)

Similar concerns were expressed by Dr. Lorenzana:

> [I]n general, this regulation seems incongruous with the ranking system for hazardous waste sites. In the ranking system, the location and number of people and other receptors affected by a contaminated media is considered. In this regulation, information concerning receptors is not considered. (Lorenzana, p. 1 of comments on October 16, 1989 draft)

Ecology's Response: Under the cleanup rules, cleanup levels are based on health risks to the reasonably maximum exposed individual. This is consistent with the policy stated in RCW 70.105D.010 that "[e]ach person has a fundamental and unalienable right to a healthful environment." Given this policy statement, Ecology would find it difficult to justify an approach where an individual's right to protection from hazardous substances is dependent upon how many neighbors are similarly situated. Indeed, given the rapid population growth in certain areas of the state it is unclear whether today's sparsely-populated areas will remain unchanged in the future. (This is discussed in Section IV, Issue #5)

Ecology recognizes that this approach contrasts with that used in the Hazard Ranking System where the size of the potentially affected population is considered in establishing priorities for cleanup. By considering population size at this stage of the process, the Department hopes to maximize the rate at which health protection is actually achieved.

Issue #9: Does the proposed rule place too much emphasis on interim cleanup actions?

Several individuals stated the concern that the proposed rule placed too much emphasis on interim cleanup actions. For example:

> Another general comment is that the current rule places too much reliance on interim cleanups. Timely and final cleanups are

> important in order for port districts to fulfill their responsibilities through such actions as industrial property transactions. Timely industrial property transactions advance the general land use goal of using existing industrial sites to the maximum extent, in preference to developing new industrial sites in rural areas. (Johnson, pp. 1-2)
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> While the use of interim status may be desirable in some circumstances, I am afraid that its use to avoid final determination may greatly increase both the cost to the parties and the cost to the agency in supervision manpower. Whatever you can do to make final clean up easier to reach would appear to benefit all concerned. Ultimately, if it were determined that final clean up did not solve critical problems, I am sure there is plenty of legal authority to support a new clean up action. (Tamblyn, p. 1)
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> We share the goal of many responsible parties: to have a final clean up. Owners are motivated by desires to assure public health and safety and to make a site available for reuse or sale. However, the proposed regulation may produce a high percentage of interim actions because the final clean up standards cannot be met. While complete removal of contamination is good public policy by itself, a long term interim status for a large percentage of otherwise usable industrial sites generates a negative impact on the public welfare. It costs jobs and tax revenues. It encourages conversion of virgin, often non-urban, sites for industrial use. We urge the Department to make final clean up status a reachable goal and offset the adverse effects cited above. (von Gohren, p. 2)

Similar concerns were expressed by Mr. Stefani.

On the other hand, some participants were concerned that regulatory efforts to modify cleanup levels to reduce the number of interim cleanups might jeopardize human health and environmental protection. For example, Ms. Tabbutt stated:

> "Cleanup standards should not be negotiable, but should be a set target for all cleanups. If meeting cleanup standards is not possible, then the Department should only agree to an "interim" cleanup and not sign off on the complete job." (Tabbutt, p. 1 of comments on December 29, 1989 draft)

Ecology's Response: Ecology agrees that achieving timely and final cleanups is an extremely important goal and believes that the final rule provides a rationale approach for attaining it.

Issue #10: Will exceedances of the cleanup standards result in the automatic listing of a hazardous substance site?

As discussed under Issue #1, several individuals expressed concerns that exceedances of the cleanup standards would result in the automatic listing and cleanup of a site.

Ecology's Response: Ecology understands this concern and is trying to address the issue through policies and procedures.

First, the process leading from the identification of elevated levels of hazardous substances to an actual cleanup involves several steps. At the first step, Ecology may receive a report of a release and must perform an initial investigation. Following the completion of the initial investigation, Ecology must determine whether the release poses a threat or potential threat to human health and the environment. The cleanup standards would be one source of information used to make this judgement. However, Ecology would also consider the areal extent of contamination, the magnitude of any cleanup standard exceedances, and the site characteristics in making a determination that further study is needed.

The same factors would also be considered when performing a site hazard assessment. At this stage, additional information would be collected to further define contamination levels, potential populations at risk, potential exposure pathways etc. As with the initial investigation, an exceedance of the cleanup standards does not automatically trigger a site listing or site cleanup. A determination that a site constitutes a threat or potential threat to human health and the environment is based on a number of factors in addition to the level of contamination.

Ecology intends to develop further guidance on the factors and interpretation criteria that will be utilized to define cleanup sites. In the interim, Ecology has incorporated regulatory language which states that exceedances of Method A cleanup levels does not necessarily trigger requirements for cleanup action under this chapter (See WAC 173-340-704(4).

PART C

IV. DEGREE OF PROTECTION

A. Background

The complete elimination of all risks posed by hazardous waste sites has sometimes been suggested as a cleanup goal. However, this is generally not achievable, nor is it usually considered necessary. Everyday activities are not risk-free; people have been described as "living in a sea of common risks." At some relatively small level, many risks are considered acceptable. Similarly, some site impacts or estimated risks may be considered too small to require cleanup action or protection. Consequently, from a regulatory perspective, the Department must address the issue of "acceptable risk" or "degree of protection".

Establishing an acceptable level of protection requires consideration of human values and does not lend itself easily to mechanical calculation. The acceptable level of protection is the essential policy question for site cleanups, and is therefore part of risk management rather than risk assessment. Many factors other than the calculation of estimated risks are involved in the choice of an appropriate level of protection (NAS 1983; Deisler 1988; Ricci and Molton 1985; Dwyer and Ricci 1989; and Paustenbach 1989a).

B. Ecology's Proposal

The proposed rule established protection levels for human health (carcinogens and non-carcinogens) and the environment:

> **CARCINOGENS**: Ecology proposed that cleanup levels for individual carcinogens must be at least as stringent as concentrations established under other applicable state and federal laws. For hazardous substances not addressed under such laws, the cleanup level would generally be established at concentrations which result in an excess cancer risk of 1 in 1,000,000. The proposed rule also provides limited flexibility to utilize a 1 in 100,000 risk level to establish cleanup levels for individual substances. In all cases, independent of whether the levels for individual carcinogens were based on applicable state and federal law or risk, the total site risk (taking into account all substances and all pathways of exposure) could not exceed 1 in 100,000.

NON-CARCINOGENS: Ecology proposed to establish cleanup levels for individual non-carcinogens at levels estimated to result in no adverse effects. As with carcinogens, cleanup levels for individual non-carcinogens would, when necessary, be lowered to take into account the potential for exposure to multiple substances and/or multiple pathways.

C. The Public's Response

First, the majority of participants expressed the opinion that the proposed rules would result in cleanup requirements that are protective of human health and the environment. However, Ecology received a wide range of opinions on whether the proposed rule required an appropriate level of protection. Some individuals stated the opinion that the proposed rule provided an excessive level of protection, while other individuals expressed concerns that the proposed rule was not protective enough.

In addition to the general statements, many participants provided detailed comments on specific issues. The issues raised during the rulemaking process which are discussed in depth below include the following:

Issue #1: **Is "natural background" an appropriate cleanup goal?**

Issue #2: **Is it appropriate to establish cleanup requirements that are more restrictive than recognized and promulgated human health and environmental protection standards?**

Issue #3: **What is an appropriate "degree of protection" or "acceptable risk" for carcinogens?**

Issue #4: **Should Ecology adopt an approach that provides the flexibility to consider a range of acceptable risks?**

Issue #5: **Should Ecology base decisions on "acceptable risk" on individual risks or population risks?**

Issue #6: **What is an appropriate "degree of protection" for non-carcinogens?**

Issue #7: **Does the proposed regulation provide Ecology with an appropriate amount of discretion in establishing cleanup levels for individual sites?**

Issue #8: **Do the proposed rules provide sufficient flexibility to address situations where correcting human health and environmental risks at cleanup sites may result in an overall increase in health risks?**

D. Ecology's Evaluation and Response

Issue #1: Is "natural background" an appropriate cleanup goal?

In the proposed rule, Ecology stated:

> All cleanup actions performed under this chapter shall attain a degree of cleanup of hazardous substances and control of further releases of hazardous substances that assures protection of present and future human health and the environment. The goal is to establish cleanup levels as close as possible to natural background levels. (WAC 173-340-700(2))

A number of participants expressed the opinion that the requirement that cleanup levels be established as close as possible to natural background levels is impractical, and in some cases, inappropriate. Several individuals stressed there was no consistent relationship between protection of human health and the environment and "natural background levels." For example:

> WAC 173-341-700(2). The last sentence of this subsection should be eliminated. There is nothing in the MTCA which states any goal of establishing cleanup levels "as close as possible to natural background levels." There is no automatic relationship between

protection of human health and the environment and "natural background levels." (Syrdal, p. 7)

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The [Science Advisory] Board agrees that the use of natural background as a cleanup goal in not scientifically justified. The Board is concerned that inclusion of background as a goal could result in serious delays in the negotiations and implementation of site cleanups, with little or no improvement in protection of human health or the environment. The Board shares the idealistic and philosophical desires of Ecology, other environmental and health regulatory agencies, environmental and citizen's action groups, and most businesses and industries to live in a world free of pollution. However, the enormous advances in analytical chemistry over the past two decades now make the identification of extremely minute and biologically insignificant concentrations of synthetic organic chemicals commonplace. The "vanishing zero" for chemical identification in environmental samples in now a reality. In addition, in certain locations naturally occurring concentrations of heavy metals or other inorganic species are above drinking water or other applicable standards *in the absence of anthropogenic input.* The pursuit of protection of human health and the environment is not supported by most current scientific perspectives on very low dose chemical risks. The Board believes that it is important to distinguish between requirements that are necessary to adequately protect human health and the environment and those that serve other purposes. To not do so could seriously impair the effectiveness of the Model Toxics Control Act, and could paradoxically result in increased human health risks and environmental degradation as a result of inaction and delays in cleanup that inevitably occur when negotiating parties have widely divergent perspectives on what is reasonable and necessary to protect human health and the environment. (Science Advisory Board, p. 2)

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The proposed regulations have the announced goal of established cleanup levels as close as possible to natural background levels WAC 173-340-700(2). Such an expression leaves ambiguous the relationship between protection of human health and the environment, risk and natural background levels. We recommend that protection of human health and the environment be clearly stated as the overarching goal. That may or may not mean natural background depending upon risk under the circumstances. (Thomson, p. 3)

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This section further states that "the goal is to establish cleanup levels as close as possible to natural background levels." Background levels do not assure protection of human health and the environment. More importantly, this goal may be counter productive in that achieving background levels at a site that are far below those necessary to protect human health and the environment can take away funds needed to cleanup other sites. (Tsuji, p. 2)

Other participants expressing similar concerns include the following: Burgess and Dunster, p. 2; Burch, p. 2; Izatt, p. 3; Butler, p. 7; and Sacha, p. 2.

Ecology's Response: Ecology is concerned that many of the individuals or groups providing comments on this issue were misreading Ecology's intent. This subsection has been redrafted several times over the last year to clarify that "cleanup levels as close as possible to natural background levels" is a goal, not a requirement. As outlined in the draft Environmental Impact Statement (EIS), a general requirement that cleanup levels be established at background concentrations was rejected for many of the reasons outlined in the above comments. (Ecology, 1990)

However, upon review of the public comments on the proposed rule, Ecology has elected to delete this phrase from the final rule. Ecology believes that the continued inclusion of the proposed language may increase regulatory uncertainties regarding cleanup levels which would then be translated into inaction and cleanup delays.

Issue #2: Is it appropriate to establish cleanup requirements that are more restrictive than recognized and promulgated human health and environmental protection standards?

RCW 70.105D.030(2)(d) requires Ecology to publish and enforce cleanup standards that are at least as stringent as requirements under other "applicable state and federal laws." Under the proposed rule, such requirements (i.e. drinking water standards) are used to establish cleanup levels for individual hazardous substances. The cleanup levels for individual substances may then be lowered to ensure that (1) the total excess cancer risk does not exceed 1 in 100,000, (2) the Hazard Index does not exceed 1.0, and (3) residual levels of hazardous substances in one media (i.e., groundwater) do not cause violations of cleanup levels in other media (i.e., surface water).

Several individuals expressed the opinion that it was poor public policy to establish cleanup levels more stringent than those established under other "applicable state and federal laws." For example:

> Where the EPA has established or proposed a maximum contaminant level, that number should be used for the state's cleanup criteria. Considering the conservative assumptions built into EPA's risk assessment models, there is no logic to setting lower standards than those proposed by the federal government. The added cost of cleaning up to a level that is lower than that required by the EPA is simply not justified. There are many more effective ways to improve our quality of life than to try to strain out every last molecule of a chemical that we "think" might be harmful. (Proby, p. 1 of comments on March 9, 1990 draft)
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> From a public policy standpoint, the proposed cleanup levels are at serious odds with acceptable levels promulgated under other state and federal statutes. This is a very serious problem ....

> similarly, the MCLs for benzene and vinyl chloride are 5 and 2 µg/l, respectively, while the DOE ground water cleanup level or each is 1.0 and 0.4 respectively. These lower values are due to assuming both inhalation and ingestion exposures to these volatile organic compounds could occur from ground water that may serve as a potential drinking water source. What is the logic behind restricting contaminant levels in water that may serve as a potential drinking water supply, but that ignores the risk to actual consumers of water. It would seem logical that if the DOE truly believed in protecting health of its citizenry, and had the conviction in its methodology, then it would require all municipal public water supplies to meet these same drinking water quality standards. (Coenen, p. 2 of comments on March 9, 1990 draft)

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> "If cleanup levels are more stringent than levels which are accepted in other state and federal programs, each incremental increase in remediation risk has a significant chance of being greater than the incremental reduction in site risk." (Landau, p. 4 of comments on December 29, 1989 draft)

Individuals expressing similar concerns include Thomson, p. 3; and Burgess and Dunster, p. 4.

Other participants urged Ecology to recognize that some of the requirements established under applicable state and federal laws were "outdated." They suggested that strict adherence to such requirements may result in requirements that are either "overprotective" or "underprotective." For example, Dr. Tsuji stated:

> Some allowance should be made for the possibility that concentrations established under applicable state and federal laws are out-dated. For example, many of the water quality criteria are as much as 10 years old and have not been updated. As a result, the arsenic ambient water quality criteria for protection of human health via fish ingestion is based on the old arsenic cancer potency factor, which is now an order of magnitude lower (less conservative). (Tsuji, p. 5)

Ecology's Response: Under the final rules, Ecology will utilize "applicable state and federal laws" to establish cleanup levels for individual substances except for situations where the use of such levels would result in total site cancer risks greater than 1×10^{-5} or a hazard index greater than 1. Where these limits are exceeded, cleanup levels more stringent than "applicable state and federal laws" will be required. Ecology believes that the decision to establish requirements more restrictive than applicable state and federal laws is appropriate for the following reasons:

> Statutory Mandate: Ecology believes this approach is consistent with the statutory requirement of establish "minimum cleanup standards" at least as stringent as "applicable state and federal laws."
>
> Technical Issues: Program experience has shown that ARARs do not, by themselves, necessarily define protectiveness. Complete reliance on existing standards suffers from several shortcomings:

- Multiple Hazardous Substances: Most existing standards were developed for individual substances (i.e. drinking water standards). As noted by EPA (1990), "in those circumstances where multiple contaminants are present, the cumulative risks posed by the potential activity of the constituents may require cleanup levels for individual contaminants to be more stringent than ARARs to ensure protection at the site."

- Multiple Pathways of Exposure: Individuals may be exposed to hazardous substances at cleanup sites by more than one pathway of exposure. Most standards have been developed on the basis of exposure to one route of exposure.

- New Scientific Information: As noted by Dr. Tsuji, sole reliance on existing standards may preclude consideration of new scientific information. For example, the current drinking water standard for lead is 50 µg/l; available health data suggest that levels up to an order-of-magnitude lower may be more appropriate.

- Multiple Endpoints: Under the Model Toxics Control Act, Ecology is required to consider both human health and the environment. Although some existing standards address human health and some address environmental endpoints, most do not address both.

- Statutory Goals: Existing standards were developed under a wide variety of statutes. In some cases the factors considered in developing those standards differs from those considered under MTCA.

Other State and Federal Programs: Ecology's approach is consistent with, although not identical to, the approach used by EPA. Under the EPA approach, EPA utilizes ARARs to establish cleanup levels unless the total site cancer risk exceeds 1 in 10,000 (EPA, 1990a). In addition, several other states (i.e. Massachusetts, Michigan, etc.) have adopted cleanup regulations which require cleanup levels more stringent than ARARs in situations where overall protection limits (either risk levels or an Hazard Index) are exceeded. In those states, site cancer risks of 10^{-5} are utilized when evaluating whether requirements more stringent than ARARs are required.

Issue #3: What is an appropriate "degree of protection" or "acceptable risk" for carcinogens?

Ecology's proposal defined acceptable risks for individual carcinogens and total site risk. For individual substances, Ecology proposed to establish cleanup levels on the basis of an excess cancer risk of 1 in 1,000,000 unless acceptable levels were specified in applicable state and federal laws. The proposal also provided the flexibility to modify cleanup levels for individual carcinogens by using a cancer risk level of 1 in 100,000 under some circumstances.

Ecology also proposed that, independent of whether cleanup levels for individual carcinogens were based upon a 10^{-6} cancer risk, a 10^{-5} cancer risk, or applicable state and federal laws, the total excess site cancer risk cannot exceed 1 in 100,000. Consequently, cleanup levels for individual carcinogens

may need to be adjusted downward to take into account potential exposures to multiple hazardous substances and/or multiple routes of exposure.

A wide range of opinions was expressed on the issue of acceptable cancer risk. First, a number of participants expressed support for Ecology's proposal to utilize an acceptable risk level of 1 in 1,000,000 to establish cleanup levels. For example:

> Cleanup levels based on "risk assessments" cannot be guaranteed to be as protective as they seem. The formulas derive from a combination of assumptions that could lead the determination to be off by several orders of magnitude. One in a million should be the absolute maximum level of risk accepted. (Cellarius, p. 1)

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> The purpose of cleanup at historic sites is to rectify practices made without concern for public health and the environment. We must, in spite of our limited knowledge and understanding, decide what risk is acceptable. In deciding on a risk level we will be faced with wide margins of uncertainty. Hazardous waste sites often present even more uncertainty than most toxicological assessments by nature of their complex mixture of chemicals and routes of exposure. If, in our cleanups, we aim for a risk of increased cancer at 10^{-6}, we could be off by several orders of magnitude; we could be accepting 10^{-5} or 10^{-4}. Therefore, we should be conservative with our risk level and not allow it to drop below 10^{-5} or we may, in actuality, be accepting actions which are only slightly protective. **The WEC supports cleanup standards aimed at an increased cancer risk of 10^{-6}.** (Tabbutt, p. 1)

Similar statements were received from Wishart, Cook, and Stembridge.

Other individuals argued that the use of a 1 in 1,000,000 cancer risk level was too conservative. For example, Mr. Thomson stated:

> Furthermore, the use of 10^{-6} and refusal to go below 10^{-5} reflects a rigidity for numerical purity at the expense of exceeding what is necessary to protect human health and the environment. This threatens to misuse limited government and private dollars. We specifically recommend that you use existing federal MCLs, which have been determined to be protective of human health, even though they may reflect a 10^{-4} risk. (Thomson, p. 3)

Similar statements were provided by Syrdal, Ryan, Aldrich, and von Gohren.

Several participants provided detailed statements describing the rationale for the use of risk levels greater than 10^{-6}. For example, Mr. Syrdal recommended that Ecology provide additional flexibility in risk level determinations in light of available information on health risks associated with other everyday activities:

> As a further indication that the 10^{-6} standard contained in the proposed regulations should, when necessary to avoid technically impracticable solutions, be modified to a higher risk level, one need only review some of the comparative risk data supplied to the

> Department by the Science Advisory Board. For example, a U.S. citizen currently has a 1 in 4 chance, or 0.25, of dying from cancer from any and all causes. If a site were cleaned to the 10^{-6} risk level, and assuming that person in fact was exposed in accordance with the risk assumptions associated with that calculation such as drinking two liters of water per day from a monitoring well at the compliance point over a 70 year lifetime, that person's risk would increase to .250001. Taking the uncertainty of the methodology into account and again assuming the validity of many potentially unrealistic, but conservative, exposure assumptions, that person's risk may really only have increased to something like .2500000001 or less. Despite these facts, the Department under these regulations would not be free to consider a lesser cleanup standard even in no one was, or was likely to be, so exposed.
>
> It is also pertinent to note that if a site were cleaned to a 10^{-6} risk level it would mean someone exposed to all of the conservative exposure assumptions at that site would have approximately the same risk of dying from that exposure as that person currently has in the United States of dying of measles, and a much lower risk than the person would have of dying from a small pox vaccination, lightning, electrocution, drowning, etc. Perhaps more importantly, the risks associated with many contaminants at the 10^{-6} risk level is far lower than the risks that person accepts or incurs nearly everyday. For example, the risks are much lower than a person experiences in eating three ounces of bacon, drinking two liters of chlorinated water per day, or eating one ounce of peanut butter per day. While this still does not justify necessarily exposing people to additional risks, it certainly should be relevant in determining what level of risks, and what level of conservative assumptions in calculating such risks, should be applied when one is considering the expenditure of scarce resources. (Syrdal, p. 7)

Several individuals also recommended that Ecology reevaluate its proposal in light of regulatory decisions made under other programs. For example:

> The target risk level for carcinogenic chemical specified by WDOE is 10^{-6} for residential exposure under Method B and 10^{-5} for industrial exposure or conditional (e.g., see WAC 173-340-720 to 173-340-760). These risk levels are 10 to 100 times more conservative than the target risk level set by the U.S. EPA for exposures to small populations, such as those exposed to contaminated waste sites. A review of decisions of the U.S. EPA indicates that 10^{-4} is the risk level below which action has never been taken to reduce risk for these smaller populations (Travis *et al*, 1987). (Tsuji, p. 3)

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> There are a great number of factors which suggest that the very stringent risk approach utilized in these regulations is inappropriate. First, it must be remembered that the state act is to apply to those sites which are not "bad enough" to be designated as Federal Superfund sites. Under federal law, all cleanups must be cost effective, and costs and other practicability issues are

utilized to determine what level of risk is appropriate to use a cleanup goal for a federal site. In general, the federal regulations in the national contingency plan provide that the risk level should lie somewhere between 10^{-4} and 10^{-6}. By requiring a 10^{-6}, with some possibility of going to 10^{-5}, risk level, the state is applying a standard which is up to 100 times more stringent than the federal government even though the sites to which it applied presumably do not present the same magnitude of risk to public health. Even the State of California has determined, in adopting regulations to implement...(sic) (Syrdal, p. 4)

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The use of a 1 in 1,000,000 acceptable cancer risk for calculating concentrations is over conservative. The states of Virginia, Maryland, Ohio, Georgia, and Alabama have employed or propose to use the one hundred thousand level in their risk management decisions. The state of Maine Department of Human Services uses a lifetime risk of one in one hundred thousand as a reference for non threshold (carcinogenic) effects in risk management decisions concerning exposures to environmental contaminants. Similarly, a lifetime incremental risk of one in one hundred thousand is used by the Commonwealth of Massachusetts as a cancer risk limit for exposures to substances in more than one medium at hazardous waste disposal sites. And workplace air standards developed by the Occupational Safety and Health Administration (OSHA) typically reflect theoretical risk of one in thousand or greater. (Holm, p. 1 of comments on December 29, 1989 draft)

The Science Advisory Board also addressed many of these topics in their final comments on the proposed rule. They stated:

The Board understands that the selection of any specific risk level [e.g., one in a million (10^{-6}) risk level] as the *acceptable* additional lifetime risk is a decision based on both policy and science. Although scientific theory (e.g., the non-threshold concept of chemical carcinogenesis) plays an important role in characterizing potential risks, the *acceptability* of such theoretical risks is largely determined by social, political, and philosophical perspectives that are perhaps influenced more by the absence of scientific considerations, examples of which can be found in Appendix A, the SAB is in unanimous agreement that strict adherence to a 10^{-6} lifetime risk level for potential chemical carcinogens as a compliance cleanup standard may go beyond what is necessary to reasonably protect human health, and may not be scientifically justified in specific situations.

The proposed cleanup regulations provide for use of an alternative 10^{-5} risk level in certain situations, such as the industrial soil cleanup levels. The Board believes that inclusion of the 10^{-5} risk range provides some desirable flexibility. However, the Board also believes that the strict adherence to even the 10^{-5} risk range, as is currently required in the proposed regulations, may not allow for full consideration of available technical and scientific information in some circumstances, and encourages Ecology to broaden the risk range by an additional order of magnitude, as is

> commonly the case with federal regulations using similar approaches to defining acceptable risk levels for chemical carcinogens. Broadening the risk range provides additional flexibility to deal with sites on a case-by-case basis, allowing decisions to be made where site-specific circumstances clearly indicate that actual risk is substantially lower than that predicted by the standard quantitative risk assessment approach, yet still allows for strict enforcement of cleanup where site-specific circumstances warrant protection of human health at a 10^{-5} or 10^{-6} risk level. The increase in flexibility gained by expanding the risk range should enable cleanup standards to be applied to all sites without the need for modification as the knowledge base in toxicology and epidemiology advances.
>
> Under no circumstances should a cleanup action be required that results in a net *increase* in total risk to human health or the environment. Although it is imperative that hazardous waste sites be dealt with in a manner that is adequately protective of human health and the environment, it must also be recognized that decisions made to ameliorate one risk inevitably result in introduction of other risks. Once contamination has occurred, one must consider the trade-offs that result when remedial actions are implemented. Seldom do such actions **eliminate** risks, rather they result in actions that **substitute** risks. Thus, in remedy selection, reduction of total risk should become the goal, and time and effort should not be spent pursuing actions that result in no net gain in human health and/or environmental protection. (Science Advisory Board, p. 3)

Finally, several individuals stated that the total site risk requirement of 10^{-5} may require cleanup levels for individual hazardous substances more stringent than 10^{-6}. For example:

> When multiple chemicals are involved at a site, the Proposed Amendments designate a target risk level that is similar to the risk level for individual chemicals. Setting overall cleanup level close to or at the same level as for individual chemicals (e.g., 10^{-5}) means that risks associated with individual chemicals must be, for example, two orders of magnitude lower (e.g., 10^{-7}) in order that total risks do not exceed a target level of 10^{-5}. Consequently, this goal will be rarely met because analytical detection limits will not be able to meet the low concentrations required and these concentrations will also probably be below background levels. The U.S. EPA recognized this problem in their National Contingency Plan (NCP) guidance that the target risk level when multiple carcinogens are involved shall be 10^{-4}. (Tsuji, pp. 3-4)

Ecology's Response: Ecology regards the decision as to whether a risk of a given magnitude is "acceptable" or "unacceptable" as a policy matter rather than a scientific matter. For individual carcinogens, Ecology proposed to base cleanup levels on a cancer risk level of 10-6. The proposed rule also specified that the total excess site cancer risk must not exceed 10^{-5}. Within this overall risk ceiling, risks from individual carcinogens would be on the order of 10^{-6}.

In selecting a 10^{-6} cancer risk level for individual carcinogens and a 10^{-5} total excess site cancer risk level, Ecology considered (1) requirements under other Ecology regulatory programs, (2) requirements under other state and federal laws, (3) experience on cleanup sites, (4) comparisons with other activities, and (5) public comment on the proposed rule.

Consistency With Other Ecology Programs: The issue of acceptable risk was identified as a major concern during the early meetings of Ecology's Rule Coordinating Committee. A subsequent informal review of regulations being developed by Ecology revealed that a 1 in 1,000,000 cancer risk is being utilized by the programs charged with establishing regulatory requirements for toxic air pollutants, ground water, surface water, and hazardous waste cleanup. The regulations requiring remediation of past problems (as opposed to prevention of future problems) are being designed to incorporate more flexibility in modifying levels (See subsequent discussion).

Consistency With Other Regulatory Agencies: The proposed approach is also consistent with requirements utilized by other state and federal programs. Under the final National Contingency Plan (EPA 1990a), EPA considers the 10^{-6} cancer risk level as the "point of departure" for establishing cleanup levels for individual carcinogens but provides the flexibility to adjust that to a cancer level of 10^{-4}. However, reviews of site records of decisions (PTI, 1989b; Baes and Marland, 1989) indicates that acceptable risk limits for cleanup sites were less variable than the range included in National Contingency Plan. Most cleanup actions were based on an acceptable risk of either 1×10^{-5} or 1×10^{-6}.

EPA has recently reviewed cleanup requirements under state programs (EPA, 1990c). That review identified 24 programs with written rules or guidance. Of those 24 programs, eight states utilized a 10^{-6} cancer risk level as their primary means of establishing cleanup levels; six relied on the National Contingency Plan; three relied on ARARs; two specified 10^{-5}; and the remaining five utilized other approaches (i.e., background, 10^{-7} cancer risk). The two states employing 10^{-5} (Massachusetts and Minnesota) specified that the standard was based on total site risk. It was unclear whether other program requirements were based upon total site risk or individual substances.

Finally, Ecology's approach is similar to requirements recently established under other laws. For example, EPA has proposed amendments to the hazardous waste incinerator regulations which specify that the "aggregate risk to the maximum exposed individual shall not exceed 10^{-5}" (EPA, 1990d). At the state level, California utilizes a 10^{-5} cancer risk level to define "significant risks" under Proposition 65.

Experience At Cleanup Sites: As noted above, recent reviews of site cleanup decisions indicate that the majority of cleanup actions are based on an acceptable risk of either 1×10^{-5} or 1×10^{-6}.

Comparisons With Other Activities: Several individuals suggested that Ecology determine what constitutes an "acceptable risk" on the basis of comparisons with risks from different types of activities. These comparisons may be broad or limited to a similar class of activities (Covello 1989; Wilson and Crouch 1987). This approach assumes that comparative risks are easier to understand than numerical statements of probabilities. In addition, it assumes that levels of risk associated with common daily activities are considered acceptable. Estimated risks for such actions as driving a car, breathing urban

air, drinking water that has been disinfected using chlorination, flying in an airplane, having a diagnostic x-ray taken, or eating typical foods are commonly used in these comparisons (Covello 1989). Risks from smoking, drinking alcoholic beverages, or other potentially injurious actions may also be included, although they may not necessarily be used to define accepted risks.

Several participants questioned the rationale for using a 10^{-6} risk level to establish requirements for contaminated ground water when risk levels associated with chlorinated public water supplies are 10 to 100 times higher. For example:

> According to the approaches defined in the proposed regulations, adhering strictly to the 10^{-6} risk level for groundwater contaminated with trichloroethylene or methylene chloride would require cleanup of contaminated groundwater to a concentration of 5 ppb. Thus, for example, individuals or communities consuming groundwater contaminated with 50 ppb of either of these chemicals (10 times greater than the standard) may well be forced to be placed on chlorinated public water supplies, often at substantial expense. Using the same assumptions and procedures to estimate the theoretical cancer risk for halo-organics (such as chloroform in public water supplies) as is used in estimating cleanup standards, it will become immediately apparent that the groundwater contaminated with 50 ppb of methylene chloride or TCE (10 times greater than the proposed cleanup standards) is actually no less "risky", and in fact is very likely substantially "safer", than the chlorinated public water supply which becomes the alternative water supply. In fact, when one examines closely the scientific data implicating methylene chloride and TCE as carcinogens, the case is considerable weaker than that for chloroform. There is no argument that the philosophical *ideal* would be that the groundwater be in its original pristine condition. However, once contamination has already occurred, one must consider the trade-offs that occur when remedy decisions are made. Seldom do such decisions eliminate risks; rather they result in actions which substitute risks. (Science Advisory Board, p. 7)

Although the Board's comments highlight an important issue regarding risk substitution, Ecology finds the comparison to chlorinated water supplies somewhat misleading in the context of defining "acceptable" or "de minimus" risk. The current trihalomethane (THM) standard of 100 ug/l was established in 1984 and took into account economic costs and technical feasibility. The issue of chlorinated drinking water supplies was subsequently reviewed by the Safe Drinking Water Committee of the National Academy of Sciences who concluded:

> "[T]he level of total (THMs) in finished drinking water, currently regulated at 100 micrograms (µg) per liter, should be reduced. Noting that chloroform is the principal THM produced by chlorination, the subcommittee found this level to be insupportable on the basis of the risk values for chloroform developed in this review." (NAS, 1987, p. 1)

In light of this recommendation, Ecology believes that it would be poor public policy to define "acceptable" risk in the state of Washington based on comparisons with a risk judged to be unacceptable at the national level.

Several participants suggested that Ecology determine "acceptable risk" levels empirically by looking at past regulatory decisions. Such a review has been performed by Travis et al (1987). They examined 132 federal regulatory decisions and noted that individual risks above 4×10^{-3} were always regulated and individual risks below 1×10^{-6} were never regulated. When risks were between these upper and lower bounds, regulatory actions were taken in some cases but not in others. At these sites, the cost-effectiveness of regulating (cost per cancer case avoided) is cited by the authors as the primary factor affecting the decision. These cutoff levels for action also changed according to the size of the populations affected; the larger the population, the smaller the level of acceptable risks. Thus, based on past federal agency actions, at least two measures of cancer risk are used to describe what is acceptable: the lifetime risk to the individual and the incidence (number of cancers) in an exposed population.

A variation of this approach considers human health risks remaining after regulatory actions are taken (Travis and Hattemer-Frey 1988). Based on actions related to 36 carcinogenic hazardous substances, the authors conclude that 70 percent of the regulations allow risks above 1×10^{-6} and about 30 percent exceed 1×10^{-4}.

Ecology believes that sole reliance on this approach has several problems. First, many of the past decisions referred to in these analyses were made under statutes which enable considerations other than human health and environmental protection to be factored into regulatory decisions on risk. Indeed, many of the regulations cited in these reviews did not even consider residual risks. This is not consistent with the intent of the MTCA. Second, many of the previous decisions reflect the policy of giving individuals less protection where they are, relatively speaking, few in number. This also appears to be inconsistent with the MTCA which states that "each person has a fundamental and unalienable right to a healthful environment..." Third, as emphasized by Dwyer and Ricci (1989), Slovic (1987), and Florino (1989), acceptability of risks depends on context and on many factors beyond the numerical risk level, such as familiarity with risk, benefits from allowing the risk, and whether the risk is a voluntary one. Finally, even if these problems were not present, it would be a circular arguement- a classic bootstrap- for Ecology to decide that what it <u>should</u> do about cancer risks can be derived from what <u>could</u> be done in the past.

Similar concerns were expressed by Ricci et al. (1989) in the paper <u>Acceptable Cancer Risks: Probabilities and Beyond</u>:

> Whether a risk is "acceptable" generally depends not only on it's objective quantitative probability and the nature and severity of the consequences, but also on societal and political factors. Single numerical estimates of individual and population risks do not incorporate those qualitative aspects of risk. Protection of individual rights, the equity of risk-benefit distribution, prudence when facing uncertainty, the absence of knowledge, the legitimacy of the risk management process, and public attitudes toward and perceptions of risks do not lend themselves well to bare numerical representations. (Ricci, et al., 1989, p. 1046)

Finally, some participants have equated "acceptable" risk with the concept of "de minimus" risk. In examining this issue from a policy perspective, it is relevant to examine <u>Alabama Power vs. Costle</u> which is generally considered the

modern origin of the "de minimus" doctrine. In that case, the Court stated that to be "de minimus", the benefit of regulation must be "trivial" or "of no value." EPA's most recent policy statement of "de minimus" risk was made in the context of pesticide regulation. In "Regulation of Pesticides in Food: Addressing the Delany Paradox", EPA announced its policy conclusion that cancer risks greater than 1 in 1,000,000 would not be considered "de minimus" under the Federal Food, Drug, and Cosmetic Act (FFDCA).

Issue #4: Should Ecology adopt an approach that provides the flexibility to consider a range of acceptable risks?

In the proposed rule, Ecology provided the flexibility to utilize a cancer risk level of 10-5 to establish cleanup levels for individual carcinogens (Method C Cleanup Levels). The use of this risk level was limited to those situations where one of several conditions is demonstrated to exist (i.e. cleanup levels are below area background). In addition, cleanup levels for individual substances must still be at least as stringent as applicable state and federal laws and the total excess cancer risk (taking into account multiple hazardous substances and multiple pathways of exposure) can not exceed 10-5.

Several participants expressed opinions on the use of a 1 in a 100,000 cancer risk level for conditional cleanup levels (Method C Cleanup Levels). Many recommended that Ecology utilize a risk range of 10^{-4} to 10^{-6} or 10^{-7}. For example:

> "The risk range used to determine compliance and conditional cleanup levels is not broad enough for the variability of site use conditions and exposure potentials. The range of 10^{-4} to 10^{-6} should be used as is done in the federal cleanup program." (Thomson p.1 of the December 29, 1989 draft)
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> **********
>
> "The EPA acceptable cancer risk range in the NCP is 1×10^{-4} to 1×10^{-6}. The requirement of a 1×10^{-6} cancer risk in all circumstances may not be practicable. We propose that the cancer risk range be revised to reflect a range comparable to the one established by EPA in order that site-specific contaminants and site-specific conditions can be best evaluated." (Fortier, p. 3 of comments on March 9, 1990 draft)
>
> **********
>
> "We recommend that the excess cancer risk for conditional cleanups be 1 in 10,000. EPA, through several of their regulations (i.e., Safe Drinking Water Act, CERCLA, and RCRA), has determined that this level is "protective of human health." (Burgess and Dunster, p. 4)
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> **********
>
> "For involuntary risks for carcinogens, the accepted risk is often in the range of 10^{-4} to 10^{-6}. As the upper end of this range is approached or exceeded, the incremental "net risk" (change in remediation risk minus change in site risk) has a likelihood of being detrimental." (Landau, p.5 of comments on December 29, 1989 draft)

Similar comments were provided by the following individuals: von Gohren p. 2; and Syrdal p. 4.

Ecology's Response: In order to address the recommendation that Ecology provide more flexibility in establishing cleanup levels, the Department developed the concept of conditional cleanup levels (renamed Method C Cleanup Levels in the final rule). Although conceptually similar to the "acceptable risk range" utilized by the Environmental Protection Agency, it differs in three significant aspects from that used by EPA. First, the proposed range is narrower than that employed by EPA ("10^{-5} to 10^{-6}" as opposed to "10^{-4} to 10^{-7}"). Second, the criteria for modifying the cleanup standards within the acceptable risk range are constrained to factors identified in the regulation. Third, the overall risk ceiling of 10-5 applies to all sites.

In selecting this approach, Ecology considered the following factors:

Reviews of Federal Program: Several recent reviews of the federal Superfund program have identified the risk range as a serious obstacle to efficient cleanup of contaminated sites. For example, the Office of Technology Assessment which concluded in a recent report (OTA 1989) that "reducing excessive flexibility in the superfund implementation is critical to reducing the constant confrontation among nearly everyone affected by and working in the program...." OTA concluded that excessive flexibility, in combination with opposing views of risks to human health and the environment, have resulted in a system in which competing interests find too many opportunities to achieve their objectives at too great an expense to their adversaries. According to the OTA, a major source of flexibility in the federal program is the risk range. Similar conclusions were reached by Clean Sites Inc., a non-profit organization which organizes/mediates superfund cleanup efforts involving large numbers of responsible parties (Clean Sites, 1990) and a coalition of environmental groups (Environmental Defense Fund, et al, 1990). The Department believes that by modifying the current EPA approach, Ecology will be able to take advantage of the strengths of such an approach while addressing some of the recent criticisms.

Minimize Program Inconsistency: Ecology believes that the use of a risk range will increase the potential for inconsistencies among site cleanup actions. This was noted by Killian (1989) who concluded that "[i]f the allowable level of risk is not held constant, "How Clean is Clean?" levels become moving targets and the probability that they will be applied inconsistently increases significantly...." [See discussion on flexibility in Section III]

Cleanup Experience: Based on a review of EPA Records of Decision (PTI, 1989b), it appears that most cleanup actions are being required to attain risk levels within the 10^{-5} to 10^{-6} risk range. This finding is consistent with EPA's conclusion that it has not utilized the lowest end of the risk range (i.e. one in ten million) at cleanup sites (OTA, 1989).

Interprogram Coordination: As noted above, other Ecology programs are in the process of developing rules which specify a general requirement of 1 in 1,000,000 cancer risk. The issue of modifying these levels has only become an issue with respect to ground water. The ground water quality standards specify that enforcement limits for ground water cleanups will

be established under Chapter 173-340 WAC. This language was inserted based on the understanding that a cancer risk greater than 1 in 100,000 would not be utilized to establish minimum cleanup standards.

Issue #5: Should Ecology make its decisions on acceptable risk on the basis of individual risks or population risks?

Cancer risks can be expressed numerically in several different ways. The two most common measures are the probability of one individual developing cancer and the expected number of cancer cases within an exposed population. Other less common measures, such as a risk distribution or the number of years that a lifetime is shortened, have also been considered by regulatory agencies.

These different measures of risk are not equivalent and the choice of a risk measure may have a large impact on the actual level of protection at a particular site. For instance, establishing an individual lifetime risk of 1×10^{-6} as acceptable implies different population risks for two sites with different sizes of exposed populations. Conversely, using a single population risk value (one cancer death in a community per year, for example) to define acceptable risk implies that different individual risks would be acceptable at sites with different exposed populations.

As noted in Section II, cleanup levels under the MTCA cleanup regulation are based on protection of the reasonably maximum exposed individual. Several participants questioned the rationale for this approach. For example:

> "Use of 1 in 10^{6} [sic] risk level as stated, allows no consideration of population size at risk. As written, this and other parts of the regulation would require this level of cleanup even if the opportunity for human exposure is very low. These are quite explicit in the Hazard Ranking System" (Eaton, p.2 of comments on October 16, 1989 draft)

Ecology's Response: Under the proposed rules, cleanup levels would be based on individual cancer risks. The Department believes this approach is appropriate for the following reasons:

> Statutory Mandate: This is consistent with the policy stated in RCW 70.105D.010 that "[e]ach person has a fundamental and unalienable right to a healthful environment...." Given this policy statement, Ecology would find it difficult to justify an approach where an individual's right to protection from hazardous substances is dependent upon how many neighbors are similarly situated. Furthermore, given the rapid population growth in certain areas of the state (Ecology, 1990b), it is unclear whether today's sparsely-populated areas will remain unchanged in the future. It is important to note that while distinctions between current and potential exposures are an important factor to consider when establishing regulatory priorities, distinguishing between the two when establishing cleanup levels would be inconsistent with the MTCA policy that "[t]he beneficial stewardship of the land, air, and waters of the state is a solemn obligation of the present generation for the benefit of future generations."

Other Regulatory Programs: This approach is also consistent with requirements under other regulatory programs. For example, a similar approach is used in the EPA Superfund program (EPA, 1989). EPA's proposed requirements for emissions from hazardous waste incinerators are also based upon exposure to the maximum exposed individual (EPA, 1990f).

Use of Indicator Hazardous Substances: Utilizing individual risk as the basis for cleanup decisions is linked to Ecology's use of indicator hazardous substances. Indicator hazardous substances are used as a means of simplification and study cost reduction. Although concerns have been expressed that this inevitably means underestimating total risks, OTA (1989, p.64) noted that "if the possible worst case individual risk, as it is currently, then using a short list of contaminants is less problematical."

Ecology recognizes that the decision to base cleanup levels on individual risk places increased importance on the selection of exposure parameters used to define "reasonable maximum exposures." For example, it is not unreasonable to assume that a single housing site will be occupied for 70 years. However, national figures indicate that it may not be reasonable to assume that the same individual will reside at the site for 70 years. Consequently, population mobility has been considered in establishing the RME scenario.

Issue #6: What is an appropriate "degree of protection" for non-carcinogens?

Ecology proposed to establish cleanup levels for non-carcinogens at concentrations that prevent all known or anticipated acute or chronic toxic effects to the human population, including sensitive subgroups. In general, these concentrations are established at levels where exposure to a substance will not exceed unacceptable levels (as measured by the reference doses). The ratio of exposure to the reference dose is called the Hazard Quotient (HQ).

Ecology proposed to utilize an Hazard Quotient and an Hazard Index of 1.0 to establish cleanup levels. Ms. Elizabeth Tabbutt urged the Department to utilize a hazard index of 0.2.

> "The hazard index for non-carcinogens should be adjusted for the fact that exposure from drinking water accounts for only a portion of the total exposure. In recent proposals on federal standards under the Safe Drinking Water Act the approach is to assign a relative contribution from drinking water at 0.2. **WEC urges that the hazard index for non-carcinogens be set at 0.2 rather than 1.0."** [sic] (Tabbutt, p.4)

This approach was included in the December 29, 1989 Work Group draft and in the March 9, 1990 Public Review draft and drew considerable criticism. For example:

> [U]sing a hazard quotient of 0.2 does not appear justified. The EPA's use of a hazard quotient of 1.0 should be followed. The only rationale I have heard for the 0.2 figure is that the public may be receiving a substantial percentage of the hazard quotient from

other everyday sources, and shouldn't be "pushed over the edge" by exposure at a cleanup site. If this scenario is true, it would be more efficient to direct societal resources into cleaning up those other sources, since they are endangering more people, rather than cleaning up a particular site to a stricter standard. (Belfiglio, p.2 of comments on March 9, 1990 draft)

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"The use of a 0.2 Hazard Index is unnecessarily restrictive. No studies have been conducted documenting what portion of a person's total exposure can be attributed to hazardous waste sites. Reference doses already incorporate conservative safety factors and the exposure parameters in this draft are likewise highly conservative. The use of a 1.0 Hazard Index would be suitable under these circumstances." (Lorenzana, p.1 of comments on March 9, 1990 draft)

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EPA has established the hazard index of 1.0 for multiple chemicals with similar toxic endpoints. The rationale for this index is given in the Superfund Risk Assessment Guidance - Human Health Evaluation Manual. There is no basis given for a hazard index of 0.2 or 1.0 in the cleanup standards. Attempting to achieve a hazard index of 0.2 at hazardous waste sites may result in no technically feasible alternatives because of the extremely low concentrations. It may be appropriate to review the derivation of the reference doses used to compute the hazard index prior to establishing a cleanup level which may not be substantiated by the quantitative toxicity information. (Cirone and Schwartz, p.1 of comments on December 29, 1989 draft)

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"The use of this hazard index [0.2] is excessive and provides a 100 percent confidence level. The risk parameters that have been developed and used by EPA provide a 95-99 percent confidence level, which has been identified as protective of human health and the environment. We propose that a hazard index of 0.2 be deleted as a variable in determining risk and cleanup levels." (Fortier, p.3 of comments on March 9, 1990 draft)

****

"[T]he approach for using the hazard quotient and hazard index suggested in the EPA guidance should be used in the cleanup standards. The EPA approach determines site specific risk based on the ratio of the estimated site specific intake to the toxicity information (RfD). The arbitrary use of a 0.2 hazard quotient proposed in the regulations is not defensible. A hazard quotient of 1.0 should be used for individual contaminants and exposures and a hazard index of 1.0 should be used for multiple contaminants and exposures." (Burgess and Dunster, pp.1-2 of comments on March 9, 1990 draft)

Comments from several participants suggested that despite potential concerns about multiple exposures, available methodologies may not be precise enough to permit meaningful distinctions between the use of 0.2 and 1.0, or some other Hazard Index value. For example:

> Too many significant figures have been attached to the compliance and conditional clean-up levels. In many circumstances specifying the use of a hazard quotient of 1.0 for decision-making is too precise when considering the numerous factors contributing to uncertainty in its derivation. For example, reference doses often incorporate large uncertainty factors (e.g. 100 to 10,000). In these cases, small variation around a hazard quotient of 1.0 are probably not significant.
>
> Many of the same uncertainties also apply to cancer risk estimates. As a result, these estimates are actually no more precise than an order of magnitude, e.g. 10^{-3} vs 10^{-4}. It would be difficult to argue scientifically that risks of 8×10^{-6} and 3×10^{-5} are significantly different.
>
> We believe it would be more scientifically supportable to express the proposed clean-up standards in terms of 1 (rather than 1.0) for the hazard index, and in terms of an order of magnitude for cancer risk. For some chemicals, an even more flexible hazard index is justified. (Findley, pp. 1-2)

Similar comments were provided by Syrdal.

Ecology's Response: In establishing cleanup levels for non-carcinogens under Methods B and C, Ecology believes it is appropriate to utilize a HQ and HI of 1.0. This approach provides a reasonable method for taking into account multiple pathways of exposure and multiple hazardous substances, appears to be consistent with the Federal Superfund Program, and recieved broad support during the rulemaking process.

However, Ecology has revised the rule to clarify that Method A cleanup levels for individual non-carcinogens are established using a Hazard Quotient of 0.2. In other words, Method A cleanup levels have been established based on the assumption that exposure to a particular hazardous substance in ground water or soil represents 20% of a person's total exposure (including other pathways at the site and off-site contributions) to a particular substance and/or other substances causing the same toxic response. The use of a Hazard Quotient of 0.2 to establish Method A cleanup levels is designed to address the following concerns:

> Multiple Pathways: A person may be exposed to a particular hazardous substance by more than one pathway of exposure (i.e., drinking contaminated water, playing in contaminated soil, breathing contaminated air). Consequently, the use of media-specific levels based on an HQ of 1 may result in unacceptable total exposure levels.
>
> Multiple Hazardous Substances: A person may be exposed to more than one hazardous substance that results in the same toxic effect.
>
> Other Exposures: A person may already be exposed to a particular hazardous substance (or a substance with similar effects) as a result of

everyday activities and the incremental exposure from the cleanup site may be sufficient to exceed the threshold for effect.

Although Ecology recognizes that the use of a 20% source contribution factor is subjective, the Department's review of available information supports this as a sound regulatory policy. For example, EPA routinely utilizes a relative source contribution (RSC) of 20% to establish MCLGs and MCLs under the federal drinking water program:

> To determine the MCLG for non-carcinogens, the contribution from other sources of exposure, including air and food, is evaluated. The approach EPA uses to estimate the relative source contribution for the purpose of calculating MCLGs has been discussed in detail at 54 FR 22069 (May 22, 1989).
>
> In summary, the Agency uses the following policy to estimate RSCs for the purpose of calculating MCLGs: If sufficient quantitative data are available on the relative contribution from each source to total exposure, EPA subtracts the actual contribution from food and air from the DWEL to calculate the MCLG, provided the drinking water exposure is between 20 and 80 percent. If the drinking water exposure is between 80 and 100 percent, EPA uses 80 percent to provide adequate protection for individuals whose total exposure to a contaminant may be higher than that indicated by available data. If the drinking water exposure is less than 20 percent of total exposure, EPA is considering the use of a 20 percent floor. In these situations, drinking water contributes a relatively small portion of total exposure. EPA believes that the most appropriate course of action in such cases is to try to reduce exposure from other sources rather than to promulgate increasingly lower MCLGs to control the relatively small exposure contributed by drinking water. The Agency requests comments on the use of a 20 percent floor for relative source contributions.
>
> In cases when sufficient quantitative data are not available on the contribution from each source of exposure, the Agency's policy in setting drinking water standards is to use 20 percent relative source contribution. (EPA, 1990e)

It is important to note that the federal standards are routinely incorporated into the state's drinking water standards (Chapter 248-54 WAC) by the Department of Health. Both the federal and state drinking water standards are identified as applicable state and federal laws in WAC 173-340-720.

Similar approaches are utilized by the World Health Organization in "Guidelines for Drinking Water Quality" (WHO, 1989), the National Academy of Sciences in "Drinking Water and Health" (Volumes 1-8), and the EPA Hazardous Waste Program in establishing air emission requirements from incinerators action levels for corrective actions (EPA, 1990d, 1990h). The Office of Technology Assessment (OTA, 1989) has questioned whether a similar approach should be utilized at Superfund sites. OTA notes "[i]t is difficult, from a health protection perspective, to judge cleanup need or extent in isolation, ignoring other exposures which, in some cases, might make the critical difference between cleanup or no cleanup, or affect cleanup standards significantly." Finally, the states of Massachusetts and Michigan have each adopted cleanup regulations which utilize a RSC of 20%.

Issue #7: Does the proposed regulation provide Ecology with an appropriate amount of discretion in establishing cleanup levels for individual sites?

In the proposed rule, Ecology specified various procedures for developing cleanup levels for ground water, surface water, soil, and air. In each case, the Ecology reserved the right to establish more stringent cleanup levels for individual sites at "[a]ny other concentration which the Department determines are necessary to protect human health and the environment."

Several individuals expressed the opinion that this provision was inappropriate. For example:

> Section 750 ... contains an impermissibly broad delegation of authority to Ecology program managers to set cleanup standards. The United States and Washington constitutions require that any grant of authority to a regulatory agency must be accompanied by standards to guide and confine the agency's discretion. Section 750 repeatedly invites Ecology to impose "Any other concentrations which the Department determines are necessary to protect human health and the environment." See WAC 173-340-750(1)(a)(v), (2)(b), (3)(c) and (4)(c). This broad statement of intent does not provide sufficient guidance to meet constitutional due process standards. (Syrdal, p. 21)

Other individuals providing similar comments included include the following: Burch, p. 3; Aldrich, p. 21.

Ecology's Response: Ecology does not believe that this phrase represents an "impermissibly broad delegation of authority." First, numerous other environmental regulations contain similar language and have not been found to be inconsistent with the U.S. and Washington constitutions. For example, Water Quality Standards for Surface Waters of the State of Washington (Chapter 173-201 WAC) contains the following language:

> Toxic substances shall not be introduced above natural background levels in waters of the state which may adversely affect characteristic water uses, cause acute of chronic conditions to the aquatic biota, or adversely affect public health, as determined by the Department. (WAC 173-201-060(4))

Second, Section 70.105D.030(1)(b) and (f) provide the Department with the authorities to "conduct, provide for conducting, or require potentially liable persons to conduct remedial actions ... to remedy releases or threatened releases of hazardous substances..." and "take any other actions necessary to carry out provisions of this chapter...." Consequently, the law already provides the administrative discretion to make such site-specific determinations.

The Department recognizes that the use of this type of narrative standard raises concerns regarding the manner in which it will implemented. To partially address those concerns, the rule has been revised to clarify that cleanup levels under this provision would be based upon a site-specific evaluation and the Department must determine that such levels are necessary to protect human health and the environment. It is also important to recognize

that if Ecology elects to utilize this provision, the opportunities for public review and comment provide a sufficient mechanism to ensure that a person's "due process" rights are not denied.

Issue #8: Do the proposed rules provide sufficient flexibility to address situations where correcting human health and environmental risks at cleanup sites may result in an overall increase in health risks?

A number of individuals expressed concerns that efforts to attain highly protective cleanup levels may actually result in an overall increase in risk when the impacts of excavation, treatment, transportation, and/or disposal of contaminated materials was considered. For example:

> Under no circumstances should a cleanup action be required that results in a net *increase* in total risk to human health or the environment. Although it is imperative that hazardous waste sites be dealt with in a manner that is adequately protective of human health and the environment, it must also be recognized that decisions made to ameliorate one risk inevitably result in introduction of other risks. Once contamination has occurred, one must consider the trade-offs that result when remedial actions are implemented. Seldom do such actions eliminate risks, rather they result in actions that substitute risks. Thus in remedy selection, reduction of total risk should become the goal, and time and effort should not be spent pursuing actions that result in no net gain in human health and/or environmental protection. (Science Advisory Board, p. 3)
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> **********
>
> Boeing recommends a clearly stated administrative principle:
>
> > Notwithstanding any other provision of this rule, no cleanup standard or level or remedy selected shall be approved which leads to a net increase of environmental risk.
>
> This concept has already been recognized in the Ecology 2010 program and the point seems intuitively obvious, but the potential exists for rigid adherence to cleanup levels without this caution. (Thomson, p. 3)

Similar concerns were expressed by Syrdal (p.2) and Johnson (p. 2).

Ecology's Response: Dr. Aaron Wildavsky (1988), in his book Searching for Safety, describes the "Joggers Dilemma" as one in which a person must decide what to do when the safe (health benefits derived from exercise) and the dangerous are inextricably intertwined. As noted in the draft EIS, Ecology faces a similar dilemma when establishing cleanup levels and selecting cleanup actions at hazardous waste sites:

> Selection of cleanup levels - The long-term impacts associated with residual levels of hazardous substances tend to be directly related to the cleanup levels for a particular site. More stringent cleanup levels

> generally are associated with lower environmental impacts. This contrasts with the relationship between cleanup levels and short-term environmental impacts which occur during a cleanup action. In these cases, environmental impacts tend to be inversely related to the cleanup levels (i.e., the more stringent the cleanup level, the greater the potential for short-term adverse environmental impacts). (Ecology, 1990a, p. 14)

In recognition of the potential for such impacts, Ecology has provided the flexibility to consider "net environmental impacts" when establishing cleanup standards and when selecting a cleanup action to attain those standards. Ecology has also incorporated the following language into WAC 173-340-360(9)(i):

> Ecology expects that cleanup actions conducted under this chapter will not result in a significantly greater overall threat to human health and the environment than other alternatives.

Ecology believes that a number of qualitative and quantitative factors will need to be considered in making this determination is developing additional guidance on implementing this provision. Important issues to be addressed:

- How should the Department address situations compare different health outcomes?
- How should the Department address the equity of risk-benefit distributions?
- How should the Department compare and weight human health impacts and impacts on the environment?
- How should the Department compare and weight short-term and long-term impacts on human health and the environment? Current versus potential future threats?

V. PROCEDURES FOR ASSESSING HUMAN HEALTH RISKS

A. Background

A determination that a hazardous substance, or mixture of hazardous substances, poses a risk to human health requires the scientific evaluation of several factors. These factors include the number and types of individuals exposed to the substance, the degree of exposure (including the levels present at the site, the frequency and duration of exposure, the conditions of exposure, including the chemical and physical form of the substance of mixture), factors influencing the susceptibility of exposed individuals (including age, sex, exposure to other substances, etc.) and data on potential adverse effects resulting from exposure to such substances.

The purpose of this section of the responsiveness summary is to address comments on the procedures for performing assessments at cleanup sites, the assumptions on which such assessments are based, and the range of uncertainty associated with current methods. This section summarizes the technical rationale for procedures in the rule and discusses their limitations and uncertainties.

B. The Public's Response

A large number of comments were received on the issues relating to the procedures used to evaluate human health risks. The opinions expressed reflected substantial disagreements about the relative merits, accuracy, reliability, and protectiveness of existing methods for characterizing risks to human health.

A number of participants provided very useful information and opinions. In evaluating these comments, Ecology places particular weight on the comments provided by individuals responsible for preparing, reviewing, or utilizing health assessments in regulatory decision making. These include Drs. David Eaton and Donald Wood (Science Advisory Board), Dr. Patricia Cirone (USEPA), Mr. Clay Patmont and Ms. Marian Wineman (Hart-Crowser), Dr. Joyce Tsuji (ETI), Dr. David Monroe (Sierra Club), and Dr. Roseanne Lorenzana (DOH).

The Department also places special weight on the reports of recent expert review committees, including the National Academy of Sciences (NAS) Safe Drinking Water Committee (NAS 1986, 1987), and the Office of Science and Technology Policy (OSTP, 1985). In addition, Ecology has reviewed and used, to the maximum extent possible, technical procedures defined in the Risk Assessment Guidance for Superfund (EPA 1989a), the Exposure Factors Handbook (EPA 1989b), and EPA Region X Statement of Work (EPA, 1990b).

For the purpose of review and analysis, the public comments received on this subject have been divided into several issues:

Issue #1: **Is quantitative risk assessment an appropriate tool for establishing cleanup levels?**

Issue #2: **Are the proposed procedures for estimating risks to human health consistent with procedures being utilized by other state and federal agencies?**

Issue #3: **Is it appropriate to base cleanup requirements on reasonable maximum exposures?**

Issue #4: **For purposes of performing risk assessments, what is a reasonable estimate of the average human lifespan?**

Issue #5: **What is a reasonable estimate for exposure duration?**

Issue #6: **Is it appropriate to utilize carcinogenic potency factors and reference doses developed by EPA when establishing cleanup levels?**

Issue #7: **Has Ecology identified appropriate procedures for selecting data for use in preparing quantitative estimates of cancer risks?**

Issue #8: **For purposes of estimating cancer risks, has Ecology identified appropriate procedures for extrapolating from high to low doses?**

Issue #9: **For purposes of estimating cancer risks, has Ecology identified appropriate procedures for extrapolating from animals to humans?**

Issue #10: **Does the proposed rule include appropriate procedures for developing and utilizing reference doses to define cleanup levels for noncarcinogens?**

Issue #11: **Is it appropriate to utilize chronic reference doses to develop cleanup levels where children are the primary population at risk?**

Issue #12: **What is the appropriate methodology for converting reference doses to reference concentrations?**

Issue #13: **What is the appropriate averaging time for noncarcinogens?**

Issue #14: **What criteria will Ecology utilize in making the determination of whether there is clear and convincing scientific data to support the use of reference doses or potency factors other than those published by EPA?**

Issue #15: **Do the uncertainties associated with current risk assessment procedures preclude their use in regulatory decisionmaking?**

Issue #16: **Are there reliable methodologies for quantifying uncertainties in quantitative risk assessments?**

Issue #17: **Do the proposed procedures take into account potential exposures to sensitive subgroups?**

Issue #18: **Are the proposed risk assessment procedures too conservative?**

Issue #19: **Does the proposed rule include appropriate procedures for addressing the potential health risks associated with multiple hazardous substances and/or multiple routes of exposure?**

Issue #20: **Is it appropriate to utilize a subset of hazardous substances present at a site to define site cleanup requirements?**

Issue #21: **Does the proposed rule provide sufficient flexibility to consider site-specific variations in exposure conditions?**

Issue #22: **Does the proposed rule provide sufficient flexibility to allow the use of new scientific information in a timely manner?**

Issue #23: **How frequently will Ecology review and update the cleanup standards?**

C. Ecology's Evaluation and Response

Issue #1: Is quantitative risk assessment an appropriate tool for establishing cleanup levels?

For purposes of establishing cleanup levels, Ecology proposed to utilize quantitative risk assessment to supplement requirements under applicable state and federal laws. Individuals or groups expressing support for this approach include the following: Science Advisory Board, p. 1; Findley, p. 1; Patmont and Wineman, p. 1; and von Gohren p. 1. Other individuals, while expressing general support, urged Ecology to be aware of limitations associated with quantitative risk assessment procedures. For example:

> Risk assessment is a newly recognized technology that is on the brink of rapid revision and enhanced refinement. Supporting in vitro, in vivo, and epidemiologic data is not comprehensive enough to permit generalized application of risk assessment modelling without close scrutiny. Caution is warranted in applying the tool of risk assessment. Inappropriate use would result in the proffering of Departmental policy shrouded in technical jargon (i.e. a sheep in wolves' clothing). (Lorenzana, p. 1 of comments on December 29, 1989 draft)

Ecology's Response: Ecology believes the quantitative risk assessment is the appropriate tool for establishing cleanup levels. Quantitative risk assessment methods have been the subject of numerous publications (OSTP, 1985; NAS (QRA), 1986; and EPA, 1989a, 1990b). Although experts and policymakers generally agree that current methods do not provide precise estimates of risk, most believe that such techniques can be used for purposes of setting regulatory priorities or establishing permissible exposure levels. Indeed, a wide range of programs within EPA and other state agencies (i.e. California, Michigan, etc.) currently utilize QRA techniques to establish regulatory levels.

Dr. Lester Lave recently summarized the general consensus on the use of QRA among scientists and policymakers:

> What risk assessment provides us is a systematic approach to analyzing complex problems. As long as we are trying to set policy in a scientific and systematic way, there is nothing better at our disposal than these admittedly imperfect risk assessments, no matter how uncertain they are. Scientific knowledge is not in a position, at this stage, to give confident answers as to how risky it is to drink water that has a certain contaminant in it at a certain dose. At least at the moment, and probably for any foreseeable future, uncertainty is ubiquitous and inevitable. Litigators will have much material for litigation. We will

> undoubtedly continue to be faced with difficult questions to resolve, and scientific experts alone will not be able to resolve them. But with risk assessment we can provide the best available health effects data and a systematic approach to estimating that risk so that more informed decisions are made by the public and its appointed decisionmakers. Risk assessment is a tool that should be used to present the evidence to the population. (Lave, 1989, p. 314)

Issue #2: Are the proposed procedures for estimating human health risks consistent with procedures being utilized by other state and federal agencies?

In preparing the cleanup regulations, Ecology has reviewed and considered approaches described in several guidance documents or regulations. Ecology has placed considerable weight on the procedures and methodologies described in the Exposure Factors Handbook (EPA 1989b), Risk Assessment Guidance for Superfund (EPA, 1989a), and the EPA Region X Statement of Work for Human Health Risk Assessments (EPA, 1990b).

Several individuals expressed the opinion that Ecology's procedures were consistent with those utilized by other state and federal agencies. For example:

> Overall, we feel the proposed amendments are a positive step towards the identification and selection of appropriate remedial actions at hazardous waste sites. The proposed regulations appear to be consistent with similar programs underway at the federal level, and this consistency will provide for a minimum of confusion at sites where both state and federal involvement occurs. The generally clear application of risk assessment methodology in the proposed cleanup standards also provides an easily understood technical foundation upon which to base future cleanup actions. (Patmont and Wineman, p. 1)

Other individuals expressed concerns that some of the procedures were out-dated, inconsistent and/or not scientifically justified. For example:

> Our general findings are that some of these guidelines involve methods that are out-dated and not scientifically justified. Because guidelines for assessing health risks are constantly being up-dated as more information is available, it is imperative that WDOE should start out with the most current methods and information. (Tsuji, p. 1)

Ecology's Response: One objective of the cleanup standards is to preserve the integrity of existing regulatory programs and avoid major inconsistencies with those programs. However, given the wide variations in some requirements and approaches, it soon became apparent that consistency with all approaches was unachievable in many cases. Consequently, in situations where conflicting recommendations exist, Ecology has attempted to balance the various recommendations to arrive at a scientifically and legally defensible approach (See discussion in Section II (Issue 4)). Specific procedures identified by Dr. Tsuji as being "out-dated and not scientifically justified" are discussed below in Section V (Issues 4, 11, 13, 19, 22, and 23), Section IX (Definitions), Section XIX (Soil Cleanup Standards), Section XX (Industrial

Soil Cleanup Standards) and Section XXI (Cleanup Standards to Protect Air Quality).

Issue #3: Is it appropriate to base cleanup requirements on reasonable maximum exposures?

Ecology proposed to base site cleanup requirements on the "reasonable maximum exposure." One individual expressed that it was inappropriate to base cleanup level determinations on "worst case" scenarios:

> A legitimate use of worst case scenarios is to determine if the exposure or risk is a low enough event at this extreme so as to dismiss concern for this scenario. It is not legitimate to use a worst case scenario to prove that there in fact exists a concern in a real population. In constructing a worst case scenario, the assessor has usually added assumptions or used particular data points that bring into question whether the scenario actually represents the real world. If the exposure or risk value estimated by a worst case scenario is high enough to cause concern, the assessor must reevaluate the parameters used and perform reality checks before deciding a problem really exists. It is critical that the results of a worst case individual scenario are not immediately applied to an entire population, since in almost all cases this will result in a substantial overestimate of a potential problem. (53 Federal Register 48846, December 2, 1988) (Coenen, p. 2 of comments on the March 9, 1990 draft)

Mr. Syrdal submitted a recent review of federal regulatory programs prepared by the Office of Management and Budget (OMB, 1990). The OMB criticized the use of the maximum exposed individual (MEI) in regulatory decision-making:

> In addition to estimating the amount of a substance that may actually be present in the environment, a risk analysis must also consider the conditions under which humans may be exposed. Actual risks vary considerably depending on location, mobility, and a host of other factors. Nevertheless, estimates often are based on the upper-bound lifetime cancer risk to the maximum-exposed individual (MEI), the hypothetical person whose exposure is greater than all others. Sometimes, risks to the entire population are estimated by assuming that everyone is exposed at the MEI level. Because environmental regulations are often justified using MEI-based risk assessments, actual risks may be substantially lower than what decisionmakers and the general public perceive them to be. (OMB, 1990 p. 22)

OMB (1990) also criticized EPA's use of the "reasonable maximum exposure:"

> EPA recently abandoned the calculation of unbiased exposure estimates for Superfund sites on the ground that it was insufficiently conservative. EPA's new protocol requires the estimation of "reasonable maximum exposure" instead of the average and upper-bound estimates. Reasonable maximum exposure constitutes a new term of art that EPA intends to be "well above the average case" but not as extreme as the upper-bound. It provides a new opportunity for embedding conservative assumptions into exposure assessment and exaggerating estimates of actual human-health risk

at Superfund sites. See *Risk Assessment Guidance for Superfund, Volume I: Human Health evaluation Manual (Part A), Interim Final*, EPA/540/1-89/002, December 1989, Chapter 6, pp. 5, 47-50. (OMB, 1990, p. 22)

Similar comments were provided by Butler, pp. 7-8.

Other individuals appeared to provide general support for this approach, but recommended that Ecology clarify the definition of RME. For example:

> The term "reasonable maximum exposure" is defined in a nonscientific manner, making use of the word "reasonable." This qualitative expression should be quantified consistent with establishing risk relative to quantitative risk standards. It is unacceptable to allow key aspects of the risk analysis to remain qualitatively stated. Thus, a probability defining reasonable, for example, 99 percent probability with 95 percent confidence that maximum exposure will not exceed the expected amount over a 100 year period considering conditions 500 years in the future, should be incorporated into the definition. It is noted that a time frame is warranted to specify for analysts a tractable problem and to standardize the exposure time to be considered for old people. (Cook, p. 7)

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> The Proposed Amendments state that cleanup levels are to be based on Reasonable Maximum Exposure (RME): however, the definition of this exposure needs further clarification. As stated by the latest U.S. EPA guidance document on risk assessment procedures for Superfund site cleanups (USEPA, 1989b), the RME scenario is a reasonable estimate of the maximum exposure that is likely to occur at the site. Under this approach, some intake variables may not be at their individual maximum values, but in combination with other exposure and toxicity variables will result in estimates of the RME. For example, U.S. EPA uses average soil ingestion rates and upper 95 percent percentile estimates of toxicity criteria. The U.S. EPA recognizes by these comments that the use of maximum exposure rates for all parameters in a risk assessment will not result in exposure that is "reasonable." The suggestion is made by the U.S. EPA that the determination of reasonable is to be based on both quantitative information and professional judgment. This section would be more scientifically reasonable if it clarified that not all exposure parameters are expected to be upper 95 percent estimates or maximums. (Tsuji, p. 3)

Ecology's Response: Ecology's decision to establish cleanup levels using estimates of the reasonable maximum exposure is based upon the following considerations:

> Consistency with the Federal Program: The Environmental Protection Agency utilizes the reasonable maximum exposure approach to establish cleanup levels under Section 121 of CERCLA/SARA):
>
> > Actions at Superfund sites should be based on an estimate of the reasonable maximum exposure (RME) expected to occur under both current and future land-use conditions. The reasonable maximum exposure is defined here as the highest exposure that is reasonably expected to occur at a site. RMEs are estimated

> for individual pathways. If a population is exposed via more than one pathway, the combination of exposures across pathways also must represent an RME. (EPA, 1989a, p. 6-4)

> Statutory Mandate: The Model Toxics Control Act states that "[e]ach person has a fundamental and inalienable right to a healthful environment..." Several policy decisions are linked to this statement (use of "conservative" or "upper bound" estimates as opposed to "average" or "mean" values represents a fundamental policy choice which is dictated, at least in part, by the laws administered by Ecology. To fulfill this mandate it is necessary to protect the whole population, including susceptible subgroups such as children. The use of conservative assumptions is consistent with this statutory directive. The use of "average" or "mean" exposure values represents an alternate policy choice, one that may be at odds with the statutory requirements.

A second policy choice, one that is intertwined with the first, is the decision to base cleanup level determinations on individual risks (as opposed to population risks). This is discussed in Section IV, Issue #5.

The RME is considered to be "reasonable" because it is the product of several factors that represent an appropriate mix of "average" and "upper bound" values. Ecology agrees with Dr. Tsuji's comments that the term "reasonable maximum exposure" should not be translated into the use of upper-bound estimates for all of the intake variables and toxicity criteria. The precautionary note is also found in EPA (1989a):

> Each intake variable in the equation has a range of values. For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at a site. Under this approach, some intake variables may not be at their individual maximum values but when in combination with other variables will result in estimates of the RME. (EPA, 1989a, pp. 6-19)

Despite general agreement with many of Dr. Tsuji's comments, the reference to EPA's use of average soil ingestion rates appears to be inconsistent with EPA's guidance on this issue (See EPA 1989, p. 6-22; EPA, 1990b).

Issue #4: For purposes of performing risk assessments, what is a reasonable estimate of the average human lifespan?

Ecology proposed to use a 70 year lifetime for establishing cleanup levels under the MTCA. Several individuals noted that recent EPA guidance documents generally specify the use of 75-76 years (Burgess and Dunster, p. 5; and Tsuji, pp. 4-5).

Ecology's Response: Ecology has revised the procedures to incorporate a 75 year lifespan. The rationale for this change includes:

Statistical Data: Statistical data on life expectancy are published annually by the U.S. Department of Commerce. Data for the year 1985 indicate that life expectancy of the total population is 74.7 years, for males 71.2 years, and for females 78.2 years (Bureau of Census 1986).

Consistency with the Federal Program: The use of a 75 year lifetime is consistent with the approaches recommended in EPA Region X Statement of Work RI/FS Risk Assessment Deliverables (EPA, 1990b), the Exposure Factors Handbook (EPA 1989b), and the EPA Risk Assessment Guidance for Superfund (EPA, 1989a).

Issue #5: What is a reasonable estimate for exposure duration?

Ecology proposed to utilize a 30 year duration of exposure for establishing cleanup levels for ground water, surface water, and air. Several individuals expressed concerns that this would lead to risks that are underestimated:

> Throughout the risk assessments in the Draft EIS, the duration of exposure was 35 years. I should point out that most residents of the State of Washington drink water and breath air for longer than 35 years, in fact, nearly twice as long. Thus the risks are underestimated by a factor of two, unless residents are required to relocate to some pristine location after spending 35 years in the polluted areas of our State. (Monroe, p. 4)

Ecology's Response: Ecology understands the concerns raised by the above individuals, but believes that the use of a 30 year exposure duration is appropriate for establishing cleanup requirements for individual sites. This value represents the upper bound (90th percentile) estimate of the number of years spent by an individual at a single residence (EPA, 1989b) and is consistent with EPA Superfund guidance on the issue:

> **Exposure frequency and duration**. Exposure frequency and duration are used to estimate the total time of exposure. These terms are determined on a site-specific basis. If statistical data are available, use the 95th percentile value for exposure time. In the absence of statistical data (which is usually the case), use reasonable conservative estimates of exposure time. National statistics are available on the upper-bound (90th percentile) and average (50th percentile) number of years spent by individual at one residence (EPA 1989d). Because of the data on which they are based, these values may underestimate the actual time that someone might live in one residence. Nevertheless, the upper-bound value of 30 years can be used for exposure duration when calculating reasonable maximum residential exposures. In some cases, however, lifetime exposure (70 years by convention) may be a more appropriate assumption. Consult with the RPM regarding the appropriate exposure duration for residential exposures. The exposure frequency and duration selected must be appropriate for the contact rate selected. If a long-term average contact rate (e.g., daily fish ingestion rate averaged over a year) is used, then a daily exposure frequency (i.e., 365 days/year) should be assumed. (EPA, 1989a, p. 6-22)

Ecology recognizes that other programs have used a 70 year duration to establish standards or advisories for the total population (See NAS (1986) and EPA (1989e) for description of procedures establishing drinking water standards). However, Ecology believes that the routine use of a 70 year exposure duration for cleanup sites may be inconsistent with other policy decisions made by Ecology as part of this rulemaking (e.g. choice of individual risk measure). Dr. Bernard Goldstein (former EPA Assistant Administrator for Research and Development) has made similar observations in the context of establishing air pollution control requirements for individual industrial facilities:

> Further, as in Figure 1, it is not unreasonable to assume that a single housing site is occupied for 70 years. However, U.S. experience demonstrates that it is highly unreasonable to assume that this location will be occupied by the *same* individual during this 70-year period. Population mobility does not alter the risk level to public health as long as the total population number remains fairly stable. But failure to take into account population mobility in calculating the risk for one individual living at the fenceline -the MEI- results in at least an additional half an order of magnitude degree of conservatism. If we are serious about using the MEI for regulatory purposes we at least need to have our risk assessors consider an approach that is appropriate for this purpose. (Goldstein, 1989)

Issue #6: Is it appropriate to utilize carcinogenic potency factors and reference doses developed by the Environmental Protection Agency when establishing cleanup levels?

Ecology proposed to utilize carcinogenic potency factors and reference doses developed by the Environmental Protection Agency and published in the Integrated Risk Information System (IRIS) database. For substances without published CPF/RfD values (or where there is clear and convincing evidence that a published value is inappropriate), Ecology would generate CPF/RfD values in consultation with the Environmental Protection Agency, the Science Advisory Board, and the Department of Health.

Ecology's Response: When establishing cleanup levels, Ecology proposed to utilize carcinogenic potency factors and reference doses developed by EPA and published in the Integrated Risk Information System (IRIS) database. While there were concerns regarding specific contaminants (e.g., See Holm, p. 1 for concerns on dioxin), there appeared to be broad agreement that such values represented a sound basis for cleanup levels unless scientific information is available to support the use of alternate values. This approach is consistent with procedures currently used at federal and state Superfund sites, EPA's Drinking Water Program, and has been explicitly adopted in one set of state regulations (MDNR, 1990).

Issue #7: Has Ecology identified appropriate procedures for selecting data for use in preparing quantitative estimates of cancer risk?

In the absence of appropriate carcinogenic potency factors from the IRIS database, the proposed rule stated that Ecology may use human epidemiology data or animal bioassay data to derive a carcinogenic potency factor. With respect to animal bioassay data, Ecology proposed that "all carcinogenesis bioassays shall be reviewed and data of appropriate quality shall be used for establishing the carcinogenic potency factor...."

Several individuals expressed concerns over the use of data from animal studies performed at the "maximum tolerable dose" to estimate carcinogenic potency factors. For example:

> Another reason why there needs to be more flexibility in the risk number utilized by these cleanup standards relates to the uncertainty of the risk number themselves. First, the basic risk methodology utilized by the Environmental Protection Agency and these regulations is currently the subject of a great deal of controversy. For example, most of the cancer potency factors have been developed through the use of animal studies where the animals are exposed to what's called the maximum tolerable dose. Many recent studies have suggested that this approach is inherently flawed because exposure to the maximum tolerable dose, a dose which is far larger than any exposures associated with most contaminated sites, greatly enhances the risk of carcinogenicity due to the dosage killing healthy cells and thereby inducing carcinogenicity that otherwise wouldn't occur. In addition, the basic assumption utilized in the methodology in these proposed regulations, that there are not threshold doses for carcinogenicity, is also subject to a great deal of scientific controversy at this time. (Syrdal, p. 5)

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> The DOE is referred to the recent paper by Drs. Samuel Cohen and Leon Ellwein ["Cell Proliferation in Carcinogenesis" Science, 249: 1007-1011 (1990)] Drs. Cohen and Ellwein posit that the tumors observed in laboratory animals are primarily due to the excessive doses administered to them under the guise of the "maximally tolerated doses". The policy and resource implications of this race to regulate animal "carcinogens" on the basis of what may be testing artifacts are clear. (Butler, p. 8)

Individuals providing similar comments include the following: Aldrich, p.5.

Ecology's Response: Based on a review of the literature, Ecology finds there is broad support for the use of animal test results as a qualitative predictor of carcinogenicity in humans (See OSHA, 1980; NAS, 1977, 1980, 1986; OSTP, 1985; EPA, 1986b; IARC, 1989; NTP, 1989). Mr Syrdal's and Mr. Butler's comments raise two additional issues which are described below.

> Maximum Tolerable Dose: Ecology has reviewed the recent papers which hypothesis that non-gentoxic chemicals cause increases in tumor incidences because they cause chronic cell proliferation due to toxicity at the maximum tolerable dose. This is not a new issue and it has been regularly considered by regulatory agencies and advisory groups over the last 15 to 20 years (NAS, 1977, 1980, 1986; OSHA, 1980; OSTP, 1985; EPA, 1986b). In a response to the most recent concerns, scientists from

National Insitute of Environmental Sciences (NIEHS) performed a review of the literature to determine whether increased incidences of liver tumors resulting from exposure to nongenotoxic carcinogens are caused solely by enhanced cell proliferation. They concluded that there is insufficient data to support this hypothesis and that it would be premature for regulatory agencies to change their risk assessment policies (Environmental Reporter, 1990, p. 1077). The National Academy of Sciences is scheduled to complete a more comprehensive review of this issue during the summer of 1991. Ecology will review the NAS findings and evaluate the need for changes to the regulation (if any).

Thresholds For Carcinogenicity: The issue of whether or not there is a "threshold" or "safe" level of exposure for carcinogens has been addressed by a number of regulatory agencies and expert review committees (NAS, 1977; OSHA, 1980; OTA, 1980; OSTP, 1985; EPA, 1986;) In reviewing this information, Ecology believes there is substantial evidence that carcinogenic processes differ from other toxic responses in that they are irreversible and originate from small groups of cells (or a single cell). These differences make it very difficult to expect a threshold for a given individual. Furthermore, even if a threshold could be identified for a given individual or group of individuals, it would be difficult to extrapolate that level to a population of exposed individuals due to the wide variations in susceptibility, potential for interactive effects resulting from exposure to multiple carcinogenic substances, and interactions with other intrinsic (pre-existing diseases, hormone levels etc) and extrinsic factors (diet, personal habits etc.). Finally, even if there was widespread support for the existence of thresholds, there does not appear to be a scientific methodology for establishing such thresholds for specific substances or exposed populations.

Issue #8: For purposes of estimating cancer risks, has Ecology identified appropriate procedures for extrapolating from high to low doses?

When estimating cleanup levels for carcinogens it is necessary to calculate a Carcinogenic Potency Factor (CPF). The CPF is a toxicity value that defines the quantitative relationship between the dose of a carcinogen and the level of response. Ecology proposed to utilize CPFs published by EPA in the IRIS database where available and appropriate. In other instances, Ecology proposed:

> The linearized multistage extrapolation model shall be utilized to estimate the slope of the dose-response curve unless the Department determines that there is clear and convincing scientific data which demonstrates that the use of an alternate extrapolation model is more appropriate;

Ms. Holm questioned the routine use of potency factors published in the IRIS database and/or developed using the linearized multistage model. She stated:

> The method A calculations reference use of EPA's IRIS database for cancer potency factors. For example, the use of EPA's cancer potency factor in conjunction with the 1 in 1,000,0000 [sic] risk level to develop cleanup levels for 2,3,7,8-TCDD is inappropriate for a variety of reasons. The same variables are also inappropriately used as the bases for setting

numeric dioxin cleanup levels in Tables A-1 through A-4 referenced in Method B. The linearized multistage model used by EPA to calculate a dioxin potency factor has been severely criticized. The biological data from the Kociba study, used as a basis for the factor, is currently undergoing reinterpretation. Several states, including Georgia, Alabama, Tennessee, and Virginia have rejected EPA's cancer potency factor as the result of scientific review and have selected other factors as the bases for setting ambient water quality standards for dioxin protective of human health. It is reasonable to expect that other cancer potency factors used in the IRIS database are similarly open to criticism. (Holm, p. 1 of comments on the December 29, 1990 draft)

Mr. Syrdal submitted a recent report by the Office of Management and Budget, which criticized the use of the linearized multistage model.

> No single mathematical model is accepted as generally superior for extrapolating from high to low doses. Consequently, Federal agencies often use a variety of different models. Rather than being a scientific footnote to the risk-assessment process, however, the choice of model is actually an important policy issue. The multistage model appears to be the most commonly used method for estimating low-dose risks from chemicals, and there are two major sources of bias embedded in this choice: its inherent conservatism at low doses, and the routine use of the "linearized" form in which the 95 percent upper bound is used instead of the unbiased estimate. (OMB, 1990 p. 19)

Ecology's Response: Ecology believes the linearized multistage model will generally provide an appropriate method for extrapolating from high-to-low doses. It has a sound biological basis and is used by a number of other regulatory agencies:

> Biological Basis: Ecology recognizes that there are a wide variety of extrapolation models currently available (See Paustenbach, 1989). Although most of the available data obtained at high doses fit the various models fairly well, they generally predict quite different answers in the low dose region. Consequently, Ecology believes it is important that extrapolation models used for regulatory purposes have a sound biological basis and not simply represent a curve-fitting exercise.
>
> The National Academy of Science's Safe Drinking Water Committee uses the LMS to predict risks associated with hazardous substances in drinking water (NAS 1977, 1980, 1981, and 1986). The committee has observed that several multistage models lead to predictions of linearity at low doses and that these models have a good theoretical basis:
>
> > Most of these theories start with the premise that the carcinogenic process consists of one or more states that occur at the cellular level, but that not all of these states are related to the carcinogen. These stages may be cell mutations or other biological or chemical events and may be monocellular or multicellular in origin. The probability of transition to an event related to the carcinogen is assumed to be proportional to the exposure. The exact nature and causes of these events are largely unknown. However, the most important aspect of these quantitative theories of carcinogenesis is that most of them lead to mathematical models for

> which the probability of tumor occurrence is generally related to a polynomial function of dose. For low exposure, the region of most importance, they are well approximated by a simple linear function of dose.... This class of dose-response model may be considered as models that are "linear at low dose." Other mathematical dose response models have been proposed for this problem of extrapolating from high dose to low doses, the most notable being the log-probit method of Mantel and Bryan (1961). These types of models have little biological justification in what is known about the carcinogenic process. In addition, some require use of preselected parameters chosen without regard to the particular experimental situation or results. A dose response model selected for extrapolation purposes should at the very least, be consistent with current knowledge of the carcinogenic process. (NAS, 1977, p. 47)
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> **********
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> The threshold issue concerns the shape of the dose response curve at increasingly small doses where little or no information is available. At present, we do not know the shapes of the low dose curves or if there is or is not a true threshold for an animal or human population for any carcinogen.... There are no convincing data to support a nonlinear dose-response curve or threshold at very low doses for any carcinogen.... This information is not available even for DES and 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), two of the better studied compounds on the conventional lists of epigenetic agents.... (NAS 1986, p. 283)

Other Regulatory Programs: Other regulatory agencies utilizing the linearized multistage model include the U.S. Environmental Protection Agency (EPA, 1986, 1989), the Occupational Safety and Health Administration (OSHA, 1990), the California Department of Health Services (See Pease et al., 1990), the Michigan Department of Natural Resources (MDNR, 1990), and the New York Department of Environmental Conservation (NYDEC).

Ecology is aware that no single model can be reliably applied to all substances and, consequently, has provided the flexibility to utilize alternate models where supported by scientific data. Ecology agrees with Dr. Robert Sheuplein (Science Director - Food and Drug Administration) who stated that:

> [D]eviation from standard carcinogenic risk-assessment procedures is possible only when special information becomes available that has five characteristics: (1) a clear and preferably not too complex hypothesis about the carcinogenic process of the chemical; (2) evidence that the carcinogenic mechanism in test animals does not operate in humans; (3) convincing evidence that demonstrates that the mechanism does operate in animals; (4) evidence that the proposed mechanism actually is the method by which cancer develops; and (5) ability to use the hypothesis and mechanistic data to argue for a no-effect level, or for a change in the potency calculation if a no-threshold model is used. Data and information must be available for all five criteria, or else the decisions have to depend on default assumptions. (Sheuplein as cited in Ad Hoc Coalition, 1990)

Finally, in the interests of "erring on the side of safety", Ecology will generally base its cleanup level decisions on statistical upper confidence limit. The Department believes that this represents a prudent policy in that the use of "best estimates" may seriously underestimate risks due to the statistical insensitivity of animal bioassays and the wide range of susceptibility in the human population. The use of statistical upper confidence limits has been recommended by NAS (1977, 1986), EPA (1986, 1989), CDHS (1990) and MDNR (1990).

OMB (1990) has argued against the use of statistical upper confidence limits on the grounds they incorporate "value judgements" into the risk assessment process that may lead to "misordered priorities" and "perverse outcomes." The use of the "upper confidence limits" is a fundamental policy choice and Ecology agrees that it does incorporate "value judgements." However, Ecology does not regard this as a problem if the upper bound is clearly identified as such. [As discussed below, the use of "best estimates" as recommended by OMB (1990) also represents a "value judgment", one that may be at odds with the intent of the Model Toxics Control Act.]

Issue #9: For purposes of estimating cancer risks, has Ecology identified appropriate procedures for extrapolating from animals to humans?

Once low dose risks have been estimated by extrapolating from high dose observations in animals, additional assumptions have to be made to extrapolate those results from animals to humans. Ecology proposed to use the following procedures in making such extrapolations:

> An interspecies scaling factor shall be used to take into account differences between animals and humans. This scaling factor shall be based on the equivalent dose between species unless the Department determines there is clear and convincing scientific data which demonstrates that an alternate procedure is more appropriate. The slope of the dose response curve for the test species shall be multiplied by this scaling factor to obtain the carcinogenic potency factor. Where adequate pharmokinetic and metabolism studies are available, data from these studies may be utilized to adjust the interspecies scaling factor.

During the rule development, several individuals expressed opinions on the issue of interspecies extrapolation or submitted reports that discussed the issue. With respect to scaling factors, Ms. Holm recommended that the rule be revised to allow the use of a body weight scaling factor in lieu of a surface area correction factor in dose extrapolations from animals to humans (Holm, p. 1 of comments dated April 12, 1990).

Mr. Syrdal submitted a recent review of procedures used by various federal regulatory programs prepared by OMB (1990). In that report, OMB criticized the routine use of the surface area approach:

> Once risk has been extrapolated to low doses in rodents, scientists must convert them to human dose equivalents. The two most common approaches involve the use of body-weight or surface area conversions, and there are scientific reasons for choosing either approach in individual cases. The surface area approach leads to estimates of risk that are between 7 and

> 12 times greater than those based on body weight method, depending upon the test species. Despite the ambiguity of the underlying science, the more conservative surface area method is often applied reflexively. (OMB, 1990, p. 22)

During the rule development, several individuals urged Ecology to fully consider potential metabolic or pharmacokinetic differences between animals and humans that would influence determinations of relative risks (Eaton and Lorenzana).

Ecology's Response: Factors involved in extrapolating from estimates of low-dose risks to animals to predict low dose risks to humans have been reviewed by EPA (1986), NAS (1977, 1986, 1987), OSTP, (1985), and OSHA (1980). Based on these evaluations, Ecology believes it is prudent public policy to extrapolate test results from the most sensitive animal test species on the basis of mg/surface area/day unless there is scientific evidence which demonstrates that an alternate approach is more appropriate. Ecology is aware of the scientific research being conducted in the areas of metabolism and pharmacokinetics and has explicitly provided the flexibility to utilize valid data where available.

Issue #10: Does the proposed rule include appropriate procedures for developing and utilizing reference doses to define cleanup levels for noncarcinogens?

Ecology proposed to utilize the EPA reference doses (or equivalent values) published in the IRIS database to establish cleanup levels for noncarcinogens. This is consistent with approaches used by EPA to establish Superfund cleanup requirements, corrective action levels, and drinking water standards (EPA, 1990a, 1990h, 1990e), the National Academy of Sciences to establish drinking water advisories (NAS, 1986), EPA, and numerous states to establish cleanup levels (See EPA, 1989; MDNR, 1990). In addition, there is a long history in using "no observed adverse effects levels" and a series of safety factors to define acceptable levels of exposure for noncarcinogens (See Casarett and Doull, 1988).

Several individuals recommended that Ecology utilize procedures consistent with EPA's Superfund and Drinking Water programs and consequently, appeared to provide implicit support for this approach. However, several participants had concerns with respect to the manner in which Ecology proposed to utilize the reference doses in certain situations. These concerns are discussed under Issues #11 through #14.

Issue #11: Is it appropriate to utilize chronic reference doses to develop cleanup levels where children are the primary population at risk?

Mr. Findley and Dr. Tsuji expressed the opinion that it was inappropriate to use chronic Rfds to evaluate less than lifetime exposure. For example:

> (Apparently) both childhood and longer term adult exposure are being compared to chronic Rfds, based on the choice of body weights, 16 and 70 kg respectively. It is most appropriate to compare chronic Rfds to an

> average lifetime exposure (dose) based on an average lifetime body weight. Acute or subchronic Rfds would be more appropriate to compare to short term exposure (e.g., childhood) using a correspondingly lower average body weight. (Findley, p. 3)
>
> **********
>
> This method for assessing noncarcinogenic risk is now recognized as no longer scientifically valid. Chronic Rfds are developed for evaluation of lifetime exposure and hence are not appropriate for evaluation of less than lifetime exposure such as only during a few childhood years. Thus, current EPA risk assessment guidelines are to evaluate the average lifetime exposure and compare this dose to the Rfd. For example, daily doses for children and adult age groups are weighted by the amount of time spent in each age group, totalled, and the total is divided by the total period of exposure, (i.e., lifetime). This procedure calculates the average lifetime exposure (i.e., childhood and adulthood). (Tsuji, p. 5)

Ecology's Response: Ecology proposed to use chronic reference doses to establish cleanup levels that protect children from chronic exposure to hazardous substances. Comments expressing the opinion that such values are inappropriate for estimating cleanup levels for less-than-lifetime exposures appear to be inconsistent with recent risk assessment guidance from EPA (1989a) which specifies the following:

> As guidance for Superfund, chronic exposures for humans range in duration from seven years to a lifetime; such long-term exposures are almost always of concern for Superfund sites (e.g. inhabitants of nearby residences, year-round users of specified drinking water sources)..... For each chronic exposure pathway (i.e. seven year to lifetime exposure), calculate a separate chronic hazard index from the ratios of the chronic daily intake (CDI) to the chronic reference dose (RfD) for individual chemicals as described in the box below. (EPA 1989a, pp. 8-11 and 8-13)

Ecology's procedures also appear to be consistent with the procedures used by the National Academy of Sciences to develop Significant No Adverse Response Levels (SNARLs) for drinking water (See NAS, 1986, pp. 294-412) and EPA's use of chronic reference doses in establishing soil action levels under the Hazardous Waste Corrective Action Program (EPA, 1990h). Under the RCRA program, soil action levels for noncarcinogens are based on the chronic reference dose and the following exposure assumptions:

> "In deriving soil action levels for hazardous constituents in soil, other than those which are known or suspected to be carcinogens, assume soil intake of 0.2 gram/day for 16 kg child/5-year exposure period (age 1-6) * [*not to be averaged over a 70 year lifetime]." (EPA, 1990h)

Issue #12: What is the appropriate methodology for converting reference doses to reference concentrations?

Ecology proposed that when converting reference concentrations (ug/m^3) in air to reference doses (mg/kg-day), the following procedures would be used:

(b) Inhalation reference doses shall be used in WAC 173-340-750. Where the inhalation reference dose is reported as a concentration in air, that value shall be converted to a corresponding inhaled intake (mg/kg-day) using a human body weight of 70 kg and an inhalation rate of 20 m^3/day.

Mr. Findley and Dr. Tsuji expressed the opinion that this approach is inappropriate:

> Reference concentrations (ug/cubic meters) in air (WAC 173-340-705(7)(b) should apply to chronic (lifetime) exposures. It is not appropriate to convert them to dosage (mg/kg-day) using a 70 kg body weight and a 20 cubic meters inhalation rate due to the methodology used in their development. At this point, it is not clear how to modify these to adjust for variations in exposure duration and inhalation rate. (Findley, p. 3)

****

> The conversion given for computing the inhalation reference dose from an acceptable air concentration is inappropriate given the equation presented for assessing cleanup levels for noncarcinogenic effects via inhalation. The exposure parameters used in the equation are those of a small child, yet the computed reference dose would be that appropriate for assessing lifetime or adult exposure. As a result, the cleanup level would be underestimated (too conservative). The correct procedure would be to either use 10 m^3/day and 16 kg for computing the inhalation reference dose or to use 20 m^3/day and 70 kg in the ambient air cleanup equation. (Tsuji, p. 5)

Ecology's Response: Ecology believes the provisions are appropriate and consistent with approaches being used by other regulatory agencies at this time. For example, EPA's Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual states:

> The inhalation Rfd is derived from the NOAEL by applying uncertainty factors similar to those listed above for oral Rfds. The UF of 10 is used when extrapolating from animals to humans, in addition to calculation of the human equivalent dose, to account for interspecific variability in sensitivity to the toxicant. The resulting Rfd value for inhalation exposure is generally reported as a concentration in air (in mg/m^3 for continuous, 24 hour/day exposure), although it may be reported as a corresponding inhaled intake (in mg/kg-day). A human body weight of 70 kg and an inhalation rate of 20 m^3/day are used to convert between an inhaled intake expressed in units of mg/kg-day and a concentration in air expressed in mg/m^3. (EPA, 1989, pp. 7-8)

Issue #13: What is the appropriate averaging time for non-carcinogens?

Finally, EPA stated that cleanup levels based on noncarcinogenic end points need to specify exposure duration and averaging time. In doing so, EPA urged Ecology to distinguish between the application of Rfds with developmental end points and other Rfds. They recommended that:

"Developmental Rfds should be compared to single doses (e.g., one day) and not adjusted for the duration of exposure, whereas subchronic and chronic Rfds are compared to doses averaged over varying exposure periods." (Findley, p. 3)

Ecology's Response: Comment noted. With respect to noncarcinogens, the averaging times for are generally assumed to be equal to the duration of exposure and, consequently, the two terms cancel each other out in the basic risk equations. In selecting from among available reference doses, Ecology will utilize the guidance in EPA (1989a).

Issue #14: What criteria will Ecology utilize in the determination of whether there is clear and convincing scientific data to support the use of reference doses or potency factors other than those published by EPA?

During the rulemaking process, several participants expressed concerns over the automatic use of EPA reference doses and/or carcinogenic potency factors. To address these concerns, Ecology's proposed rules provide the flexibility to consider new scientific data which may be used to develop new toxicological parameters if there is clear and convincing scientific data that demonstrates the EPA values are inappropriate. Mr. Burch stated:

"If Ecology intends to dispute the reference doses established by EPA, Ecology must outline in the administrative rules, the exact standard it will use for the determination of "clear and convincing scientific data" that will be used to determine that use of the EPA data is inappropriate." (Burch, p. 2)

Ecology's Response: Ecology believes that only in rare instances will alternate RfD values be used to establish cleanup levels under the Model Toxics Control Act. [This will generally involve the identification of significant new information not available when the IRIS value was developed.] In making determinations on whether to use reference doses which differ from those published in the IRIS database, Ecology will consult with the Science Advisory Board, the Department of Health, and the Environmental Protection Agency. Ecology anticipates developing additional guidance for implementing this portion of the rule.

Issue #15: Do the uncertainties associated with current risk assessment procedures preclude their use in regulatory decisionmaking?

Several individuals expressed concerns that Ecology had not fully taken into account the uncertainties in quantitative risk assessments when establishing cleanup requirements. For example:

"A very troublesome aspect of this "science by rote" type of regulation is the absence of any recognition or discussion of uncertainty." (Coenen, p. 2 of comments on March 9, 1990 draft)

Mr. Syrdal identified several sources of uncertainty in quantitative risk assessment and urged Ecology to consider this when evaluating technical practicability:

> Assuming that the methodology utilized in the risk assessment approach adopted by these regulations is correct, even the supporters of the methodology recognize there is a great deal of inherent uncertainty in the resultant risk level calculation. For most contaminants, the calculation of the cancer potency factor depends upon a very conservative extrapolation from very high dose levels in animal experiments. As pointed out by the Science Advisory Board, these extrapolations themselves involve a very high degree of uncertainty in most cases. This uncertainty may range several orders of magnitude. The cancer potency factor derived from these extrapolations, and thus the resultant cleanup standard, could thus be several orders of magnitude higher than the actual risk if the experiments could be conducted at the exposure levels associated with a contaminated site. (Syrdal, pp. 5-6)

Mr. Syrdal also submitted a recent report prepared by OMB, which criticized federal regulatory proposals which failed to consider the uncertainties associated with risk assessment and the implications for regulatory decisionmaking:

> In accordance with the recommendations of the National Academy of Sciences, the *OSTP Guidelines* explicitly call for the quantification of uncertainty, particularly as it arises in the selection of dose-response models and exposure assumptions. Unfortunately, Federal regulatory proposals that utilize risk assessment rarely provide this information, nor do they analyze the implications of uncertainty for decisionmaking. Instead, many risk assessments only identify a lifetime upper-bound level of risk.
>
> The differences between upper-bound and expected-value estimates may be considerable. As we indicated earlier, the upper-bound risk estimate for dioxin may be 5,000 times greater than the most likely estimate. Plausible risk estimates for perchloroethylene (the primary solvent used in dry cleaning) vary by a factor of about 35,000. (OMB, 1990)

Finally, Mr. Findley urged Ecology to avoid attaching too much significance to small variations in risk estimates:

> Too many significant figures have been attached to the compliance and conditional cleanup levels. In many circumstances specifying the use of a hazard quotient of 1.0 for decisionmaking is too precise when considering the numerous factors contributing to uncertainty in its derivation. For example, reference doses often incorporate large uncertainty factors (e.g. 100 to 10,000). In these cases, small variation around a hazard quotient of 1.0 are probably not significant.
>
> Many of the same uncertainties also apply to cancer risk estimates. As a result, these estimates are actually no more precise than an order of magnitude, e.g., 10^{-3} vs. 10^{-4}. It would be difficult to argue scientifically that risks of 8×10^{-6} and 3×10^{-5} are significantly different.

> We believe it would be more scientifically supportable to express the proposed cleanup standards in terms of 1 (rather than 1.0) for the hazard index, and in terms of an order of magnitude for cancer risk. For some chemicals, an even more flexible hazard index is justified. (Findley, pp. 1-2)

Ecology's Response: Ecology has reviewed and considered recent analyses which highlight the uncertainties associated with quantitative risk assessment (See Maxim, 1989; Paustenbach, 1989; Finkel, 1989, 1990). While recognizing that such estimates should be viewed as "crude" indicators of cancer risk, the Department also believes that the use of appropriate extrapolation models and statistical techniques will provide reasonable estimates of the upper bound of cancer risk. Similar conclusions have been reached by other regulatory agencies and scientific review panels:

> Considering all the variables encountered in the process of estimating risks, the 1980 committee remarked, "If the estimates of risk from low doses of carcinogens are made with reasonable data and reasonable models [there will be] a precision of 1 or 2 orders of magnitude in the estimates" (NRC 1980, p. 60). It has since been pointed out that the maximum likelihood estimates (MLEs) are extremely sensitive to the data in that very small differences can lead to large differences in the MLEs.... The 95% upper confidence limit estimates are much more stable. (NAS, 1986, p. 256)

In assessing whether QRA provides a reliable tool for establishing cleanup levels, Ecology believes it is important to distinguish between "upside" and "downside" uncertainties. Current risk assessment procedures are designed to provide an upper bound estimate of excess cancer risk (i.e. we are fairly confident that the true risk lies somewhere between zero and this upper bound value). Consequently, most of the uncertainty is of the "downside" variety. From a public health perspective, this is much less problematical than the situation where our concerns center around the issue of how much higher is the true cancer risk (upside uncertainty).

Ecology also believes that some types of uncertainty can be reduced through more systematic data collection. This is particularily true for parameters associated with exposure assessment (i.e. bioavailability).

Finally, Ecology believes that some of the claims of large uncertainties are frequently undocumented and overstated. This is particularily true for comparisons among available procedures for performing low-dose extrapolations. For example, Cornfield (1977) has stated that estimates from available low-dose extrapolation models can differ by a factor of 100,000 or more. However, no documentation is provided to support this claim. Alternately, attempts have been made to compile available cancer potency factors for individual contaminants and then claim that the large range in values is evidence of the "non-utility" of risk assessment techniques. Such compilations have been prepared for vinyl chloride (OSHA, 1980), PCBs (Maxim, 1989), saccharin (NAS, 1978), and trichloroethylene. In examining the various tables, one finds that people are generally trying to compare "apples and oranges" in that each one contains a mixture of (1) average and upper bound values, (2) values based on different studies, and (3) values derived using difference approaches for interspecies extrapolation.

Issue #16: Are there reliable methodologies for quantifying uncertainties in quantitative risk assessment?

Several methodologies are available for characterizing uncertainty. With few exceptions, individuals did not provide recommendations on which of those methodologies Ecology should consider using in establishing cleanup standards. Mr. Butler urged Ecology to consider the recommendations in the recent report, Confronting Uncertainty in Risk Management (Finkel, 1990):

> As a recent U.S. EPA sponsored report stated: "If all the recommendations in this report were adopted, the typical risk assessment document would therefore undergo major changes both in structure and presentation - the linear process of moving singlemindedly towards a unique bottom line (the point estimates of potency or risk) would be supplanted by a self correcting process leading to a variety of "answers" at various levels of confidence. (Butler, p. 2 citing Finkel (1990))

Ecology's Response: Extensive documentation on the uncertainties involved in a quantitative risk assessment has been introduced into the rulemaking record and reviewed by Ecology (see Paustenbach 1989; Finkel, 1990; and OSHA, 1980). Although such uncertainties are unavoidable, Ecology believes it is important from a regulatory perspective to distinguish between the three areas of uncertainties that must be considered when establishing cleanup requirements:

- Uncertainties due to lack of data: The uncertainties resulting from insufficient data can often be reduced through the systematic collection of additional information. For example, in performing risk assessments for soil contamination, it is generally assumed that 100 percent of soil-bound contaminants are bioavailable. However, limited studies (Paustenbach et al., 1986; and EPA, 1984) suggest this may be an overestimate for some substances. Additional studies may reduce the level of uncertainty associated with this particular aspect of assessment. The rule encourages the collection and use of this type of information.

- Uncertainties due to lack of scientific knowledge: The second type of uncertainty, that attributes to the current state of knowledge or lack of knowledge, is far more resistant to brute force data collection efforts. People may be willing to perform additional studies, but practical limitations often stand in the way of concrete scientific answers. For example, the selection of the most appropriate method for extrapolating animal test results obtained at high levels of exposure to predict human responses at much lower concentrations is an example of this type of uncertainty. Rowe (1983) uses the term "transcience" to describe the area where judgments must be made, but the science is limited: "the judgments involved are about science, but not science in themselves...."

- Uncertainties due to future exposure conditions.

Methods for characterizing uncertainties in risk assessments have been discussed by EPA (1986, 1990) and by numerous risk assessment practitioners (Morgan et al., 1985; Morgan, 1986; Paustenbach, 1989; and Finkel, 1990). The methods that have been used or recommended vary widely in the amount of effort required as well as the amount of information needed. Available methods include:

- Qualitative evaluations of uncertainties may be performed that identify the contributing factors, their probable direction of uncertainty, and their possible magnitude.

- Conservative assumptions can be used and standardized across risk assessments to estimate reasonable maximum exposures and risks; these results can be used as upper bounds on risks in making risk management decisions.

- Mathematical approaches can be used to determine the uncertainty distribution for overall risk estimates; these approaches usually require a number of additional assumptions.

- Sensitivity analyses of specific risk assessment variables can be performed to provide partial estimation of uncertainties.

- Expert opinions can be used to construct subjective uncertainty evaluations.

Ecology proposed an approach that utilizes conservative/reasonable maximum exposure assumptions to develop an upper-bound estimate of risk. Although the procedures proposed by Finkel (1990) appear promising, Ecology is concerned that the use of detailed mathematical procedures for developing quantitative measures of uncertainty is somewhat premature given the large number of assumptions required to perform the uncertainty analysis are also subject to substantial uncertainty. Hattis (1990) has also evaluated various approaches for attempting to quantify uncertainties and concluded:

> 1. Nearly all parameter distributions look lognormal, as long as you don't look too closely.
>
> 2. Any estimate of the uncertainty of a parameter value will always itself be more uncertain than the estimate of the parameter value.
>
> 3. The application of standard statistical techniques to a single data set will nearly always reveal only a trivial proportion of the overall uncertainty in the parameter. (Hattis, 1990, p.11)

Issue #17: Do the proposed procedures take into account potential exposure to sensitive subgroups?

Several individuals recommended that Ecology adopt procedures that protect sensitive subgroups such as children and the elderly. For example:

> It should be noted that old people as their livers degrade and become less functional are increasingly vulnerable to health effects and cancer caused by toxins. Therefore, long exposure times are reasonable to

consider. In addition, it is necessary to correct dose/response data to account for the age and liver/kidney function of individuals. The long time frame for consideration of exposure will assure this phenomena shall be considered in determining a hazard index for individuals. (Cook, pp. 7-8)

Several other individuals expressed the opinion that the proposed procedures did not provide an adequate level of protection for sensitive subgroups. For example:

> "The risk assessments are based on the effects on average adults, so sensitive populations will not be protected, and there currently exist quite a few categories of these." (Cellarius, p. 1)

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> "The risk assessment framework spelled out in these rules is not adequately protective of sensitive populations. The more conservative estimates of 70 years of exposure and children's weights should be the normal factors unless there is strong proof that these should not apply." (Tabbutt, p. 4)

Ecology's Response: Ecology agrees that the procedures for establishing cleanup levels must take into account the growing body of scientific evidence which indicates that several very common genetic, environmental, and lifestyle factors can result in wide variations in susceptibility. Ecology believes that the procedures in the final rule result in levels that protect susceptible subgroups.

Ecology is aware of the complexities associated with addressing this variability in establishing health-based standards. These complexities were discussed by the Safe Drinking Water Committee in the report Drinking Water and Health:

> More and more patterns that are useful for extrapolation to man are being recognized and can be identified in the course of studying pharmacological disposition of a substance. Most of the differences that have been observed suggest that man is more sensitive than the usual experimental animal, and this should be kept in mind in establishing permissible exposures for humans.
>
> There are great difficulties in comparing the median animal to the not-so-average man. Man is not genetically homogeneous and is usually exposed to a much wider range of environmental conditions than the usual experimental animal. Differences in environmental factors are known to affect the toxicity of a substance. Differences in genetic makeup of the individual can affect toxicity. These must be considered in the extrapolation of laboratory-animal toxicity data to man. We must predict for, and protect, the highly sensitive individual as well as the average or median person. Because of the multitude of man-made chemicals, the different habits and lifestyles of populations, and the different eating habits of populations, there is considerable variation in the intake of, or exposure to, environmental pollutants. These must also be considered in establishing permissible exposures to environmental agents. (NAS, 1977, p. 41)

Recent advances in biochemistry and other basic sciences have revealed variations in susceptibility of several orders of magnitude. Some key findings are excerpted below:

> "The polymorphism of human drug metabolism indicates that the range of intrahuman variability may be as high as 100-fold, implying that the uncertainty factor of 10 may not be adequately conservative." (NAS, 1986)

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> A preliminary study using epidemiologic data on lung and colorectal cancer (Finkel, 1987) concluded it would be plausible (and not particularly conservative) to describe human susceptibilities to carcinogenesis as lognormally distributed such that five percent of the population is about 25 times more (and five percent is 25 times less) susceptible than the average person, and one percent each about one hundred times more or less susceptible. (Finkel, 1989)

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> The pharmacogenetic differences described herein [describing variations in cytochrome P450] range between 10 and 200 fold. If these data could be extrapolated directly to risk of human disease, we can conclude that -- -- at any dose of drug or environmental pollutant -- one individual will be 10-200 times more sensitive to toxicity or cancer due to differences in expression of a particular gene. (Nebert, 1988)

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> We know that there are extensive variations in repair capacity, as measured by the ability of cells in culture to repair ultraviolet damage. For example, unscheduled DNA synthesis, a measure of DNA repair, in epidermal cells varies as much as 3-fold among individuals of similar ages from whom the epidermal cells were obtained. In addition, the average repair decreases almost 3 fold from age 20-80." (Setlow, 1988)

Issue #18: Are the proposed risk assessment procedures too conservative?

Several individuals provided comments on whether the proposed rule incorporated an appropriate degree of conservatism. For example, some individuals expressed the opinion that Ecology should adopt conservative procedures for performing risk assessments in recognition of the large uncertainties in current estimates and the large variability in human susceptibility to hazardous substances. For example:

> While we recognize that this is a difficult area due to the number of unknowns, we feel very strongly that the Department should err on the conservative side until we are more certain as to the effects of these chemical and more confident that we understand exposure pathways.
>
> From our perspective, this approach represents the most significant "loophole" in the entire regulation. We are extremely disappointed that you have chosen to gamble with human health in this fashion. [See:

Robert, "Is Risk Assessment Conservative?" Science (March 24, 1989)]. (Wishart, p. 4)

See also the comments of Dr. Landau on the March 9, 1990 draft.

In addition, during the scoping of the cleanup regulations in March 1989, the General Electric Company recommended that Ecology consider utilizing a conservative approach to setting cleanup standards at smaller sites - not because conservatism is generally appropriate, but rather because the costs of acquiring and monitoring and administering the gathering of additional site-specific information are not justified by the potential savings in unnecessary remedial action.

At the other end of the spectrum, Mr. Syrdal submitted a recent OMB report which criticized current risk assessment procedures as "too conservative:"

> "*The continued reliance on conservative (worst-case) assumptions distorts risk assessment, yielding estimates that may overstate likely risks by several orders of magnitude.* Many risk assessments are based on animal bioassays utilizing sensitive rodent species dosed at extremely high levels. Conservative statistical models are used to predict low-dose human health risks, based on the assumption that human biological response mimics that observed in laboratory animals. Worst-case assumptions concerning actual human exposure are commonly used instead of empirical data, further exaggerating predicted risk levels.
>
> *Conservative biases embedded in risk assessment impart a substantial "margin of safety." The choice of an appropriate margin of safety should remain the province of responsible risk-management officials, and should not be preempted through biased risk assessments.* Estimates of risk often fail to acknowledge the presence of considerable uncertainty, nor do they present the extent to which conservative assumptions overstate likely risks. Analyses of risk-management alternatives routinely ignore these uncertainties and treat the resulting upper-bound estimates as reliable guides to the likely consequences of regulatory action. Decisionmakers and the general public often incorrectly infer a level of scientific precision and accuracy in the risk-assessment process that does not exist." (OMB, 1990, p. 14)

Several other participants also expressed the opinion that the proposed risk assessment procedures were overly conservative. For example:

> "Risk assumptions and exposure scenarios are extremely conservative." (Sacha, p. 3)

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> "Reference doses already incorporate conservative safety factors and the exposure parameters in this draft are likewise highly conservative." (Lorenzana p.1 of comments on March 9, 1990 draft)

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> The health-based cleanup levels derived from the equations in the proposed regulations are excessively conservative. Each assumption made includes a safety factor. When these assumptions and their underlying

> safety factors are combined, the calculated risk is greatly overestimated, resulting in derived cleanup levels which are much lower than is necessary to protect human health. (Thomson, p.3 of the December 29, 1989 draft)

Other individuals expressing similar opinions include the following: Syrdal, p. 3, and Belfiglio, p. 1.

Finally, a number of participants observed that Ecology's use of conservative assumptions was compounded when a series of such assumptions were multiplied together to calculate a cleanup level. For example:

> Much of the problem is that conservative assumptions is piled on top of conservative assumption. For example, risks are arbitrarily considered additive in defining cleanup levels. Thus, requirements compound quickly to a unattainable degree of complexity and stringency--particularly in Commencement Bay where multiple chemical and multiple media contamination is the norm. The regulation needs to provide a basis for stepping back and taking a realistic view of site contamination in context of the surrounding area and the realistic level of exposure and risk. Improvement must be emphasized over perfection. (Sacha, p. 1)
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> **********
>
> The draft cleanup standards ... include a number of conservative assumptions or "factors of safety." The process of developing cleanup standards involves the combination or multiplication of these factors of safety....
> ....
> While each of these assumptions can possibly, when considered individually, be justified from a policy standpoint, it appears likely that the combined impact of these safety factors will result in a predicted hypothetical risk which is 1000 or more times greater than the risk for the average "at risk" individual on the average site using the most probable toxicity information.... While some degree of conservatism is desirable, I suggest that Ecology ... reduce the degree of conservatism in the model." (Landau, pp.1-3 of comments on the December 29, 1989 draft)

Similar comments were provided by Mr. Butler on page 2.

While some individuals were concerned that the proposed procedures were too conservative, others expressed the opinion that they were not protective enough. For example:

> We believe that many of the assumptions made under "method B" risk assessments will not work to insure that standards are protective of human health and the environment. Most notably, the standards do not factor in: synergistic effects; inhalation and dermal exposure routes; impacts on the environment (non-human impacts); average lifetime exposure (i.e.-the rule does not utilize a 70 year exposure assumption). See Comments on Draft EIS for Multimedia Cleanup Standards (Monroe, Oct. 1989).
>
> "These omissions and others will result in the establishment of cleanup standards which fall far below the 1 in 100,000 level for carcinogenic chemicals, and below what we consider acceptable for non-carcinogens." (Wishart, p. 4)

Ecology's Response: Ecology recognizes that a frequent criticism of quantitative risk assessment is that the standard approach is overly conservative and at variance with new theories or scientific data to the contrary (Paustenbach, 1989; Maxim, 1989, Sielkin, 1990). Critics have argued that the preoccupation with the "worst case" has driven out scientific rules of reason and that the use of multiple conservative values within the risk assessment combine to produce a highly conservative result. However, others have expressed the opinion that quantitative risk assessment may not be conservative at all (Finkel, 1989; and Commoner, 1989). They have pointed to the large variabilities in susceptibility among the population, potential synergistic interactions, and the overall uncertainties associated with the risk assessment process.

Ecology believes that the popular belief that risk assessment is overly conservative is somewhat exaggerated. For example, Finkel (1989) and others have noted several areas where an increased degree of conservatism may be justified:

Use of Linear Dose Response Models: Finkel noted that this inference has been characterized as universally conservative, but identified several situations where supralinear functions that are steeper at low doses than at higher doses fit observed animal data better than linear functions do. He referenced the analysis by Bailar et al. (1988), who found that cancer risks were underestimated in 2.5 - 4.0 percent of the cases and overestimated in about 5 to 7 percent of the cases. In the case of vinyl chloride, for example, standard risk assessment methodology underestimated risk by a factor of nine. Similar observations have been made by the National Academy of Sciences:

> In general quantitative biochemical information is not sufficient for low-dose extrapolation. For carcinogenic risk assessment, the data suggest that a multistage model is consistent with certain qualitative aspects of cancer biology. This model is attractive because for most experimental data, the curve becomes linear at low doses. However, the biochemistry also suggests that regulatory agencies should not be complacent about such a dose-response model, despite its simplicity and its apparent conservative approach to extrapolation at low doses. The dose response may be fundamentally nonlinear at low doses, and a linear extrapolation may underestimate risk for certain individuals, species, or tissues. (NAS, 1986, p.284)

Susceptible Subgroups: As noted above there is considerable variability in human susceptibility to hazardous substances. Finkel (1990) notes that, given this variability, claims that current potency estimates are "more applicable to a rat than a human" actually represent "an indictment of the process as nonconservative if in general or in particular cases rats are actually less sensitive than humans." Ecology's use of "conservative" or "upper-bound" as opposed to "average" or "mean" values represents a fundamental policy choice which is dictated, at least in part, by the Model Toxics Control Act which states that "[e]ach person has a fundamental and inalienable right to a healthful environment...." To fulfill this mandate it is necessary to protect the whole population, including sensitive subgroups such as children. The use of conservative assumptions is consistent with this statutory directive. The use of

"average" or "mean" exposure values represents an alternative policy choice, one that may be at odds with the statutory requirements.

Assumption that Multiple Risks are Additive in Nature: Dr. Monroe (p.3) noted that two different substances can have a synergistic effect. For example, the cancer risk among asbestos workers with a history of cigarette smoking is approximately three times higher than the estimate one would derive by adding the excess risk from each separate exposure. Consequently, the compartmentalization that is central to quantitative risk assessment may be inherently nonconservative given the multi-factor, multistage nature of cancer.

Finally, a number of participants observed that Ecology's use of conservative assumptions was compounded when a series of such assumptions were multiplied together to calculate a cleanup level. Finkel (1989) has concluded that this concern is often overstated in that it does not take into account the overall uncertainty distribution of the risk estimate, the wide variations in human susceptibility, and the highly skewed nature of most of the parameter distributions. Indeed, the results of Burmaster and von Stackelburg (1988) indicate that the use of standard risk assumptions will result in an "upper bound", but not ultraconservative estimate of risk. Specifically, Burmaster and von Stackelburg compared a risk estimate for drinking water obtained using standard risk assessment assumptions with series of risk distributions obtained through a series of Monte Carlo analyses. They observed that the estimate obtained through standard procedures generally fell somewhere between the 60th and 95th percentile of the overall risk distribution.

Issue #19: Does the proposed rule include appropriate procedures for addressing the potential health risks associated with multiple hazardous substances and/or multiple routes of exposure?

Ecology proposed to address potential health risks associated with multiple hazardous substances and/or multiple routes of exposures when establishing cleanup levels. Several individuals expressed support for incorporating such procedures into the regulation. For example:

> "[R]isks associated with multiple contaminants, multiple routes of exposure, sensitive populations, and foodchain contamination should be evaluated for all environmental media." (Lorenzana, p.3 of comments on the October 16, 1989 draft)

Other individuals providing similar recommendations included the following: Tabbutt p. 5; and Cellarius, p.1.

However, several individuals questioned whether the proposed rule, particularly the use of numeric standards, resulted in full consideration of potential interactive effects. For example:

> "The promulgation of absolute, numeric standards would prohibit evaluation of exposures from multiple route of exposure and multiple routes of exposure." (Lorenzana p.2 of comments on December 29, 1989 draft)

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> Under the proposed rules, method A allows for the use of lists and tables to establish cleanup standards. These tables are calculated assuming single chemicals and single routes of exposure, which is seldom the case in actual sites. There needs to be more careful constraints on the use of these tables so that they will ONLY be applied in vary simple cleanups with few chemicals and no possibility of synergistic effects or multiple exposure opportunities. (Tabbutt, p. 5)

Finally, Dr. Tsuji recommended that Ecology clarify the proposed rule as it might be applied in evaluating the additive effects of multiple noncarcinogenic substances:

> In evaluating the additive effects of multiple noncarcinogenic chemicals at a site, the level at which toxic effects occur should be considered along with whether chemicals have similar "toxic responses." For example, many chemicals will have various similar toxic effects in the body at high enough exposure levels. The relevant effects for determining cleanup levels, however, are only those that occur for each chemical at their lowest doses. Thus, these sections should clarify that in evaluating additive effects, the toxic responses to consider are only those on which the reference doses (Rfds) are based and not on those which occur at higher doses. (Tsuji, p. 4)

Ecology's Response: At most cleanup sites, Ecology is required to consider the potential health effects of more than one hazardous substance and/or exposure via more than one exposure pathway. For purposes of assessing the risks posed by multiple substances/multiple pathways, Ecology will assume dose additivity unless there is specific information that demonstrates that an alternate approach is more appropriate.

This approach is consistent with EPA's approach for chemical mixtures described in Guidelines for the Health Risk Assessment of Chemical Mixtures (EPA, 1986) and the Risk Assessment Guidance for Superfund (EPA, 1990). A similar approach has also been recommended by the National Academy of Sciences' Safe Drinking Water Committee (NAS 1986) who noted that "in general, there is not likely to be sufficient information on [the action of] mixture.... Consequently, estimates will ... have to be based on an ... assumption of additivity...." (NAS, 1986, pp. 255-256).

Chen et. al. (1990) have discussed the scientific basis for this approach. They noted:

> Humans are frequently exposed to many chemicals either simultaneously or in sequence. Several chemicals may be naturally or artificially present in the air, water, food, or industrial or commercial products. The health risks from exposure to a mixture of chemical carcinogens may combine additively, multiplicatively, or in some other fashion. Based on the Armitage-Doll[1] multistage theory of carcinogenesis, an additive effect would be produced if different carcinogens in a mixture act on the same stage of the process, and a multiplicative model would be produced if different carcinogens act on different stages in the case of constant lifetime exposure.[2,3] At low risk levels, the risk calculated from the product of relative risks is essentially the same as the sum of individual risks; for example, if the relative risk for each component is

> 1.00001, in the absence of synergism or antagonism, the relative risk from 10 multiplicative components is $(1.00001)^{(10)} \approx 1.0001$. Thus, the total risk under the multiplicative risk model is effectively additive at doses where the relative risks are near one. (Chen et al., 1990 p. 285)

Ecology recognizes and acknowledges that these approaches have several limitations. This was also noted by EPA:

> There are several limitations to this approach that must be acknowledged. First, because each slope factor is an upper 95th percentile estimate of potency, and because upper 95th percentiles of probability distributions are not strictly additive, the total cancer risk estimate might become artificially more conservative as risks from a number of different carcinogens are summed. If one or two carcinogens drive the risk, however, this problem is not of concern. Second, it often will be the case that substances with different weights of evidence for human carcinogenicity are included: The cancer risk equation for multiple substances sums all carcinogens equally, giving as much weight to class B or C as to class A carcinogens. In addition, slope factors derived from animal data will be given the same weight as slope factors derived from human data. Finally, the action of two different carcinogens might not be independent. New tools for assessing carcinogen interactions are becoming available, and should be considered in consultation with the RPM (e.g., Arcos et al. 1988). The significance of these concerns given the circumstances at a particular site should be discussed and presented with the other information described in Section 8.6. (EPA, 1989a, p.)

Chen et al. (1990) have developed a procedure that addresses these concerns. This was summarized as follows:

> "In the absence of data from multiple-compound exposure experiments, the health risk from exposure to a mixture of chemical carcinogens is generally based on the results of the individual single-compound experiments. SA procedure to obtain an upper confidence limit on the total risk is proposed under the assumption that total risk for the mixture is additive. It is shown that the current practice of simply summing the individual upper-confidence-limit risk estimates as the upper-confidence-limit estimate on the total excess risk of the mixture may overestimate the true upper bound. In general, if the individual upper-confidence-limit risk estimates are on the same order of magnitude, the proposed method gives a smaller upper-confidence-limit risk estimate than the estimate based on summing the individual upper-confidence-limit estimates; the difference increases as the number of carcinogenic components increases. (Chen et al. 1990, p. 285)

Ecology also recognizes the need for clarity in specifying procedures for handling multiple noncarcinogens (see Tsuji above). The regulation specifies that Hazard Indices for multiple substances will be segregated by effect and mechanism of action. In addition, Ecology intends that Hazard Indices will generally be based on the effects that occur for each chemical at their lowest doses (critical effect)(the range of effects at higher dose levels will also be considered) and that separate Hazard Indices will be developed for chronic, subchronic, and shorter term exposures. Ecology plans to develop rulemaking guidance for implementing these provisions.

Issue #20: Is it appropriate to utilize a subset of hazardous substances present at a site to define site cleanup requirements?

Ecology proposed to provide the flexibility to base cleanup requirements on "indicator hazardous substances." Indicator hazardous substances are defined as "the substance or substances at a site which pose the most serious threats to human health and the environment...."

During the rule development, several individuals expressed general support for this approach (see Thomson, p. 2; and Fortier, p. 5). Other individuals expressed concerns that this provision might be abused and urged Ecology to exercise caution in this area. For example:

> Under no circumstances should "the frequency that individual has[ardous] subst[ances] have been detected at the facility" eliminate a contaminant from further consideration at a site. It is unreasonable to expect that contaminants are homogeneously distributed over a site. Periodic detection of a contaminant may indicate the presence of a "hotspot", or site-specific features that influence the fate and transport of contaminants. Rather than eliminate constituents with these characteristics, further investigation may be required. (Lorenzana, p.2 of comments on December 29, 1989 draft)

Ecology's Response: Ecology understands the above concerns, but is in basic agreement with the Office of Technology Assessment who stated in the recent Superfund review:

> "As a means of simplification and study cost reduction, using a short-list of representative site contaminants stands on its own merits. The problem lies in implementation of the concept, especially by relatively inexperienced people, and unintended uses of the short-list." (OTA, 1989, p. 6)

OTA identified two primary concerns with implementing this approach. First, they noted the potential for underestimating total site risk:

> First, indicator chemicals used in risk assessment may not produce accurate risks because too many site contaminants are left out. The extent of this problem is linked to what concept of risk is employed. If risk assessment is centered around possible worst case individual risk, as it is currently, then using a short-list is less problematic, as long as the worst site contaminants in terms of health effects are chosen. However, if the risk concept is population risk, reflecting actual or likely total risks to a whole exposure group, then using a short-list of contaminants could greatly underestimate total estimated risk and the total benefits from risk reduction. The latter is favored by people who want to have cleanups justified by cost-benefit analysis. But using only indicator contaminants inevitably means *underestimating* total risk and total benefits (or total risk reduction) from cleanup. (OTA, p. 6)

Indicator substances are often used during technology evaluation and implementation and OTA noted that this represents a potential problem:

> "[S]election of indicator chemicals because of their documented health effects is not necessarily consistent with differences among site contaminants with regard to their chemical and physical properties which are critical to cleanup. Therefore, decisions regarding remedy selection, design of remedy, and--most critically--measurement of cleanup success may be seriously affected by the originally selected indicator chemicals. For example, it is quite conceivable that a cleanup could be judged to be successful on the basis of cleanup levels for indicator chemicals. But such a cleanup could leave a site contaminated with other contaminants which, in their own right, pose unacceptable levels of risk to health or--especially--environment, because environmental effects are not used on a par with health effects in the selection of indicator chemicals. Or site contaminants which are **not** indicator chemicals might seriously reduce the effectiveness of chosen cleanup technologies. (OTA, 1989, p. 65)

Ecology believes that by basing site cleanup decisions on individual risks and exercising best professional judgment on a site-specific basis, the potential for underestimating risks will be minimized. In addition, technology evaluations performed during the feasibility study will be required to take into account all hazardous substances. Ecology will prepare more detailed policy guidance on the procedures for identifying indicator hazardous substances in 1991.

Issue #21: Does the proposed rule provide sufficient flexibility to consider site-specific variations in exposure conditions?

Ecology proposed to base cleanup level determinations on the reasonable maximum exposure and/or the highest beneficial use. Defining the reasonable maximum exposure for a particular site generally involves two steps: (1) definition of the RME scenario and (2) specification of the individual exposure parameters to be used to estimate exposure levels. In the proposed rule, Ecology defined "default" RME scenarios for each media and criteria for demonstrating that the default scenario was inappropriate for a particular site. For example, WAC 173-340-720 specifies that drinking water and other domestic uses generally represents the RME, but includes criteria for demonstrating this is inappropriate for a particular site. With respect to individual exposure parameters, the proposed rule defines the parameters to be used at individual sites, but provides some flexibility for modifying those on the basis of new scientific or site-specific data.

Several participants expressed concerns over the use of prescribed exposure scenarios:

> "Exposure scenarios should not be circumscribed by regulatory fiat, rather they should be allowed to be site-specific in order to properly account for differing exposure scenarios." (Coenen, p. 2 of comments on March 9, 1990 draft)

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> "WAC 173-340-700(4). This section, along with the referenced sections which, in reality, establish the exposure assumptions, does not provide

> sufficient flexibility to give realistic estimates of maximum exposures. Procedures should be identified to allow a PLP to provide justifiable site-specific reasonable maximum exposure estimates for purposes of determining Method B cleanup standards." (Syrdal, p. 7)

A number of individuals also urged the Department to provide greater flexibility in defining individual exposure parameters. For example:

> Additional flexibility in the exposure parameters is needed to allow use of new scientific information.(sic) Short of revising the regulation, only three exposure parameters may be modified; gastrointestinal absorption rate; inhalation correction factor; and the bioconcentration factor. This is very inflexible. There are many situations which justify the use of other exposure parameters. These include chemical specific factors such as dermal absorption rates, unique land use patterns, and new scientific knowledge. (Findley, p. 3)
>
> **********
>
> This section states that exposure parameters cannot be modified with the exception of the exposure parameters specified in (b). This is too limiting. For example, the surface water cleanup standard requires use of a fish consumption rate of 30 grams/day and a fish diet fraction of 0.5. These exposure assumptions may be totally inappropriate for site specific conditions. There are probably only very isolated conditions where these assumptions would be valid as "reasonable maximum exposure." We understand the desire to establish consistent levels of cleanup, while reducing areas of potential dispute. However, there should be more flexibility to allow realistic RME parameters to be developed for determining site specific cleanup levels. (Burgess and Dunster, p. 4)

Similar comments were provided by Butler on page 1.

Ecology's Response: Ecology believes that many of the recommendations to provide more flexibility to develop exposure scenarios which reflect "actual" or "realistic" exposure scenarios do not take into account Ecology's responsibility to take into account both current and potential future exposure scenarios. However, given the level of concern on this issue, Ecology is currently reevaluating whether additional flexibility is needed in specifying "reasonable maximum exposure" scenarios and parameters.

Issue #22: Does the proposed rule provide sufficient flexibility to allow the use of new scientific information in a timely manner?

A number of individuals stated that it is appropriate for Ecology to utilize new scientific information to develop cleanup levels for individual sites. For example:

> It is appropriate that Ecology consider new scientific information as it becomes available. It is unclear how this subsection relates to the remainder of the substantive portion of the regulation actually setting cleanup standards. Does this mean that, notwithstanding the mandatory provisions of the regulation establishing cleanup levels, Ecology

reserves the right to establish some other cleanup level based on "new scientific information?" If that is the case, and we think it should be, Ecology should make this point specific, either in a general portion of the regulation, or as subsections to the actual cleanup standards. (Syrdal, p. 10)

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"DON'T limit what new scientific information can be considered in a regulation! This is counterproductive, and in fact would be worse than saying nothing at all." (Eaton, p.3 comments on October 16, 1989 draft)

Several participants expressed the opinion that the proposed rule provided in an insufficient amount of flexibility to utilize new scientific information when developing cleanup levels for individual sites. For example:

"The Board ... agrees that the basic framework for implementation of the cleanup standards is workable. However ... certain portions of the document do not yet appear to allow for the best and fullest use of scientific information." (Science Advisory Board, p.1)

Although most of the exposure assumptions used to derive the cleanup standards are consistent with current scientific information, the data upon which the exposure assumptions are based is evolving rapidly. It is therefore likely that in a period of a few years, at least some of the exposure assumptions defined by the proposed regulation (e.g., soil ingestion and dermal absorption rates) may soon be outdated, and likely modified for the federal Superfund program. In this situation, significant inconsistencies between various programs is possible, and the technical foundation upon which the MTCA cleanup standards are based will erode. (Patmont and Wineman, p. 1)

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The Proposed Amendments allow for modification of only three parameters: "where there is clear and convincing scientific data which demonstrates (sic) that one or more of the following parameters should be modified for an individual hazardous substance or site: (i) gastrointestinal absorption rate: (ii) inhalation correction factor; or (iii) bioconcentration factor. Nevertheless, scientific evidence does exist for modification of other exposure parameters which are currently invariant by the proposed amendments "as a matter of policy." Examples of these other exposure parameters are soil ingestion rates and inhalation absorption rates, which are discussed in some detail below. (Tsuji p. 4)

However, one individual expressed concerns that there was too much flexibility:

"If Ecology wishes to set standards based on new scientific information, the administrative rules should be changed to reflect this new scientific information. Ecology must share the content of new scientific information in a clear and concise manner with those it intends to regulate, and make this determination available for all to see and judge." (Burch, p. 2)

Ecology's Response: As noted above, Ecology is committed to utilizing sound scientific and technical judgment when establishing cleanup requirements under this Chapter. Because it appears that many individuals did not realize this fact, Ecology has articulated this goal in Section 702(6) (General Policies) and the rule provides several mechanisms for responding to future scientific developments. These include:

> Periodic Review: WAC 173-340-702 specifies that Ecology will periodically review and, as appropriate, update the cleanup standard amendments. As noted below, such reviews will be performed at least once every five years.
>
> Chemical-Specific Information: The rule provides considerable flexibility to utilize new substance-specific data to modify individual parameters used to establish cleanup requirements. These include carcinogenic potency factors, reference doses, bioconcentration factors, and several absorption factors.
>
> Site-Specific Data: The rule provides the flexibility to modify the soil-to-ground water ratio based on site-specific information.

Ecology believes that these provisions will allow the timely consideration of new scientific information, while at the same time, prevent the constant "relitigation" of previously resolved scientific policy issues. The Department also believes these provisions will minimize the potential that cleanup requirements are based upon out-dated science and technology.

Issue #23: How frequently will Ecology review and update the cleanup standards?

Ecology proposed to review and periodically update the cleanup standards rules no less frequently than once every five years. Two individuals expressed the opinion that more frequent reviews were necessary:

> "Review of Standards: Standards should be reviewed annually, not once every five years to accommodate increased knowledge in this field. Data documenting alternate standards or cleanup methods should be publicized as it is received." (Sacha, p. 3)
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> **********
>
> The frequency specified for review and update of the rule is excessive. Many changes to applicable state and federal laws may occur within a five year period. An annual review should be specified with at least annual updates of the rule accomplished as necessary to be consistent with the RCW 70.105D.030(2)(d). It is unreasonable to allow a 5 year delay in accomplishing protection of human health and the environment. Procedures for publishing the updated standards should be specified in 173-340-705. (Cook, p. 8)

Ecology's Response: Ecology believes a five year review is sufficient. However, the rule provides the flexibility to perform more frequent reviews should Ecology decide that a sufficient amount of new information is available. See previous response.

VI. PROCEDURES FOR ASSESSING ECOLOGICAL HEALTH RISKS

A. Background

Under the Model Toxics Control Act, cleanup standards must protect human health and the environment. To date, the process of developing cleanup standards has focused on using human health risk assessment models to derive cleanup levels that protect human populations. For some hazardous substances, cleanup levels that protect human health will also protect ecological resources (Ecology, 1990). However, at present, detailed guidelines for assessing ecological impacts have not been developed by Ecology or other state and federal agencies.

B. The Public's Response

Several individuals expressed concerns over the lack of specific requirements for establishing ecologically-based cleanup levels. For example:

> "The rules address risk to public health with not enough attention to risk to ecosystems, wildlife and biological resources. It was a strong intent of the Initiative that cleanups be protective of not only public health but of the environment in total." (Tabbutt, p. 5)

Other individuals expressing similar concerns include the following: Chartrand, (Seattle hearing); Orme, p. 1; Cook, p. 2; and Stembridge, p. 2.

C. Ecology's Evaluation and Response: Ecology agrees that cleanup standards for individual sites must protect both human health and the environment. To address the latter, the Department has developed a three-part strategy:

> Regulatory Requirements: Under the final rule, Ecology would establish cleanup levels using either (1) applicable state and federal laws or (2) site-specific ecological risk assessments. Each of the methodologies for establishing cleanup levels provide a mechanism for addressing environmental effects. For example, environmental protection was considered in establishing Method A cleanup levels in Tables 1-3 and forms the basis for several applicable state and federal laws (i.e., surface water quality criteria).
>
> Interim Guidance: The Department is developing interim guidelines which specify ecologically-based cleanup levels for high priority hazardous substances in soils. This is scheduled for completion by mid-1991.
>
> Final Guidance/Regulatory Amendments: The Department is currently developing detailed procedures for establishing ecologically-based cleanup levels. This effort is being coordinated with similar development efforts at the federal level. To provide advice on this, Ecology has formed a subcommittee of the Science Advisory Board.

VII. CONSIDERATION OF CLEANUP COSTS

A. Background

The question of how and when to consider the cost of cleanup in defining requirements under the MTCA was identified early in the process as a key policy issue to be addressed by Ecology. In response, Ecology requested that the Office of the Attorney General review Ecology's authority to consider costs when developing cleanup standards or selecting cleanup actions. The portions of the informal legal opinion which addressed these issues indicated:

> The Department has the legal authority to consider costs in setting cleanup standards under the MTCA (Model Toxics Control Act). However, cost considerations can never be used to justify cleanup standards or cleanup actions that do not protect human health and the environment and are not as stringent as Section 121 cleanup standards, all applicable state and federal laws, and health-based standards under state and federal law.
>
> The Department has the legal authority to consider costs and technical feasibility when selecting a remedial action alternative. However, all remedial actions must protect human health and the environment and meet the cleanup standards promulgated under Section 3(2)(d). (Manning, 1989)
>
> The Department has the authority to consider costs of a remedial action when evaluating whether such an action satisfies the statutory preference for permanent solutions to the maximum extent practicable.

Based on this informal legal opinion, it appears that Ecology has a certain amount of discretion in deciding how cleanup costs are factored into the cleanup decision-making process. This discretion gives rise to a number of policy issues relating to how Ecology chooses to exercise this discretion.

B. The Public's Response

During the rulemaking process, a number of individuals emphasized that cost was an important issue and noted the potential problems associated with a regulation that failed to provide the flexibility to consider the cost of cleanup at individual sites. For example:

> We feel that the restrictions on using cost as a significant item in determining cleanup may result in:
>
> a. hardship on the parties, possibly resulting in productive economic operations being shut down and/or curtailed, thus costing jobs and tax revenue;
> b. extensive 'transaction costs' as parties use all available methods to avoid truly burdensome and perhaps fatal cost consequences; and
> c. great time delay in effecting cleanup. (Tamblyn, p. 1)
>
> **********
>
> Why should cost - or a variety of alternatives - be an issue of public policy, rather than a private problem of the responsible party. Consider the following reasons:

a. "Responsibility" is determined arbitrarily, without a serious consideration of "guilt."
b. Responsible parties in many cases will be governments, such as owners of landfills and vehicle maintenance facilities.
c. Excessive costs lead to private bankruptcies, costing workers their jobs, and lenders and creditors their resources. Vacant sites in prime industrial areas result; while at the same time a public policy of restricting urbanization in out-lying areas is being implemented.
d. Strategies to defer costs, such as litigation or interim clean up, are pursued, which may increase costs and environmental burdens on public resources, and will not meet the goal of permanent clean up. (von Gohren, p. 4)

In recognition of the potential economic impacts associated with performing site cleanups, Ecology has spent a considerable amount of time evaluating the appropriate role of cost in the cleanup process. The principal issues raised and considered during the rulemaking process were the following:

Issue #1: **Is it appropriate for the Department to consider the cost of cleanup when establishing cleanup levels?**

Issue #2: **Is it appropriate for the Department to consider the relative costs of cleanup action alternatives during the selection of final cleanup actions?**

Issue #3: **What is the most appropriate methodology for considering the relative costs of cleanup action alternatives?**

Issue #4: **Should fund-balancing be a factor that is considered when making decisions on cleanup levels or final cleanup actions for state-funded actions?**

Issue #5: **What types of costs should Ecology consider during the evaluation of cleanup action alternatives?**

C. Ecology's Evaluation and Response

Issue #1: Is it appropriate for the Department to consider the cost of cleanup when establishing cleanup levels?

Ecology's proposal provided limited flexibility to consider cost of cleanup when establishing cleanup levels for individual hazardous substances. The proposed rule specified that "technical practicability" was one factor that could be considered when modifying the compliance cleanup level and establishing a conditional cleanup level. In this instance, a compliance cleanup level could be considered technically impracticable if the costs of complying with the more stringent cleanup level were "substantial and disproportionate to the anticipated benefits." However, in no case could cost considerations justify cleanup levels which exceeded applicable state and federal laws, a total risk level of 10^{-5}, and a Hazard Index of 1.0.

Several individuals and organizations expressed strong opposition to the proposal. For example:

> "WEC (Washington Environmental Council) feels that standards should be set without regard to cost. Costs may be considered when choosing between remedial actions which meet the goals (the standards and the priority for permanent solutions). This meets the widely accepted practice of cost-effective analysis as opposed to benefit-cost analysis." (Tabbutt, p. 2)

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> "Cost considerations are established throughout Ecology's proposed regulations and may result in clean ups less protective of human health and the environment than would otherwise be allowed." (Sullivan, p. 3)

Mr. Wishart and Ms. Cellarius stated that an approach which provides the flexibility to consider costs when establishing cleanup levels was inconsistent with the intent of Initiative 97. For example:

> As you know, during the legislative debate over the issue of toxic waste cleanup, the central issue was the role of cost in the cleanups. Since the legislature was unable to resolve the question, environmental groups put the issue up for a vote by placing Initiative 97 on the ballot in 1988.
>
> The central theme in our campaign was "make the polluters pay" for the cost of cleaning up these sites. When the voters affirmed this theme at the polls, they assumed that a program would be created to clean sites to levels protective of human health and the environment without much regard to cost.
>
> Unfortunately, the Department has ignored this message in drafting rules for the cleanup program. Throughout the rule, you use the term "practicable" to cost modify decisions made on the cleanups. The point of compliance, the type of remediation, the timing of the cleanup, even the standards themselves are subject to cost considerations. This language will, in many cases, limit the ability of the Department to achieve cleanups which are protective of human health and the environment.
>
> We strongly suggest that you remove language of this sort as it is inconsistent with the overall intent of the law. (Wishart, p. 1)

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> Cost considerations should not determine cleanup levels. It was the intent of Initiative 97 that cost considerations should only be used to decide between two cleanup actions that equally meet cleanup standards. Further, it was the intent of Initiative 97 that the polluters should pay, and different polluters will be paying for cleanups in different areas. They will not be diverting financial resources one from another. (Cellarius, p. 1)

Other individuals or organizations recommending that costs not be considered when establishing cleanup levels included the following: Roberts (Seattle hearing); and the Science Advisory Board, p. 4.

However, there were also a number of people who expressed the opinion that the Department should consider costs when establishing cleanup levels. For example:

> Technical practicability must be considered in selecting a cleanup level. The establishment of cleanup levels in this section fails to adequately address technical impracticability, even though many standards developed from either method A or B or conditional cleanup levels may still be below limits of practicability by available methods. This section must be revised to provide a means for modifying cleanup levels based on impracticability. There have been several suggestions for how to accomplish this, with most involving some increase in the risk level range if necessary to allow for selection of a technically practicable response action. One possibility for carcinogens would be to allow for a deviation from use of the upper 95% confidence level, such as use of the most probable value, when the cancer potency factor for the contaminant in question has a great deal of uncertainty. Similarly, with non-carcinogens, a lower safety factor for the NOAEL could be used when necessary to allow a technically practicable response. (Syrdal, p. 15)

Other participants who expressed support for providing the flexibility to consider costs when establishing cleanup levels include: Izatt, p. 3; and Butler, p. 7.

Ecology's Response: Following the review of the public testimony and written comments, Ecology finds that a large number of citizens strongly opposed Ecology's proposal to consider costs when establishing cleanup levels. In response to those comments, Ecology has deleted WAC 173-340-700(5)(d)(iv) and (v) from the final rule.

Ecology considered a number of factors before arriving at a decision to eliminate "cost" or "practicability" from the list of factors that might justify a less stringent cleanup level. These include the following: (1) the large adverse response from citizens, environmental groups, and Indian Tribes; (2) comments from the regulated community which expressed the opinion that there was very little difference between compliance cleanup levels (Method A and B) and conditional cleanup levels (Method C); (3) Comments from the Environmental Protection Agency that cost of cleanup is not considered when establishing cleanup levels under the federal program; and (4) the fact that Ecology has provided the flexibility to consider the cost of cleanup when selecting from among several cleanup actions.

Issue #2: Is it appropriate for the Department to consider the relative costs of cleanup action alternatives during the selection of final cleanup actions?

Ecology's proposal identified cost of cleanup as one of several factors that would be considered when selecting a final cleanup action. During the rulemaking process, there appeared to be general agreement that it was appropriate to consider costs or technical practicability at this stage of the process. For example:

"In addition, consideration of cost is clearly contemplated by Section 3(1)(b) which requires consideration of practicability in the choice of remedial actions. The courts have consistently interpreted practicability to include cost considerations." (Brothers, p. 3)

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"Costs may be considered when choosing between remedial actions which meet the goals (the standards and the priority for permanent solutions). This meets the widely accepted practice of "cost-effective analysis" as opposed to "benefit-cost analysis." (Tabbutt, p. 2)

Other individuals or organizations providing similar comments include the following: Science Advisory Board, p. 4; and Meyer (Seattle hearing).

Despite the apparent agreement that it was appropriate for Ecology to consider costs when selecting a final cleanup action, there was considerable range of opinion on the degree to which costs could be considered. For example, there were several individuals who expressed concerns that the consideration of costs at this stage may result in cleanups that fail to protect human health and the environment:

The proposed rules contain the concept that cleanup standards will be fixed within the risk range of 10-6 down to 10-5 when conditions apply. However, there are escapes which will allow cleanups to fall below 10^{-5}...Argue cost. There is some attempt to bound cost considerations, but it is not clear under which decisions those boundaries will apply and exactly when cost will drive the decision. (Just count the number of times "practicability" is used!) (Tabbutt, p. 2)

Other individuals expressing similar concerns include the following: Pearson (Seattle hearing); and Wishart (Seattle hearing).

Ecology's Response: Ecology believes it is appropriate to provide the flexibility to consider cost of cleanup when selecting from among several cleanup action alternatives that comply with cleanup standards. This is based upon the following considerations:

Statutory Requirements: As summarized in the informal legal opinion from the Office of the Attorney General (Manning, 1989), Ecology appears to have the discretion to consider cost of cleanup when selecting a final cleanup action. However, the cost of cleanup cannot be used to justify the selection of a final cleanup action that is not protective of human health and the environment.

Other State Programs: Most other states appear to include the cost of cleanup as one of several factors considered when selecting a final cleanup action (Clean Sites, 1989; and EPA, 1989i) For example, under the State of Michigan's cleanup regulations, the cost of remedial actions can be considered when choosing among alternatives which adequately protect human health and the environment and comply with all legally applicable or relevant and appropriate state and federal requirements (MDNR, 1990).

Federal Superfund Program: The approach for evaluating alternatives and selecting remedies for federal Superfund sites is described in the

National Contingency Plan (EPA, 1990a). Under that approach, all potential alternatives must be protective of human health and the environment, and attain ARARS or provide grounds for invoking Section 121 waivers. Thereafter, EPA directs that a remedy be selected which provides the best balance of trade-offs among alternatives regarding long-term effectiveness, short-term effectiveness, reduction of toxicity, mobility or value, implementability, and cost. The selection must be made considering the use of permanent solutions and alternative treatment to the maximum extent practicable.

Public Comment: Comments on the proposed rule appear to reflect broad support for including cost among the factors considered when choosing from among several cleanup action alternatives.

Issue #3: What is the most appropriate methodology for considering the relative costs of cleanup action alternatives?

This issue is addressed under Section X (Issue #18)

Issue #4: Should fund-balancing be a factor that is considered when making decisions on cleanup levels or final cleanup actions for state-funded actions?

Section 121(d) of CERCLA specifies that remedial actions must "attain a degree of cleanup ... at a minimum which assures protection of human health and the environment...." Protection of human health and the environment is to be achieved, at least in part, through compliance with ARARS. Section 121 (d)(4) identifies six conditions where compliance with ARARS could be waived by EPA. One of those conditions is fund-balancing. Fund-balancing under the federal law may be invoked when EPA is performing the cleanup action and determines that an ARAR would (1) entail extremely high costs of compliance in relation to the added degree of protection or reduction in risk provided by the particular requirement and 2) jeopardize remedial actions at other sites because of lack of funds.

Ecology's proposal included a provision (WAC 173-340-700 (5)(d)(v)) which provided the Department with the flexibility to develop alternate cleanup levels for cleanup actions if it could be demonstrated that attainment of compliance cleanup levels would limit a person's ability to respond to other environmental threats at the site. This was intended to apply to the Department, as well as to PLPs. The proposed language is similar to the federal requirements in that cleanup levels would always need to protect human health and the environment. However, fund-balancing could not be used to justify cleanup levels less stringent than those specified in applicable state and federal laws.

Mr. Findley supported Ecology's proposal, but expressed the concern that this provision might not apply to state and federal agencies:

> As currently written, WAC 173-340-700 (5)(d)(v) could not be used by either the State of Washington or any federal agency, including EPA. This section allows conditional compliance levels to be used if

attainment to the compliance clean-up levels would limit the ability of a person to respond to other environmental threats. One requirement is that the financial savings be used to fund actions that are not otherwise required under applicable state and federal laws. As the clean-ups performed by Ecology and EPA are required under state and federal laws, it appears that conditional compliance levels could not be justified using this option for any Fund-funded or government-funded action. We recommend that this section be changed to allow Ecology and EPA to use this exception when it is necessary. (Findley, p. 4)

Several individuals objected to this provision. For example:

> The Sierra Club strongly objects to subsection (v) which allows for lower standards if the savings incurred would be used to address other environmental threats. While, in principle, this would seem to be a reasonable approach, we believe it would be extremely difficult to administer. It could, for example, require the Department to weigh the benefits of a wetlands mitigation against the human health benefits of a cleanup that attains compliance cleanup standards. Even within the same general area of concern this balancing would be problematic. How can one compare the effects of benzene in water to carbon monoxide in the air. (Wishart, p. 3)

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> "It [subsection v] is a mitigation approach and will be argued continually. Not appropriate to the goals or policy of the cleanup law." (Tabbutt, p. 3)

Ecology's Response: Based on public testimony, Ecology has elected to delete this provision from the final rule. In making this change, Ecology considered the following factors:

> Historical Experience: Based on historical experience, the Department believes it is unlikely that the issue of fund-balancing will be a significant factor at sites in the State of Washington. The fund-balancing waiver has rarely, if ever, been used at federal Superfund sites in Region X.
>
> Interim Actions: The Department has the authority to undertake interim actions to address significant threats to human health and the environment.
>
> Other State Programs: Few state programs appear to provide explicit provisions for fund-balancing. California and New York propose flexibility for considering cost differently for state financed vs. PLP cleanups. However, the purpose is apparently different than the EPA waiver provision. In those states, the fund-balancing provision is used to justify the selection of more costly alternatives for state funded sites than those for typical PLP funded cleanups, in order to assure that state goals are addressed (eg., the preference for permanent solutions).

Issue #5: What types of costs should Ecology consider during the evaluation of cleanup action alternatives?

The Department proposed to consider the following types of costs when evaluating cleanup actions:

- Present and future direct and indirect capital costs;
- Operation and maintenance costs; and
- Other foreseeable costs.

Several individuals recommended that the environmental costs associated with the loss of environmental resources should be considered:

> "This section concerning practicability should consider costs associated with loss of future beneficial uses. Intangible benefits, for example, nature preserves, should be assigned a worth to allow such evaluation. Such "lost beneficial usage" costs should subtract from costs associated with cleanup actions in evaluation required by item (c)." (Stembridge, p. 8)

Similar recommendations were submitted by Tabbutt, p. 3 and Cook, p. .

Ecology's Response: Ecology believes that costs associated with lost beneficial usage should be considered among "other foreseeable costs." However, the availability of information to quantify such costs will vary from site to site. In addition, such evaluations must be coordinated with similar evaluations performed as part of a natural resource damage assessment.

VIII. ANALYTICAL ISSUES

A. Background

The question and issues associated with the measurement of trace levels of hazardous substances have been among the issues addressed during the development of the cleanup regulations. These issues have taken on greater importance with the recognition that even trace levels of hazardous substances can pose risks to human health and the environment.

B. Ecology's Proposal

The evaluation of trace levels of hazardous substances is frequently limited by the chemical concentrations that are below detection limits. In the proposed rule, Ecology stated:

> If a hazardous substance is not detected or is detected at a concentration below the practical quantitation limit utilizing sampling and analytical procedures approved by the department and the practical quantitation limit is higher than the cleanup level for that substance, the cleanup level shall be considered to have been attained only when the more stringent of the following conditions are met:
>
> (i) The practical quantitation limit is no greater than ten times the method detection limit; or
>
> (ii) The practical quantitation limit for the particular hazardous substance, medium, and analytical procedure is no greater than the practical quantitation limit established by the Environmental Protection Agency.

C. The Public's Response

Several individuals provided comments on the analytical issues associated with evaluating compliance with cleanup levels and a wide range of opinions were expressed. The principal issues raised during the rulemaking were the following:

Issue #1: **Should Ecology be concerned about concentrations of hazardous substances below current detection limits?**

Issue #2: **What is an appropriate method for measuring compliance with cleanup levels that are below current analytical limits?**

Issue #3: **What is an appropriate procedure for demonstrating compliance with cleanup levels in instances where measured values are less than the practical quantitation limit but greater than the method detection limit?**

Issue #4: **What is an appropriate method for establishing an upper limit on acceptable quantitation limits?**

Issue #5: **What additional measures should Ecology utilize for situations where cleanup levels are below analytical limits?**

Issue #6: **What process will Ecology utilize to approve special analytical procedures?**

D. Ecology's Evaluation and Response

Issue #1: **Should Ecology be concerned about concentrations of hazardous substances below current detection limits?**

The procedures in the proposed rule reflect Ecology's position that there will be situations where the Department will be concerned about environmental concentrations that are below detection limits. One commentor, Mr. Burch expressed the opinion that this approach was inappropriate:

> "Not logical to deal with values lower than the detection level. To assign a value of one-half the method of detection limit is arbitrary. Use the accepted practice of indicating that the substance was present in a concentration less than the detection limit....Cleanup levels less than the method of detection limits for approved analytical procedures do not make any sense." (Burch, p. 3)

However, Dr. Lorenzana expressed the opposite concern in her comments on an earlier draft of the rule:

> "In specifying compliance cleanup levels will not be established below...method detection limits, places the protection of human health at the mercy of analytic quantitation limits. In the experience of the Dept. of Health, quantitation limits for many compounds (e.g., vinyl chloride, PCBs, MCPA, dioxin, etc.) in various media are commonly above health-based guidelines." (Lorenzana, p. 2 of comments on December 29, 1989 draft)

Ecology's Response: Under the Model Toxics Control Act, Ecology is required to protect human health and the environment. Although analytical limitations do place constraints on the Department's ability to enforce standards, Ecology agrees with Dr. Lorenzana that simply ignoring concentrations below current detection limits would place human health and the environment at the "mercy of analytic quantitation limits" and would be inconsistent with the statute's overriding objectives.

Issue #2: **What is an appropriate method for measuring compliance with cleanup levels that are below current analytical limits?**

Ecology proposed that in circumstances where the cleanup level is below the practical quantitation limit (PQL) and hazardous substances are not detected or quantified, compliance with cleanup levels would be based on the PQL. During the rulemaking, Ecology received several comments on this issue. Many people supported the use of the PQL. For example:

> "On a positive note, this draft of the rule contains many improvements over previous drafts, such as the use of practical quantitation limits." (Johnson, p. 3)

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> Ecology needs to have a means of evaluating achievement of cleanup levels in situations where the compliance levels are lower than those typically achievable by commercial laboratories. MDLs are poorly suited for this purpose and is recommended that PQLs be used instead, with recognition of the shortcomings and limitations associated with them as well as the uncertainty and variation inherent in any analytical result. (Trudell, p. 3 of comments on March 9, 1990 draft)
>
> **********
>
> "Ecology has proposed the establishment of cleanup levels at the 'practical quantitation limit.' This level of control may be substantially more relaxed than accepted detection limits." (Sullivan, p. 2)

Ecology's Response: Ecology believes it is appropriate to utilize the PQL to evaluate compliance with cleanup levels. In making this determination, Ecology considered the following factors:

> Public Comment: The majority of individuals providing comments on this issue recommended that Ecology utilize PQLs for evaluating compliance with cleanup levels that are below current analytical capabilities.
>
> Other State and Federal Programs: Many other regulatory programs utilize PQLs when establishing or evaluating regulatory limits. For example, EPA has established a number of drinking water standards for carcinogens at the PQL (EPA, 1989d; EPA, 1990e). Under the Resource Conservation and Recovery Act (RCRA), EPA has stated that "EPA believes that the appropriate way to deal with a calculated regulatory level that is below the analytical detection limit is to use (for the regulatory level) the lowest level of detection that can be achieved (EPA, 1990j).
>
> Enforceability: The use of the PQL will reduce the potential for false positive results. The MDL, on the other hand, minimizes the potential for false negatives. From an enforcement perspective, the advantages of minimizing false positives generally outweigh the advantages of greater analytical sensitivity.
>
> Five-Year Reviews: Where a PQL is used to measure compliance with cleanup levels, Ecology will evaluate current analytical capabilities during the periodic reviews required under WAC 173-340-420.

Issue #3: **What is an appropriate procedure for demonstrating compliance with cleanup levels in instances where measured values are less than the practical quantitation limit but greater than the method detection limit?**

Ecology proposed that when evaluating compliance with cleanup levels, detectable levels below the practical quantitation limit shall generally be assigned a value equal to the method detection limit. Mr. Leonard Butler (Waste Management) expressed concerns with this approach:

> "DOE is mistaken in its use of the Method Detection Limit (MDL) instead of the Practical Quantitation Limit (PQL) as the basis for demonstrating

compliance with cleanup levels in instances where measured concentrations are less than the PQL but greater than the MDL." (Butler, p. 2)

Several other individuals expressed similar concerns in the context of evaluating compliance with ground water, surface water, or soil cleanup levels (See discussions in Sections XVII, XVIII, and XIX)

Ecology's Response: Ecology believes that the proposed approach is consistent with approaches being used by other regulatory programs. It was selected because it is simple to apply and tends to minimize false negatives. However, the Department recognizes that a number of alternate approaches are available. Consequently, both the proposed and final rules contain a provision which allows Ecology to approve alternate statistical procedures for handling non-detected values or values below the practical quantitation limit.

Issue #4: **What is an appropriate method for establishing an upper limit on acceptable quantitation limits?**

During the rulemaking process, concerns were expressed that PQLs may greatly exceed the detection limit for certain substances in certain matrices. To address this concern, Ecology proposed that the PQL would be used as a measure of compliance only if the more stringent of the following requirements are met:

(i) The practical quantitation limit is no greater than ten times the method detection limit; or

(ii) The practical quantitation limit for the particular hazardous substance, medium, and analytical procedure is no greater than the practical quantitation limit established by the Environmental Protection Agency.

Several individuals expressed the concern that PQLs often exceed ten times the method detection limit. For example:

"This provision presents some significant difficulties in that the PQL established by U.S. EPA is often much more than ten times the method detection limits depending on the waste matrix. Thus, if one had a site where the PQL was greater than ten times the method detection limit, one could never conclude that the cleanup standards had been attained pursuant to this paragraph." (Syrdal, p. 9)

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Use of the practical quantitation limits (PQL) for determining cleanup effectiveness: This section states that the PQL may be used for determining that the cleanup level is met only when the PQL is no more than 10 times the method detection limit. In many cases, the PQL for a standard method will be much greater than 10 times the MDL, depending upon the waste matrix. For example, Method 8120 of the U.S. Environmental Protection Agency (EPA) Test Methods for Evaluating Solid Waste (one of the analytical procedures specified in WAC 173-340-830) indicates that the PQL for ground water contamination is a factor of 10 times the method detection limit (MDL), but the PQL for low-level soil contamination is a factor of 670 times the MDL. In many cases, the calculation of health-based limits for carcinogens could result in a cleanup standard which is well below the MDL, let alone the PQL. The EPA

has recognized this problem in the hazardous waste delisting program, and taken that stance that it is inappropriate to penalize a waste generator because the technology is not available to prove that a constituent is not present at a given level. The WAC 173-340 regulations should consider the practicability of this approach. The proposed rules, which could require cleanup levels which cannot be verified by any available analytical technology, may preclude the completion of cleanup in many instances. (Izatt, pp. 4-5)

Ecology's Response: Ecology has reviewed the above comments and believes the proposed approach is appropriate. In reaching this conclusion, Ecology considered the following:

Other Regulatory Programs: Several EPA programs have defined the quantitation limit as five or ten times the Method Detection Limit. For example, in promulgating the final rule on designating wastes as hazardous using the toxicity characteristic leaching procedure (TCLP), EPA stated that in order "to provide a consistently enforceable regulatory limit which provides assurance that those wastes that clearly pose hazards are subject to subtitle C regulatory programs, the Agency will set the regulatory level at five times the detection limit. The Agency has a high degree of confidence in setting the regulatory level at the quantitation limit (i.e. five times the detection limit) because other programs within the Agency have successfully used this method in the past to set regulatory levels (e.g. the Contract Laboratory Program under the Superfund Program)" (EPA, 1990). Similarly, under the Safe Drinking Water Act, EPA has determined that calculated PQLs are approximately 5 to 10 times the MDL.

Nature of MDLs: MDLs are generally established for use by the laboratory in determining the effectiveness of an analysis by comparing the MDL to the calibration of the instrument. A PQL is intended to reflect actual samples. Consequently, there is some difficulty in predicting real samples.

Nature of Samples: Most of the samples used to evaluate compliance with cleanup levels will actually be much cleaner than pre-cleanup levels.

Laboratory Variability: Laboratory determined quantitation limits are highly variable. Concerns have been expressed that reliance on such an approach would represent a significant regulatory "loophole." (See Eaton, p. 3 of comments on October 16, 1989 draft)

Issue #5: **What additional measures should Ecology utilize for situations where cleanup levels are below analytical limits?**

To address situations where the cleanup level is below the practical quantitation limit, Ecology also proposed the following:

> "In cases where a cleanup level required by this chapter is less than the practical quantitation limit using an approved analytical procedure, the department may also require one or more of the following:
> (i) Use of surrogate measures of hazardous substance contamination;

(ii) Use or development of specialized sample collection or analysis techniques to improve the method detection limit or practical quantitation limit for hazardous substances; or

(iii) Monitoring to assure that the concentration of a hazardous substance does not exceed detectable levels."

Ecology's Response: There are several measures that may be utilized in situations where cleanup levels are below analytical limits. These include:

Special Sampling Techniques: There may be situations where special sampling techniques (i.e. larger sample sizes, special collection procedures) could be be used to improve analytical capabilities.

Special Laboratory Techniques: There may be situations where special laboratory techniques (i.e. special analytical methods, greater sample cleanup and preparation) could be utilized to improve analytical capabilties. For example, the EPA Contract Laboratory Program provides for Special Analytical Services (SAS) where lower analytical limits are required.

Use of Indicator Substances: Where the presence of two or more hazardous substances are strongly correlated, one or more of those substances may be selected as the indicator hazardous substance. Compliance determinations would be based on that substance(s).

Issue #6: **What process will Ecology utilize to approve special analytical procedures?**

Mr. Stefani expressed concerns over the proposal to allow the use of specialized analytical techniques:

We also have numerous questions about the technical basis for analytical procedures and cleanup standards. For example, proposed amendments under WAC 173-340-705(12)(c)(ii) allow use or development of specialized analytical techniques to improve the method detection limit or practical quantitation limit for hazardous substances. This amendment provides an opportunity for widely varying procedures to be considered on a case-by-case basis, with no standard for comparison between specialized analytical techniques or for consistency with SW-846 procedures." (Stefani, p. 1)

Ecology's Response: Comment noted. Ecology shares these concerns and will work to develop guidance that facilitates the development and use of methods that are compatible with one another.

IX. DEFINITIONS (WAC 173-340-200)

A. The Public's Response

The Department received numerous comments which addressed one or more of the definitions in WAC 173-340-200. The comment(s) on each definition and Ecology response to those comments are addressed below.

"Acute Toxicity"

Mr. Cook and Ms. Stembridge commented that the definitions of "acute toxicity" and "chronic toxicity" should include allergic health effects. They also suggested that 72 hours be used as the maximum time of exposure for "acute toxicity."

Ecology's Response: Ecology believes the proposed definitions incorporates a wide range of toxic effects, including allergic responses.

"All Practicable Methods of Treatment"

Mr. Syrdal recommended that the last sentence of the definition of "all practicable methods of treatment" be deleted. He commented that including AKART and BACT within this definition is "unworkable" because they are specific to water discharge and air programs.

Ecology's Response: Ecology believes that it is appropriate to include BACT and AKART within the definition of all practicable methods of treatment. The Department has sought to clarify when these requirements would be applied by incorporating two new subsections in WAC 173-340-710.

"Applicable State and Federal Laws"

Several individuals recommended that the reference to "relevant and appropriate requirements" be deleted from the definition of "applicable state and federal laws (Burgess and Dunster, p. 2; Thomson, p. 5; and Syrdal, p.1)

Ecology's Response: Compliance with relevant and appropriate requirements is a requirement under the federal cleanup law and, consequently, represents a minimum requirement under the MTCA. The definition has been revised to clarify that only those relevant and appropriate requirements determined to be relevant and appropriate by the Department are relevant and appropriate.

"Appreciable Risk"

Mr. Cook and Ms. Stembridge suggested that Ecology include a definition of the term "appreciable risk

Ecology's Response: Comment noted. Ecology believes that this term needs no further definition at this time

Beneficial Use"

Mr. Cook suggested that Ecology include a definition of the term "beneficial use He included a possible definition.

Ecology's Response:

The highest beneficial use for each media of concern has been defined in the appropriate section describing cleanup standards.. Ecology believes this is sufficient at this time.

"Bioconcentration Factor"

Dr. Tsuji expressed concern that the factors used in determining the "bioconcentration factor" are "for the most part out of date and often based on laboratory data which have little relevance for the field She also pointed out that the chemical form that is accumulated in tissues may not be the same as the form in the environment.

Ecology's Response: The rule has been revised to allow the use of other bioconcentration factors.

"Carcinogen"

Mr. Cook and Ms. Stembridge commented that the definition of "carcinogen" is too restrictive and not conservative enough. On the other hand, Mr. Syrdal recommended that only malignant tumors be included in the definition.

Ecology's Response: Ecology believes the proposed definition is consistent with the definitions used by EPA (1986). This definition includes substances which induce malignant and benign tumors. Ecology also believes the definition is consistent with interpretations by a wide range of scientific bodies (NAS, 1977, 1986; OSTP, 1985; and NTP, 1989).

"Carcinogenic Potency Factor"

Mr. Butler, Mr. Syrdal, and Dr. Tsuji pointed out that the "carcinogenic potency factor" (CPF) is not always set at the upper 95th percentile confidence limit of the dose-response curve. Dr. Tsuji also cautioned that cancer potency factors are uncertain by an order of magnitude or more. Mr. Cook and Ms Stembridge proposed that the definition of cancer potency factor be separate from that of carcinogen, and that it be clarified by explaining how it is used.

Ecology's Response: Comment noted. The definition will be expanded to clarify that the carcinogenic potency factor is not always set at the upper 95th percentile confidence limit.

"Conditional Cleanup Level"

Mr. Weiner commented that the terms "conditional" and "compliance" are unclear and "foreign to common understanding He proposed eliminating both terms and using the terms "Method A", "Method B", and "Method C Mr. Syrdal expressed concern that the restriction of "conditional cleanup level" to only those sites with restricted site use is "inappropriate

Ecology's Response: This term, as well as "compliance cleanup level", has been deleted from the regulation. The terms Method A, B, and C have been incorporated into the rule.

"Containment"

Mr. Cook and Ms. Stembridge suggested that the definition of "containment" be changed to refer to structures that prevent release to the environment and to delete the phrase "hindered from release

Ecology's Response: The phrase "hindered from release" has been deleted from the definition.

"Developmental Reference Dose"

Dr. Tsuji suggested that the development of "developmental reference dose" criteria for each site "should not be a requirement given the present lack of EPA guidance

Ecology's Response: Comment noted.

"Exposure"

Mr. Dobratz recommended using a definition of "exposure" consistent with other regulations and common usage.

Ecology's Response: Ecology agrees and the definition has been revised to ensure consistency with EPA risk assessment guidance (EPA, 1989).

"Exposure Pathway"

Mr. Butler suggested that the definition of "exposure pathway" is incomplete without the four elements presented in EPA's Risk Assessment Guidance for Superfund.

Ecology's Response: Ecology agrees and the definition of exposure pathway has been expanded to incorporate these elements.

"Facility"

Mr. Butler expressed the opinion that the definition of "facility" does not give enough guidance "as to the actual scope of the regulation He

suggested that the broad definition of facility as now written could include public water supply distribution systems. He also expressed the opinion that Ecology needs to provide more guidance concerning the phrase "comes to be located

Ecology's Response: Ecology believes it would be inappropriate to change this definition since it is a statutory definition. It is important to note that the MTCA definition of "facility" is virtually identical to the EPA definition published in the National Contingency Plan (EPA, 1990a).

"Federal Cleanup Law"

Mr. Butler recommended that the definition of "federal cleanup law" be expanded to include "the corrective action authorities promulgated pursuant to the Resource Conservation and Recovery Act of 1976 and the Hazardous and Solid Waste Amendments of 1984

Ecology's Response: Ecology has adopted the statutory definition of federal cleanup law and does not intend on modifying that definition as part of this rulemaking.

"Ground Water"

Mr. Cook and Ms. Stembridge recommended that the definition of "ground water" "be expanded to explicitly include the water in the vadose zones of soils and stratum

Ecology's Response: Ecology's definition of ground water is limited to water in the saturated zone and does exclude water in the vadose zone or unsaturated soils. This is consistent with the definition in the Water Quality Standards for Ground Water of the State of Washington (Chapter 173-200 WAC) and the National Contingency Plan (EPA, 1990a).

"Hazardous Substances"

Mr. Cook and Ms Stembridge proposed that the definition of "hazardous substances" make it clear that it includes radionuclides.

Ecology's Response: Radionuclides are defined as hazardous substances under the MTCA. Ecology has added a sentence under the definition of "radionuclides" which clarifies this point.

"Hazardous Waste Site"

Mr. Syrdal suggested the term "hazardous substance site" be used instead of "hazardous waste site" since the term "hazardous waste" only refers to those wastes determined to be hazardous by EPA.

Ecology's Response: Ecology agrees that the present definition is potentially confusing when interpreted within the context of the EPA

definition under RCRA. However, throughout the MTCA, there are references to hazardous waste sites (RCW 70.105D.010(2), 030(2)(b), 030(3), and 030(5)) Consequently, Ecology has elected to continue to use the term "hazardous waste site" in this regulation.

"Highest Beneficial Use"

Mr. Cook and Ms Stembridge recommended that the definition of "highest beneficial use" state that drinking water quality is the limiting determining factor for all current and future beneficial uses, not just a "great variety

Ecology's Response: For some hazardous substances, uses other than drinking water may require a more stringent cleanup level. Ecology agrees, however, that the use of the term "great variety" is inappropriate and will be deleted.

"Inhalation Reference Dose"

Dr. Tsuji noted that EPA defines chronic reference doses for both inhalation and oral pathways, while the regulation only defines "inhalation reference dose

Ecology's Response: Comment noted. This definition has been deleted, and the definitions for chronic reference dose, reference dose, and subchronic reference dose expanded to clarify that toxicity values may be developed for both inhalation and oral pathways.

"Institutional Controls"

Mr. Findley and Mr. Syrdal commented that the term "institutional controls" is inconsistently defined.

Ecology's Response: Comment noted. The definition of the term "institutional controls" has been revised. See discussion in Section XII (Issue #2).

"Natural Background"

Mr. Butler recommended that the word "natural" be deleted from the definition of "natural background" and that Ecology clarify the distinction between naturally-occurring and anthropogenically-related hazardous substances.

Ecology's Response: The proposed and final rules contain definitions for both "natural" and "area" background levels. Ecology believes the curent definition adequately defines natural background.

"No Observed Adverse Effect Level"

Dr. Tsuji recommended that the definition of "no observed adverse effect level" (NOAEL) be clarified so it will not be interpreted to mean that the highest level at which any exposed test organism does not show an

adverse effect. She also pointed out that when there is more than one NOAEL, the focus should be on the highest one.

Ecology's Response: Comment noted. Ecology has revised the definition to ensure consistency with the definition in EPA's risk assessment guidance (EPA, 1989a)

Null Hypothesis"

Mr. Syrdal and Ms. Tsuji commented that the definition of "null hypothesis" is inconsistent with EPA Risk Assessment Guidance and is a "guilty until proven innocent approach Ms. Chou commented that when evaluating compliance with risk-based standards, the null hypothesis was appropriate. She noted, however, that it was inappropriate for background-based standards.

Ecology's Response: The definition has been clarified to indicate that the definition applies to risk-based standards.

"Owner or Operator"

Syrdal recommended that the definition of "owner or operator" be changed to agree with the standard of liability in RCW 70.105D.040(1)(b) which limits liability of former owners to those who "owned or operated the facility at the time of disposal or release of the hazardous substance

Ecology's Response: The regulatory definition is identical to the statutory definition and Ecology does not intend to revise it in a manner that might lead to conflicting interpretations. The concerns regarding the liability of a former owner/operator are addressed under the definition of "potentially liable person This definition references RCW 70.105D.040(1)(b) and consequently incorporates statutory limitations on liability.

"Permanent Solution"

Mr. Syrdal and Mr. Haagensen commented that the definition of "permanent solution" precludes transport to an incinerator or permitted landfill although these options may present "far fewer permanent risks than many recycling or reuse technologies which have a higher priority

Ecology's Response: Comment noted. The definition has been revised. See discussion in Section X (Selection of Cleanup Action).

"PAHs Carcinogenic"

Dr. Tsuji observed that in the definition of "PAHs (carcinogenic)", "dibenzo(z,h)anthracene" should be "dibenzo(a,h)anthracene

Ecology's Response: Comment noted and correction made.

"Polychlorinated Biphenyls"

Dr. Tsuji proposed that the definition of "polychlorinated biphenyls" be based on the percentage of chlorine, rather than the presence of two benzene nuclei with two or more substituted chlorine atoms.

Ecology's Response: Ecology believes an approach similar to that proposed by Dr. Tsuji may prove useful in the future. However, as Rodricks (1989) has stated, further information is needed on comparative potencies.

"Practical Quantitation Limit"

Mr. Syrdal recommended that Ecology replace the word "achieved" with the word "measured" in the definition of "practical quantitation limit

Ecology's Response: Comment noted. Ecology has replaced the word "achieved" with the word "measured This appears to be consistent with recent EPA regulatory definitions (EPA, 1990e, EPA, 1990j).

"Public Interest"

Mr. Cook suggested that Ecology include a definition of the term "public interest

Ecology's Response: Comment noted. The Department is considering alternate definitions of "public interest" as part of the triennial review of the state water quality standards. Following the completion of that review, the Toxics Cleanup Program will evaluate whether definitions and/or criteria developed as part of that process are appropriate for incorporation into rules and/or guidance under the MTCA.

"Reasonable Maximum Exposure"

Mr. Cook expressed concern that the word "reasonable" is included in the definition of "reasonable maximum exposure He suggested that this should be quantified using a probability.

Ecology's Response: This definition has been used to provide consistency with the federal program. Ecology believes it would be potentially confusing to adopt a different definition.

"Reference Dose"

Dr. Tsuji suggested that a more accurate definition of "reference dose" is "that it is the upper bound of the tolerance range within which there is essentially no chance of adverse effects associated with this dose, even to sensitive populations.

Ecology's Response: Comment noted. The definition in the proposed rule was used to provide consistency with EPA's definition.

"Release"

Mr. Butler suggested that the definition of "release" should be expanded in order to clarify that "before liability is imposed it should be shown that the release violates (or a threatened release is likely to violate) an applicable state or federal standard

Ecology's Response: Comment noted. Ecology has prepared two policies which provide additional regulatory interpretation. (POL 101 and 102.) These can be obtained from the Toxics Cleanup Program (Phone # (206)438-3000).

"Risk"

Mr. Cook and Ms Stembridge recommended that the definition of "risk" be changed to refer to a confidence statement such as 95 percent. They suggested some factors, such as proper quantification, to consider in rewording the definition.

Ecology's Response: Ecology believes it would be inappropriate to constrain this definition by putting a specific probability limit on this term at this time.

"Site Use Restrictions"

Mr. Findley and Mr. Syrdal commented that it is unclear if the definition of "site use restrictions" is the same as "restricted site use conditions Mr. Syrdal suggested that if they are the same, then restricting access to the site is not as important as eliminating exposure at the site.

Ecology's Response: Ecology recognizes that there was not a clear distinction between site use restrictions, restricted site use, and institutional controls in the proposed rule. To address this concern the term institutional controls has been expanded and the other two terms deleted. (See Section XII, Issue #2).

"Subchronic Reference Dose"

Dr. Tsuji indicated that "subchronic reference doses" are considered interim values and EPA does not have sufficient guidance for their calculation. She recommended Ecology not base cleanup decisions on such values. Mr. Cook and Ms. Stembridge expressed the opinion that the definition is too flexible and that Ecology should "attempt to state the conservativeness of the estimate in a different way He suggested alternate wording.

Ecology's Response: The proposed definition has been used in order to provide consistency with the US EPA definition (EPA, 1989a). As discussed in Section V, Ecology will not routinely utilize subchronic

reference doses to establish cleanup levels under this chapter. In situations where such values are used, Ecology will consider whether there is clear and convincing scientific data which demonstrates that the use of a particular subchronic reference dose value is inappropriate.

"Technically Feasible"

Mr. Kenneth Weiner observed that the terms "technically feasible" and "technically practicable" are synonymous and therefore confusing. He suggested substituting "technically possible" for "technically feasible" and substituting "feasible" for "technically practicable

Ecology's Response: Ecology agrees and this change has been made. See discussion in Section II(D).

"Technically Practicable"

Ms. Elizabeth Tabbutt recommended new wording for the definition of "technically practicable," stating that a remedial action is considered practical unless certain conditions are met.

Ecology's Response: This definition has been deleted from the regulation and relaced with the term "practicable The definition has been modified to address, in part, these concerns. (See comment and response above).

"Threat to the Public Health or the Environment"

Mr. Cook and Ms. Stembridge recommended a definition for "threat to the public health or the environment" be added to this section. They suggested that risk-based quantitative definitions be used to define unacceptable threats.

Ecology's Response: Comment noted. This is a statutory phrase that Ecology believes would be inappropriate to define at this time.

"Type I Error"

Burgess and Dunster, Butler, Chou, and Tsuji stated that the definitions for "Type I error" and "Type II error" are incorrect. They indicated that a Type II error should be the acceptance of a false null hypothesis.

Ecology's Response: See response to comments on "null hypothesis" above.

"Volatile Organic Compound"

Mrs. Dobratz, Izatt and Butler all requested clarification of the definition of "volatile organic compound," specifically the phrase "easily evaporated at room temperature."

Ecology's Response: This definition has been clarified. The definition now refers to volatile substances that are measured using EPA approved analytical methods for volatile substances.

"Wetlands"

Mr. Daniel Syrdal proposed that the definition of "wetlands" be replaced since the US Fish and Wildlife definition used in the regulation has not been used for regulatory purposes. He recommended different wording.

Ecology's Response: The proposed definition for wetlands appears in several state rules and guidance documents and, consequently, Ecology does not intend to develop a new definition.

X. SELECTION OF CLEANUP ACTIONS (WAC 173-340-360)

A. Background

RCW 70.105D.030 establishes three basic requirements for cleanup actions performed under the Model Toxics Control Act. Cleanup actions shall: (1) comply with cleanup standards established under Section 030(2)(d); (2) utilize permanent solutions to the maximum extent practicable; and (3) include adequate monitoring to ensure the effectiveness of the remedial action.

The cleanup standards established under RCW 70.105D.030(2)(d) must be at least as stringent as Section 121 of CERCLA/SARA. Section 121 establishes a series of requirements and preferences similar to those under the state law. First, the cleanup action must "attain a degree of cleanup ... which assures protection of human health and the environment." Unlike the other three elements in Section 121, this requirement is not subject to any qualifications or waivers. Protection of human health and the environment is to be achieved, at least in part, by the second element, the identification and compliance with "applicable or relevant and appropriate requirements" (ARARs). Finally, Section 121 specifies that remedial actions must be cost-effective and utilize permanent solutions to the maximum extent practicable.

B. Ecology's Proposal

The proposed rule defined seven basic requirements for cleanup actions performed under the MTCA. The first three requirements included the following:

(1) Be protective of human health and the environment, including complying with cleanup standards;

(2) Comply with all applicable state and federal laws; and

(3) Provide for monitoring.

Unlike the remaining four requirements, these requirements are not subject to any qualifications or waivers.

When selecting from among cleanup action alternatives which fulfill the first three requirements, Ecology proposed that the selected cleanup action shall:

(4) Utilize permanent solutions to the maximum extent practicable;

(5) Be technically practicable at the site;

(6) Provide for a reasonable restoration time frame; and

(7) Consider public concerns.

C. The Public's Response

The Department received numerous comments on the selection of cleanup action provisions and a wide range of opinions were expressed. The principal issues raised during the rulemaking proceedings were the following:

Issue #1: **What is the relationship between cleanup standards and selection of cleanup actions?**

Issue #2: **Will the proposed rules unnecessarily restrict the range of viable cleanup options at individual sites?**

Issue #3: **What factors will Ecology consider when selecting a cleanup action?**

Issue #4: **What is the relative weighting of the seven criteria identified as general requirements for cleanup actions?**

Issue #5: **What are Ecology's expectations with respect to the use of various technologies or combinations of technologies?**

Issue #6: **Must all cleanup actions be performed at the cleanup site?**

Issue #7: **What is the relationship between protecting human health and the environment and compliance with cleanup standards?**

Issue #8: **When should Ecology require application of AKART to cleanup actions?**

Issue #9: **Is Chapter 90.48 RCW applicable to restoration of contaminated ground water?**

Issue #10: **Does the requirement to utilize "all known available and reasonable methods of treatment" take precedence over cleanup standards?**

Issue #11: **Are there situations where it would not be appropriate to pursue active ground water restoration?**

Issue #12: **When should Ecology require application of BACT to cleanup actions?**

Issue #13: **What is an appropriate definition of permanent solution?**

Issue #14: **What factors will Ecology consider when evaluating whether permanent solutions are practicable?**

Issue #15: **Are there situations where isolation and containment is the preferred method of cleanup?**

Issue #16: **Can cleanup actions be accomplished by simply requiring institutional controls and monitoring?**

Issue #17: **What is the role of cost in selecting cleanup actions?**

Issue #18: **What procedures will Ecology utilize to determine whether cleanup costs are disproportionate to benefits?**

Issue #19: **What types of costs should Ecology consider when determining what is practicable?**

Issue #20: **What factors will Ecology consider when establishing a reasonable restoration time frame?**

Issue #21: **How will Ecology handle situations where offsite background concentrations are higher than cleanup levels?**

Issue #22: **How will Ecology handle situations where cleanup levels are more stringent than technically feasible levels?**

Issue #23: **What is the relationship between determinations under the MTCA and regulatory decisionmaking under other state and federals laws?**

Issue #24: **What is the relationship between this process and decisionmaking under the federal cleanup law?**

D. Ecology's Evaluation and Response

Issue #1: What is the relationship between cleanup standards and selection of cleanup actions?

As discussed in Section III(D), there was considerable confusion on the relationship between cleanup standards established under Sections 700 through 760 and the requirements for selecting cleanup actions under Section 360.

Ecology's Response: In order to clarify this relationship Ecology incorporated the following provision into WAC 173-340-700(2):

> (a) Cleanup standards are identified for the particular hazardous substances at a site and the specific areas or pathways, such as land or water, where humans and the environment can become exposed to these substances. This part provides uniform methods state-wide for identifying cleanup standards and requires that all cleanups under this chapter meet these standards. The actual degree of cleanup may vary from site to site and will be determined by the cleanup action alternative selected under WAC 173-340-360. Establishing cleanup standards for individual sites requires the specification of the following:
>
> (i) Hazardous substance concentrations that protect human health and the environment ("cleanup levels");
>
> (ii) The location on the site where those cleanup levels must be attained ("points of compliance"); and

(iii) Additional regulatory requirements that apply to a cleanup action because of the type of action and/or the location of the site. These requirements are specified in applicable state and federal laws and are generally established in conjunction with the selection of a specific cleanup action.

(b) For most sites, there are several cleanup technologies or combinations of cleanup technologies ("cleanup action alternatives") that may be used to comply with cleanup standards at individual sites. Other parts of this rule govern the process for planning and deciding on the cleanup action to be taken at a site. For example, Section 350 (state remedial investigation and feasibility study (RI/FS) specifies the studies that are prepared to define the nature and extent of contamination ("RI") and to identify and evaluate cleanup action alternatives ("FS"). Section 360 (selection of cleanup action) specifies the criteria for selecting the preferred alternative. Section 410 specifies the monitoring required to assure that the remedy is effective.

(c) The department recognizes that cleanup actions selected under WAC 173-340-360 may involve containment of hazardous substances. In these cases, the cleanup action may be determined to comply with cleanup standards, provided the compliance monitoring program is designed to ensure the long-term integrity of the containment system, and the other requirements for containment technologies in WAC 173-340-360(8) are met.

Issue #2: Will the proposed rules unnecessarily restrict the range of viable cleanup options at individual sites?

Several participants expressed concerns that the proposed rules may limit the range of cleanup technologies that could be applied to a particular site. For example:

> "It is important that cleanup standards create a range of alternative actions." (Thomson, p. 4)

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> "[T]he concurrent emphasis on permanence and waste management priorities will severely limit choice of affordable cleanup options." (Sacha, p. 3)

Ecology's Response: Ecology agrees with the concept that it is important to have a range of cleanup alternatives to consider for individual sites. Ecology believes that, while the final rule will result in some changes in the mix of technologies used to perform site cleanup actions, it will not unreasonably restrict the range of viable cleanup options at sites.

This concern appears to have three components. First, there is the question of whether a full range of treatment-based cleanup technologies is currently available. The Office of Technology Assessment has concluded that "in large measure, the answer is yes..." (OTA, 1989, p. 139). However, OTA and others have identified many areas where improvements are needed in order to bring

treatment technologies on-line in a more streamlined fashion. Ecology believes that the final rule, by placing greater emphasis on permanent solutions, will facilitate more rapid development and use of such technologies.

The second issue revolves around the question of whether cleanup levels will be established at concentrations which are attainable using available treatment and destruction technologies. An initial review of concentrations that could be achieved by a variety of treatment technologies has been completed by ICF (1989). Based on that review, it appears that soil cleanup levels for most substances are achievable through the use of available treatment technologies. The Department recognizes that limits of achievability will often need to be determined on a site-specific basis and that interference with the treatment method by a mix of hazardous substances or a complex medium could raise achievable concentrations. With ground water, the situation is more complex. Available information suggest that technologies are available to attain health-based levels for the more volatile substances, but metals and semivolatile organic compounds may be problematic in some situations (ICF, 1989; EPA, 1990a; OTA, 1989). Ecology recognizes that treatment technologies will not always be available or appropriate for use at particular sites and the rule provides the flexibility for combinations of technologies to be used.

The third issue appears to center on whether the final rule will lead to more expensive cleanup actions. In many situations, this will be the case. Greater use of treatment technologies (as opposed to containment) will result in increased costs. Available data on the impacts of similar requirements under the federal law suggests that increases of four to six times would not be unexpected (OTA, 1989; EPA, 1990a). As noted below, the determination of cleanup costs is a site-specific exercise and Ecology has included provisions which are designed to avoid situations where the use of a treatment-based cleanup technology results in cleanup costs that are "substantial and disproportionate to the incremental degree of protection" achieved through the use of a lower preference cleanup action such as containment.

Issue #3: What factors will Ecology consider when selecting a cleanup action?

In the proposed rule, Ecology identified seven factors that would be considered when selecting a cleanup action. Several individuals expressed concerns that it was difficult to determine how Ecology would weigh the various factors when selecting a cleanup action. (See Issue #4 below.) Other commentors expressed the opinion that some of the provisions were duplicative and may result in too much emphasis being placed on the cost of cleanup. (See Issue #17 below.)

Ecology's Response: Ecology agrees that many of the concerns have merit. In particular, the Department agrees that the two requirements "use permanent solutions to the maximum extent practicable" and "be practicable for the site" involve consideration of similar factors and are essentially duplicative of each other. In order to minimize confusion on the use of Section 360, Ecology has deleted the provision "be practicable for a site" from the final rule. This change should not be viewed, however, as a substantial change in that permanent solutions must still be practicable for a site.

Issue #4: What is the relative weighting of the seven criteria identified as general requirements for cleanup actions?

The proposed rule identified seven general requirements that must be satisfied when selecting a cleanup action. Several individuals recommended that Ecology clarify the relative importance of these factors. Most expressed the opinion that overall protection of human health and the environment should be the primary consideration when selecting a cleanup action. For example:

> "The primary consideration in selection of a final cleanup solution should be "overall protection of human health and the environment", which includes the health of humans and the environment at off-site disposal locations. The extreme difficulty of finding off-site disposal locations and the often prohibitively high cost of on-site permanent solutions require this consideration." (Johnson, p. 2)

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> "Ecology should make the criteria of overall protection of human health and the environment the primary criteria in selecting a cleanup method. In no event should a higher preference treatment method be required simply because it is technically practicable without taking into account the overall protection of human health and the environment." (Syrdal, p. 5)

A similar recommendation was provided by Ms. Tabbutt who stated that protection of human health and the environment was the primary consideration in selecting a cleanup action and recommended that WAC 173-340-360(2)(a)(i) through (iii) should be inclusive. (Tabbutt, p. 2)

Ecology's Response: The rule has been revised to clarify that protection of human health and the environment (including compliance with cleanup standards), compliance with applicable state and federal laws, and compliance monitoring are "threshold requirements" that must be met by all cleanup actions. In evaluating whether a cleanup action protects human health and the environment, Ecology will consider threats or potential threats associated with the excavation, transport, treatment, and/or redisposal of hazardous substances. However, such considerations may not serve as justification for cleanup actions that do not comply with cleanup standards.

Ecology agrees that cleanup actions should address overall protection of human health and the environment and has incorporated the following expectation into the rule:

i. Ecology expects that cleanup actions conducted under this chapter will not result in a significantly greater overall threat to human health and the environment than other alternatives.

Some of the difficulties associated with evaluating the overall protectiveness of a cleanup action are summarized in Section IV (Issue #8)

Issue #5: What are Ecology's expectations with respect to the use of various technologies or combinations of technologies?

In the National Contingency Plan (EPA, 1990a), EPA has identified its "expectations" on the types of cleanup technologies to be used to address particular types of problems. EPA does not consider these expectations to be "binding requirements." They are "intended to share collected experience to guide those developing cleanup options."

As noted in the preamble to the NCP, EPA received strong support for the principles underlying the expectations. Not surprisingly, several individuals recommended that Ecology incorporate similar language into section 360:

> "We recommend that this section include language similar to that provided in the National Contingency Plan (NCP) in 40 CFR 300.430(a)(iii), which states EPA expectations in selecting realistic and appropriate remedial alternatives. Such language would greatly simplify the selection of a remedy as compared to language provided in section 360 of the proposed regulations." (Burgess and Dunster, p. 2)

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> "Cleanup standards should encompass both cleanup levels and the hierarchy of cleanup actions. We draw your attention to the National Contingency Plan which directs the thinking of participants toward the importance of treatment, but more clearly avoids the potential for treatment for treatment's sake alone. 40 C.F.R. 300.430." (Thomson, p. 4)

Ecology's Response: Ecology agrees with many of the expectations identified in 40 CFR 300.430(a)(iii) and has added a new subsection into Section 360 which enumerates Ecology's technology preferences. These include:

a. Ecology expects that treatment technologies will be used wherever practicable. Use of treatment technologies should be emphasized at sites containing liquid wastes, areas contaminated with high concentrations of hazardous substances, highly mobile materials, and/or discrete areas of hazardous substances which lend themselves to treatment.

b. To minimize the need for long-term management of contaminated materials, Ecology expects that hazardous substances will be totally destroyed, detoxified, and/or removed to levels below cleanup levels throughout sites containing small volumes of hazardous substances.

c. Ecology recognizes the need to use engineering controls, such as containment, for sites or portions of sites that contain large volumes of materials with relatively low levels of hazardous substances or where treatment is impracticable.

d. Ecology expects institutional controls such as water use restrictions and deed restrictions, will be used to supplement engineering controls in order to prevent or limit exposure to hazardous substances and protect the integrity of the cleanup action.

e. Ecology expects that cleanup actions will return useable ground waters to their beneficial uses wherever practicable, within a reasonable time frame. When restoration of ground water to beneficial uses is not practicable, Ecology expects to require measures to prevent further migration, control/eliminate ongoing sources, prevent exposure to contaminated water, and other appropriate measures (See WAC 173-340-360(7)).

f. In order to minimize the potential for migration of hazardous substances, Ecology expects that active measures will be taken to prevent precipitation and subsequent runoff from coming into contact with contaminated soils and waste materials. When such measures are impracticable, such as during active cleanup, Ecology expects that site runoff will be contained and treated prior to release from the site.

g. Ecology expects that when hazardous substances remain on site at concentrations which exceed cleanup levels, those hazardous substances will be consolidated to the maximum extent practicable where needed to minimize the potential for direct contact and migration of hazardous substances.

h. Ecology expects that, for facilities adjacent to a surface water body, active measures will be taken to prevent/minimize releases to surface water via surface runoff and ground water discharges. Ecology expects that dilution will not be the sole method for demonstrating compliance with cleanup standards; and

i. Ecology expects that cleanup actions conducted under this chapter will not result in a significantly greater overall threat to human health and the environment than other alternatives.

With the additional language, the Department has tried to correct the misperception that Ecology intends to require "treatment for treatment sake." In all cases, utilization of treatment technologies will be directed towards selecting cleanup actions which protect human health and the environment, that maintain protection over time, and that minimize untreated waste.

Issue #6: Must all cleanup actions be performed at the cleanup site?

One individual expressed concerns that the Department was intending to limit consideration of practicability/feasibility to those actions performed at the site. Mr. Haagensen stated:

> "Section (ii) of this proposed rule, which requires that a cleanup action must be "technically practicable at the site" implies a requirement that only technologies that can be used at the site may be employed." (Haagensen, p. 3)

Ecology's Response: The rule has been revised to clarify that Ecology will require technologies that are practicable for the site. The Department did not intend to eliminate from consideration off-site treatment facilities. Nor was it the Department's intent to completely eliminate from consideration the use off-site disposal facilities.

However, it is the Department's policy to minimize the use of land disposal without treatment and, consistent with that policy, the rule states that cleanup actions involving offsite transport and disposal of hazardous substances without treatment shall not be used if practicable treatment technologies are available (WAC 173-340-360(5)(e)(v)).

Issue #7: What is the relationship between protecting human health and the environment and compliance with cleanup standards?

One individual stated:

> "In order to avoid the implication that cleanup levels can be set at levels more stringent than those protective of human health and the environment, which does not have a valid or statutory or public policy basis, WAC 173-340-360(2)(a)(i) should be amended by deleting `including complying with cleanup standards.' That addition is at best redundant and potentially ambiguous or in excess of statutory authority." (Thomson, p.3)

Ecology's Response: For purposes of this chapter, determinations on whether a cleanup action protects human health and the environment will be based on whether the action complies with cleanup standards as required under RCW 70.105D.030(2)(d). In order to emphasize the relationship between cleanup levels and the protection of human health and environment, Ecology has made several changes in the rule:

- A new subsection, WAC 173-340-700(7)(e), has been added. It states that "Cleanup actions that achieve cleanup levels under methods A, B, or C (as applicable) and comply with applicable state and federal laws shall be presumed to be protective of human health and the environment".

- The phrase stating that "[t]he goal is to establish cleanup levels as close as possible to natural background levels" has been deleted from WAC 173-340-700(2).

- The provisions in WAC 173-340-720 through WAC 173-340-750 which allow Ecology t establish more stringent cleanup levels for individual sites have been revised to clarify that such cleanup levels will be based upon site-specific evaluations and that the department must determine that such levels are necessary to protect human health and the environment.

However, as recommended by those providing comments on Issues #4 and #5 above, Ecology will also consider potential cleanup action-related impacts in off-site areas when evaluating "protection."

Issue #8: When should Ecology require application of AKART to cleanup actions?

In the proposed rule, Ecology identified several technology-based requirements that would have to be satisfied when performing cleanup actions. These

included the use of "all known available and reasonable methods of treatment" (AKART) for the discharges of hazardous substances to waters of the state. Several individuals expressed the opinion that this requirement was too broad and may result in the application of AKART to situations not originally envisioned under the Water Pollution Control Act. For example:

> "These regulations are unnecessarily broad in requiring the application of AKART and BACT to cleanup actions. AKART and BACT were designed to apply to new and ongoing discharges, not to remedial actions. Unless the AKART and BACT requirements are, in fact, ARARs, they should not be required." (Syrdal, p. 8)

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> "The Water Pollution Control Act (RCW 90.48) specifically applies to prevention activities, not remedial activities. If a discharge to ground results because of a cleanup action, then AKART is appropriate, but AKART should not be considered applicable during the initial evaluation of cleanup alternatives." (Izatt, p. 1)

Ecology's Response: The Water Pollution Control Act (Chapter 90.48 RCW) and the Water Resources Act of 1971 (Chapter 90.54 RCW) specify that discharges of pollution to waters of the state must be provided with AKART prior to entry into the state's waters. Since the passage of these statutes, Ecology has determined AKART on a case-by-case basis. AKART includes not only treatment, but also prevention and control. Prevention can take the form of waste minimization, waste/source reduction, and segregation of waste streams to reduce total contaminant loading to the environment.

In reviewing this requirement from the perspective of the Model Toxics Control Act, there are three situations where AKART could be an applicable state and federal law for purposes of defining cleanup action requirements. These include:

1. Current Discharges: There are cleanup situations where there is an ongoing discharge or a proposal to discharge hazardous substances to surface water or ground water as a result of the cleanup activities (or nonactivities in the case of surface water runoff). In these situations, the person undertaking the cleanup action would be required to obtain a NPDES or state waste discharge permit which would require, among other things, use of AKART. As with other types of permit actions, "reasonableness" would include consideration of cost, technical feasibility, and stage of planning.

2. Contaminated Soils: There are sites where contaminated soils are releasing or have the potential to release hazardous substances to waters of the state. Although Ecology believes that RCW 90.48.010 may require the use of AKART in these situations, it appears that this requirement is equivalent to the use of "permanent solutions to the maximum extent practicable." Consequently, the specific reference to the use of AKART for contaminated soils has been deleted from the final rule.

3. Ground Water Restoration: There are cleanup sites where the ground water is currently contaminated as a result of past discharges. Although Ecology believes that reasonable methods of treatment should be required to restore such waters, several individuals providing comments noted that

it is not clear whether Ecology has the authority under Chapter 90.48 RCW and Chapter 90.54 RCW to require that AKART be applied to correct such historical problems. This is discussed in greater detail under Issue #9 below.

Issue #9: Is Chapter 90.48 RCW applicable to restoration of contaminated ground water?

In the proposed rule, Ecology specified that "all known, available, and reasonable methods, consistent with the policy stated in RCW 90.48.010 and 90.54.020 to insure the highest possible quality of all waters of the state shall be used to protect and restore the quality of ground water affected by a release from a site." A number of individuals expressed the opinion that Ecology had misinterpreted these statutes and that these statutes did not require AKART to be applied to historical releases. For example:

> "We question whether all known, available and reasonable methods of treatment (AKART) specified as policy in RCW 90.48.080.010 should be defined in this section as an applicable state law for restoration of ground water. This law applies to prevention, however, we question whether it is applicable to restoration." (Burgess and Dunster, p. 3)

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> "We recommend that the wording be changed in this section to clarify that RCW 90.48 is applicable to discharges to the ground for the prevention of pollution and not for the restoration of contaminated waters." (Izatt, p. 1)

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> This section requires the use of AKART when dealing with protection and restoration of the quality of ground water affected by a release from a site. The above comments regarding AKART therefore apply. This section is unclear whether this AKART requirement is mitigated by the provisions of its subsections (A) through (D). Assuming this was the intent, then the AKART is modified by a practicability standard unless the public interest demands more. This wording should be clarified to ensure that these are limitations to the opening paragraph of (ii) and that this whole section applies to both 360(2)(a)(i) and (ii). (Syrdal, p. 4)

Ecology's Response: Ecology agrees that Chapter 90.48 RCW is unclear as to whether AKART must be utilized to restore contaminated ground water. While we continue to believe that this is a correct interpretation, Ecology has revised the language in the final rule to require that "all practicable methods of treatment" shall be used to restore contaminated ground water. This provision is derived from the basic authorities under the Model Toxics Control Act and is consistent with the expectations stated by EPA in 40 CFR 300.430 (a)(iii)(F):

> EPA expects to return useable ground waters to their beneficial uses wherever practicable, within a time frame that is reasonable given the particular circumstances of the site. When restoration

> of ground water to beneficial uses is not practicable, EPA expects to prevent further migration of the plume, prevent exposure to the contaminated ground water, and evaluate further risk reduction. (EPA, 1990, p. 8846)

Issue #10: Does the requirement to utilize "all known available and reasonable methods of treatment" take precedence over cleanup standards?

Ms. Elizabeth Tabbutt (WEC) questioned how the requirements for AKART were related to cleanup standards and recommended the following:

> "It should be made more explicit that cleanup standards must be met in addition to ARARs. Therefore the reasonable test of AKARTS or BACT is applied only if standards are met." (Tabbutt, p. 3)

Ecology's Response: Under the MTCA cleanup regulation, technology-based requirements such as AKART cannot be used to justify cleanup levels less stringent than those specified in WAC 173-340-700 through 750. However, the Department recognizes that there may be situations where limitations in the available treatment technologies will require that Ecology either (1) approve a conditional point of compliance or (2) establish an enforcement/compliance schedule. This approach is consistent with the approach used by the Water Quality Program for discharges to surface waters. Under that approach, a dilution zone may be approved by the Department where a discharge is provided with AKART and still causes violations of water quality standards. Available technology is periodically reviewed and the dilution zone reduced in size as advances in technology provide lower treatment limits.

Issue #11: Are there situations where it would not be appropriate to pursue active ground water restoration?

Ecology proposed that "ground water treatment to achieve standards in WAC 173-340-720 throughout the ground water shall be required where such treatment is practicable or in the public interest." Ecology also proposed a series of measures which would be required in lieu of active ground water restoration. The Department received numerous comments on this provision:

> Section 360 seems to promote treatment for treatment sake. For example, 360(4)(b)(ii)(A) states that ground water treatment shall be required when it is "practicable or in the public interest." This should be practicable and in the public interest. Failure to meet both criteria should be sufficient to justify selection of other alternatives. Treatment should not be required just because it is practicable, but rather it should be utilized where it is determined to be the most suitable alternative (or portion of an alternative) based on evaluating all the criteria conducted during the feasibility study. (Burgess and Dunster, p. 3)

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The use of the term "practicable" throughout this section could place significant constraints on the Department's ability to require more sophisticated forms of treatment. While we do not object to cost being considered when a choice is made between two or more equally protective types of remediation, we do not support the use of cost to discriminate against more protective technologies. We are especially disturbed by the use of the word "practicable" in relation to ground water treatment. This language should be eliminated. (Wishart, p. 4)

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This section [WAC 173-340-360(4)(ii)] incorporates the concept of reasonable. The cleanup must still meet the other requirements. Reasonable becomes a test only if the requirement for AKART takes you below the standard. Reference to policy stated in water pollution law should define "reasonable" in that situation. Avoid confusing this with the "practicable" tests specific for these rules. (A)<(B) should be deleted here, as they imply that the standard (10-5 or better) will not be met and cost will determine the degree of control. The remaining sections discussing responsibilities while groundwater standards are being attained should be in the institutional controls section. (Tabbutt, p. 4)

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This section requires that source control measures be implemented to prevent additional releases to the ground water. Is this intended to apply to any releases, including discharges of clean water, or only to releases which could result in additional discharge of hazardous substances? In the former instance, it may be appropriate to allow discharge of uncontaminated solutions contingent upon a demonstration that such discharge will not result in significant mobilization of the hazardous substances present in the soil column or in undue spread of contamination already in the ground water. (Izatt, p. 2)

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Subsection (A) seemingly requires the use of ground water treatment to achieve standards where such treatment is either practicable or in the public interest. This ignores other possibilities for meeting the standards. Thus while we agree that where ground water treatment is not practicable, other alternatives are necessary, the reverse is not necessarily true. (Syrdal, p. 4)

[S]ubsection (b)(II) presents problems as well. There are many circumstances wherein implementing containment to the maximum extent practicable would provide no significant increased benefit to the ground water resource. For example, while a plume may be expanding, it may be doing so in a way in which, due to dispersion, attenuation, biodegradation, etc., poses no significant threat to human health or the environment even though some violation of ground water cleanup standards does occur near the source of the plume. If treatment of the portions of the plume which violate the standards is not practicable, it would probably in some circumstances, be a waste of money to do containment to the maximum extent practicable. (Syrdal p. 4)

This subsection deals with various presumptions which are intended to be interpretation of certain requirements regarding applicable state and federal laws. However, the provisions in subsection (4) would, therefore, not apply to the general requirement of this section in subsection (2) that all cleanup actions comply with cleanup standards. Therefore the provisions contained in (4) may not modify the requirements of compliance with cleanup standards. This would mean that the provisions regarding requirements for ground water treatment to achieve standards may only apply to the ARAR portions of the standards and not to the risk-derived cleanup levels. I don't believe this is the Department's intent. This subsection should be rewritten to make it clear that it applies to the general requirements under both subsection (2)(a)(i) and (2)(a)(ii). (Syrdal, p. 3)

Ecology's Response: Ecology believes that current data indicate that there will be situations where remediation of contaminated ground water may be impossible or impracticable using currently available technology. Other agencies and technical review committees have reached similar conclusions. For example, EPA (1989e) has recently completed a review of ground water extraction systems at 19 Superfund sites. Key findings include the following:

- Ground water extraction systems were generally effective in maintaining hydraulic containment of contaminant plumes, thus preventing further migration of contaminants. In all but three of the 19 case study sites, successful plume containment has been demonstrated.

- Significant removal of contaminant mass from the subsurface is often achieved by ground water extraction systems. When site conditions are favorable and the extraction system is properly designed and operated, it may be possible to remediate the aquifer to health-based limits. Of the 19 sites, 13 had aquifer restoration as their primary goal, and only one has been successful. Several of the other systems show promise of eventual restoration, but unfortunately progress toward this goal is far behind schedule.

- Sites that are favorable for aquifer restoration have relatively simple stratigraphy with fairly homogeneous, unconsolidated aquifer materials and contaminants that are present primarily as dissolved constituents in ground water. Most departures from these ideal conditions tend to impede the progress of aquifer restoration. However, even if the concentrations are not rapidly reduced to cleanup levels, the extraction systems may still significantly reduce contaminant mass in the aquifer.

In their review of the federal Superfund program, the Office of Technology Assessment evaluated the effectiveness of ground water pump and treat technologies and concluded:

1. Superfund implementation (i.e. Records of Decisions) currently conveys a sense of certainty about ground water contamination and cleanup that is inconsistent with the above kinds of insights [treatment difficulties].

2. Because of the difficulty in cleaning up ground water, much more attention should be given to identifying and removing the source of ground water contamination.

3. Making pump and treat more predictable and effective requires improved practices which will tax the current workforce and may increase costs substantially.

4. Cleanups using pump and treat may be stopped because data on pumped ground water indicates that contaminant concentration has reached a stable low level, but in fact subsequent testing (or testing in different locations) might show that contaminant levels have increased or rebounded.

5. There is a distinct possibility that, for some sites, natural attenuation, including biodegradation, of contamination within the aquifer might produce essentially the same cleanup results as the lengthy and costly pump and treat.

6. It should be understood that there are appropriate uses of pumping ground water to contain the movement of a plume of contamination and to treat relatively simple, well understood aquifers and relatively simple and well identified types of contamination. Indeed, beginning pump and treat very early at a site may be important as a recontrol measure. (OTA, 1989, pp. 155-159)

Ecology has reviewed these and other findings and believes that a workable approach to cleanup must recognize current technical constraints and specify the procedures to be followed when such constraints arise. Ecology understands the concerns raised by environmental representatives on this issue and is evaluating the rule to identify ways to provide additional constraints on the unwarranted consideration of practicability. The Department believes that the final rule is consistent with EPA's approach as stated in the National Contingency Plan:

> "EPA expects to return useable ground waters to their beneficial uses wherever practicable, within a time frame that is reasonable given the particular circumstances of the site. When restoration of ground water to beneficial uses is not practicable, EPA expects to prevent further migration of the plume, prevent exposure to the contaminated ground water, and evaluate further risk reduction...." (EPA 1990, p. 8846)

Issue #12: When should Ecology require application of BACT to cleanup actions?

In the proposed rule, Ecology identified several technology-based requirements that would have to be satisfied when performing cleanup actions. These included the use of "Best Available Control Technology" (BACT) for air emissions. Several individuals expressed the opinion that this requirement was too broad and may result in the application of BACT to situations not originally intended under the Clean Air Act. For example:

> "[T]hese regulations are unnecessarily broad in requiring the application of AKART and BACT to cleanup actions. AKART and BACT were designed to apply to new and ongoing discharges, not to remedial actions. Unless the

AKART and BACT requirements are, in fact, ARARs, they should not be required." (Syrdal, p. 8)

Ecology's Response: Ecology will routinely require the use of "Best Available Control Technology" as defined in Chapter 173-403 WAC for air emissions associated with cleanup actions. These represent new sources and include air stripping towers and gas extraction units. For existing sources of contamination, Ecology will require the use of "reasonably available control technology" as required under WAC 173-400-040 (General Standards for Maximum Emissions). In both cases, additional control measures may be required where residual emissions result in ambient air concentrations which exceed cleanup levels established under WAC 173-340-750 (Cleanup Standards to Protect Air Quality).

Issue #13: What is an appropriate definition of permanent solution?

The Model Toxics Control Act directs Ecology to consider the use of "permanent solutions to the maximum extent practicable." Ecology proposed to define a permanent solution as "one in which the cleanup standards under WAC 173-340-700 through 173-340-750 are achieved without further action being required at the original site or any other site involved with the cleanup action, such as an offsite landfill...."

> Waste Management agrees that the preferred remedy should not rely heavily on long-term operation and maintenance, but the order of preference for selecting a protective remedy provided for in draft WAC 173-340-360 (6)(b)(i) though (b)(vi) is improper. "Permanence" should be evaluated relative to the degree of risk presented by the hazardous substances found at a site. Permanence may well be achieved without reliance on destruction or detoxification if the substances are not particularly toxic or mobile in the first instance. Containment, particularly secure containment, of stabilized or otherwise relatively mobile substances, may be effectively permanent. The regulations should recognize that reuse or recycling or destruction or detoxification may not be realistic for some sites, especially landfills with large volumes of low concentrated materials. The regulations should recognize that the decontamination of a site will not be practicable in many situations. Where sites have large volumes of materials containing low concentrations of hazardous substances, or where the waste is highly variable in composition, treatment is likely to be impracticable. (Butler, p. 6)

Several individuals suggested that Ecology expand the definition of permanent solution to include situations where a waste is treated and the treatment residuals are taken to an off-site landfill. For example:

> The definition of permanent solution should be revised to clarify that the reference to "off-site landfill" means that after a disposal in such a landfill of treatment residuals, no further action is feasible and the cleanup is thus "permanent". Flexibility should exist in the definition so that off-site cleanup actions that are permanent are not excluded and can be used in cleanup actions. In many cases these type of actions are the only

> option available. In addition, commercial off-site facilities in many instances possess superior knowledge and technical capability in treating hazardous wastes because it is their business. The use of this capability should not be thwarted. (Haagensen, p. 3)

Other individuals providing similar comments include the following: Weiner; Butler, p. 6; and Aldrich, p. 2.

Ecology's Response: Comments noted. The definition has been revised. WAC 173-340-360(5) has been revised to clarify what types of technologies will generally be considered "permanent solutions" and which technologies will not. The Department believes that a determination on what constitutes a permanent solution is a technical decision. This contrasts with a determination on what constitutes a "permanent solution to the maximum extent practicable" which takes into a number of technical, environmental, and economic factors (See discussion under Issue #14).

Issue #14: What factors will Ecology consider when evaluating whether permanent solutions are practicable?

The Model Toxics Control Act requires Ecology to give preference to permanent solutions to the "maximum extent practicable". In the proposed rule, Ecology identified a hierarchy of preferred technologies which was designed to provide a framework for evaluating whether a particular cleanup technology or combination of cleanup technologies fulfilled that requirement. More permanent solutions, such as resource recovery were placed at the top of the list and identified as preferable to technologies or methods lower on the list (i.e. containment). The proposed rule did not impose any particular option, but was intended to make it more difficult to choose a technology lower on the hierarchy without careful evaluation. In performing that evaluation, Ecology proposed five evaluation criteria:

- overall protection of human health and the environment;
- long-term effectiveness;
- short-term effectiveness;
- permanent reduction of toxicity, mobility, or volume; and
- practicability

Some individuals recommended that Ecology consider other factors when evaluating whether a permanent solution is "practicable." For example:

> Section 360 also appears to have too strong a bias towards permanent solutions, at the expense of more practical solutions which still meet the statutory requirements of protecting human health and the environment. The primary consideration in selection of a final cleanup solution should be "overall protection of human health and the environment", which includes the health of humans and the environment at off-site disposal locations. The extreme difficulty of finding off-site disposal locations and the often

> prohibitively high cost of on-site permanent solutions require this consideration. (Johnson, p. 2)

Several individuals expressed the opinion that Ecology should clarify whether the various factors were of equal importance. For example:

> First, there is no indication whether the selection criteria are weighted or whether they are all given equal consideration during the decisionmaking process. Second, we assume that a higher preference technology that fails the selection criteria such as overall protectiveness of human health and the environment, is automatically rejected and a lesser technology can be chosen even though the higher technology is "practicable." This should be so stated. (Syrdal, p. 5)

Similar comments were provided by the following individuals: Izatt, p. 2; and Johnson, p. 2.

Finally, several individuals recommended that Ecology develop different tests of what is practicable for different situations. For example:

> CWMNW supports the principle that in general and for most waste categories, treatment, recycling or reuse technologies should be preferred over land disposal of untreated wastes. CWMNW also believes, however, that the Department of Ecology should recognize that some contaminated materials, most particularly soil and debris, are not presently amenable to treatment technologies designed for the raw waste, and that a generator of contaminated soil and debris should not have to make the same showing as generators of other wastes (for example, spent solvents) before land disposal occurs. (Haagensen, p. 6)

Ecology's Response: Ecology has revised WAC 173-340-360 to more clearly distinguish between identification of "permanent solutions" and "permanent solutions to the maximum extent practicable." With respect to the latter, Ecology agrees that a number of factors must be considered in making a determination on what constitutes a "permanent solution to the maximum extent practicable." These factors have been identified in WAC 173-340-360(5) and include the following:

- Overall protection of human health and the environment;
- Long-term effectiveness;
- Short-term effectiveness;
- Permanent reduction of toxicity, mobility and volume;
- Ability to be implemented;
- Cleanup costs; and
- Community concerns.

Although protection of human health and the environment is of greatest importance, the relative weight placed on the various factors will vary from site-to-site.

Issue #15: Are there situations where isolation and containment is the preferred method of cleanup?

Ecology proposed that "a cleanup action relying only on isolation and containment of hazardous substances shall not be used if a cleanup action

alternative that utilizes a higher preference cleanup technology or method for all or a portion of the site is technically practicable." (WAC 173-340-360(6)(e)(v) Several individuals expressed the opinion that there may be situations where the "best" alternative is isolation and containment, but the selection of that alternative would be precluded under the proposed rule. For example:

> Finally, subsection WAC 173-340-360(6)(e)(v) should be deleted. This subsection provides that a cleanup action relying only on isolation or containment of hazardous substances shall not be used if a cleanup action alternative that utilizes the higher preference cleanup technology or method for all or a portion of the site is technically practicable. This means that the other balancing criteria would be irrelevant, and that even if an isolation alternative is the best alternative for protection of human health and the environment, it would be rejected. This is inappropriate, especially given the fact that there are many circumstances where selection of another, higher priority alternative could substantially increase the risks to human health or the environment. (Syrdal, p. 5)

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> The proposed new section on administrative principles should clearly express a preference for containment or isolation as the cleanup action for indestructible substances. See 40 CFR Section 300.430 (a)(1)(iii). In other words, they should clearly recognize the appropriateness of a lower level of hierarchy in some instances. (Thomson, p. 5)

Similar comments were provided by the following individuals: Johnson, p. 2; and Stefani.

Ecology's Response: The final rule includes two new subsections which address containment actions. The first one, WAC 173-340-360(8) specifies the basic requirements for selecting and utilizing containment technologies. The second subsection, WAC 173-340-360(9) describes Ecology's expectations regarding the use of various cleanup technologies. This includes the following provision which provides some additional clarification on when containment options may be considered appropriate:

> Ecology expects to use engineering controls, such as containment, for sites or portions of sites that contain large volumes of materials with relatively low levels of hazardous substances or where treatment is impracticable.

Issue #16: Can cleanup actions be accomplished by simply requiring institutional controls and monitoring?

Ecology proposed that "a cleanup action relying solely on institutional controls and monitoring shall not be used if a cleanup action alternative that utilizes a higher preference cleanup technology or method for all or a portion of the site is technically practicable." Mr. Wishart recommended that Ecology clarify that such measures do not constitute "cleanup":

> You seem to indicate that final cleanups could be accomplished by simply instituting institutional controls and monitoring (WAC 173-340-360(6)(b)(vi). We do not accept that this type of action would serve as a "cleanup" in any sense of the word. We ask that you remove this language and clarify that cleanups must involve physical actions on site which are protective of human health and the environment. (Wishart, p. 5)
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> "Site use restriction are subject to too much uncertainty. Accidents or natural disasters, such as the storm that opened up the Butler Tunnel can always happen." (Cellarius, p. 1)

Ecology's Response: Ecology agrees that institutional controls alone do not constitute a cleanup action. However, the department believes that such controls may be one of several components of a cleanup action. The final rule includes a new subsection which describes Ecology's expectations regarding various cleanup technologies and institutional controls. With respect to institutional controls, the rule states:

> Ecology expects institutional controls, such as water use restrictions and deed restrictions, will be used to supplement engineering controls as appropriate for short and long-term management to prevent or limit exposure to hazardous substances and protect the integrity of the cleanup action.

Issue #17: What is the role of cost in selecting cleanup actions?

Ecology proposed that all cleanup actions must protect human health and the environment (including compliance with cleanup standards), comply with applicable state and federal laws, and provide for compliance monitoring. When selecting from among those alternatives which fulfill those requirements, Ecology specified that the selected cleanup action shall:

- Use permanent solutions to the maximum extent practicable;
- Be technically practicable at the site;
- Provide for a reasonable restoration time frame; and
- Consider public concerns.

Ecology proposed that "practicability" would be evaluated on the basis of technical feasibility, ability to be implemented, and costs. Ecology also specified that cost would be considered in accordance with the following:

> (i) A cleanup action shall not be considered technically practicable if the incremental cost of the cleanup action is substantial and disproportionate to the incremental degree of protection it would achieve over a lower preference cleanup action.

> (ii) For cleanup action alternatives which meet the requirements of subsection (2)(a) of this section and which have an equivalent order of preference under subsection (6)(b) of this section, preference shall be given to the cleanup action which cost the least. (WAC 173-340-360 (7)(c)(i))

As noted in Section VII, there was a broad consensus that Ecology should consider the cost of cleanup when selecting from among several cleanup actions. However, there was a wide range of opinion on the procedures to be used. For example, several individuals noted that Section 121 of CERCLA specifies that cleanup actions must be cost-effective and recommended that Ecology incorporate a similar requirement into the cleanup standards amendments:

> "I recommend the inclusion of cost effectiveness as a primary factor equal, at least, to the criterion of permanence in the identification of remedial options." (Landau, p. 3 of comments on December 29, 1989 draft)

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> The draft standards do not adequately allow for the consideration of cost-effectiveness. Section 3(2)(d) of the Model Toxics Control Act contemplates cleanup standards at least as stringent as cleanup standards under Section 121 of CERCLA. Section 121 of CERCLA clearly specifies consideration of cost-effectiveness. For example, Section 121(a) states that remedial actions shall provide for cost-effective response. Similarly, Section 121(b) provides for selection of a remedial action that is cost-effective. The subordinate role assigned to cost in draft WAC 173-340-360 is inconsistent with the approach taken by EPA under Section 121, will provide a disincentive for PLPs to negotiate cleanups with Ecology, and could result in substantial waste of public and private resources. The draft standards should be revised to take into account cost-effectiveness to at least the degree provided in the National Contingency Plan. (Thomson, p. 4 of comments on December 29, 1989 draft)

Other individuals expressed concerns that cleanup costs may receive too much weight in the selection process and place constraints on the Department's ability to require permanent solutions. For example:

> The use of the term "practicable" throughout this section could place significant constraints on the Department's ability to require more sophisticated forms of treatment. While we do not object to cost being considered when a choice is made between two or more equally protective types of remediation, we do not support the use of cost to discriminate against more protective technologies. We are especially disturbed by the use of the word "practicable" in relation to ground water treatment. This language should be eliminated. (Wishart, p. 4-5)

Ecology's Response: Ecology has reviewed the comments on this issue and believes that further clarification is needed on how and when cleanup costs are considered in selecting cleanup actions. Under the revised rule, cost may be a considered in making three determinations:

1. that the cleanup action utilizes permanent solutions to the maximum extent practicable;

2. that the cleanup action is performed in a reasonable time frame (See discussion under Issue #20); and
3. establishing conditional points of compliance (see discussion in Section VII.

[As noted under Issue #3, the requirement that actions "be practicable for the site" was viewed as duplicative and potentially confusing and, consequently, has been deleted from the final rule.]

With respect to the first item, Ecology views the requirement that permanent solutions be "practicable" in providing a check on unreasonable outcomes (i.e., causing greater harm than good), unworkable solutions and unreasonable expenditures. In this light, Ecology believes that cost is a relevant factor in deciding whether various permanent solutions are "practicable."

In the final rule, Ecology has constrained the role that cleanup costs may play in evaluating whether a cleanup action is practicable. First, Ecology has clarified that costs can never be the sole reason for a finding that a permanent solution is impracticable. Cost comes into play only when there are substantial concerns over the engineering feasibility, effectiveness, and other relevant factors. This is consistent with the legislative history for the 1986 SARA amendments. For example, Senator Bentsen stated:

> "In determining whether these remedies are practicable, the Administrator may take into account technical feasibility, cost, state and public acceptance of the remedy, and other appropriate criteria." (132 Congressional Record S14910, October 3, 1986)

Second, a finding that a permanent solution is impracticable can be made only if it is demonstrated that the incremental costs of the permanent solution are substantial and disproportionate to the incremental degree of permanent protection provided by a cleanup action relying on containment and engineering controls. A discussion of "substantial and disproportionate costs" is provided under Issue #18.

The final rule specifies that when selecting from among alternatives that provide an equivalent level of permanent protection, Ecology will give preference to the least-cost alternative. However, Ecology views the cost-effectiveness analysis as more than just a cost-minimization exercise. Ecology will also consider the relative merits of various treatment options, the degree to which expenditures of larger sums of money will enhance the durability of a non-permanent solution, and whether an action provides for a reasonable restoration time frame.

Issue #18: What procedures will Ecology utilize to determine whether cleanup costs are disproportionate to benefits?

Several individuals faced with the responsibility of performing or overseeing cleanup actions expressed the opinion that the exact mechanism for evaluating and demonstrating that "costs are disproportionate to the incremental degree of protection" was unclear. For example:

> The analysis required to demonstrate practical feasibility (in contrast to technical feasibility) in light of restrictive cleanup standards will further complicate choice of methods. And while we appreciate consideration of costs, the means of demonstrating "disproportionate cost to benefit" is very unclear. Compliance (and the supporting analysis) will be at the expense of timely expedited cleanups." (Sacha, p. 3)

Ecology's Response: Ecology believes this is a site-specific determination and will provide additional guidance following promulgation of the final rule. Ecology considered incorporating some general "rules of thumb" into the final rule (i.e., the cost of a permanent solution is substantial and disproportionate if it is five to 10 times greater than a containment-based option). Ecology rejected this approach largely because it believes that determination of what constitutes substantial and disproportionate will vary depending on the size of the site, the nature of the risks, the technologies to be used, etc., and is not easily reduced to a straight numerical comparison of costs. For example, ten times the cost of a $100 million cleanup is much different than ten times a $10,000 cleanup action.

Issue #19: What types of costs should Ecology consider when determining what is practicable?

The Department proposed to consider the following types of costs when evaluating cleanup actions: present and future direct and indirect capital costs, operation and maintenance costs, and other foreseeable costs. Several individuals suggested that the environmental costs associated with loss of beneficial uses be considered:

> This subsection concerning practicability should consider costs associated with loss of future beneficial uses. Intangible benefits, for example nature preserves, should be assigned a worth to allow such evaluation. Such "lost beneficial usage" costs should subtract from costs associated with actions in evaluation required by (c). (Cook, p. 8; and Stembridge, p. 9)
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> If the term "practicable" is used, then it should be defined in the definition section so that it is clear that any cost modification that occurs weighs the cost of the decision against the environmental benefits of the decision. The cost should be a determining factor only in instances in which the cost is substantial and disproportionate" to the benefits. If you choose to retain the very broad definition of cost found in 173-340-360(7), then the benefits of such decisions should be defined broadly, including short and long-term benefits. (Wishart, p. 2)

Ecology's Response: Ecology believes that costs associated with lost beneficial usage could be considered among "other foreseeable costs." Ecology is currently developing procedures for performing natural resource damage assessments.

Issue #20: What factors will Ecology consider when establishing a reasonable restoration time frame?

The Department proposed that cleanup actions shall provide for a reasonable restoration time frame and identified several factors to be considered when evaluating "reasonable." Mr. Butler expressed general support for the factors identified in the proposed rule and recommended that several others be considered:

> Additionally, when considering criteria for selecting a cleanup action under subsection (8)(a), it would be prudent to include a factor relating to the likelihood of exposure in developing restoration time frames. The DOE is to be commended on the scope of the factors compiled in this section. In particular, the natural degradation processes factor identified in subsection (8)(ix) is an important addition. The DOE should further consider including attenuation and dispersion in this subsection as other natural processes that affect the concentration of hazardous substances in media at a site. (Butler, p. 6)

Mr. Syrdal recommended that natural degradation be included among the evaluation criteria:

> Subsection (a)(ix) of this subsection relates to natural degradation processes at the site. Similarity, natural degradation processes affecting contaminants migrating from the site are relevant to the question of the restoration time frame. This subsection should be amended to include natural degradation at both locations. (Syrdal, p. 5)

He also recommended that Ecology provide additional details on how the Department would determine when an extended time frame was being substituted for active cleanup actions:

> Subsection (8)(e) is also subject to abuse. It indicates that one cannot extend the restoration time frame as a substitute for active cleanup actions which are technically practicable. The question of extending from what is not answered. For example, if the restoration time frame of one year could avoid the need for an expensive, but technically practicable solution, would it make sense in all cases to implement the technically practicable solution at substantial cost? The same question could be asked with respect to one month or ten years. (Syrdal, p. 6)

Ecology's Response: The public comments summarized above can be categorized into several issues.

Likelihood of Exposure: Ecology identified potential future use of the site, surrounding areas, and associated resources as one of the factors to be considered when establishing a reasonable restoration time frame. This would include consideration of the likelihood of exposure.

Natural Processses: Ecology believes that natural processes which result in the reduction of hazardous substance concentration be considered when establishing a reasonable time frame. OTA (1989) has also recommended that natural

processes be considered, particularly in light of available information on the effectiveness of ground water pump and treat systems. Ecology has broadened this provision to include degradation and attenuation. The final rule also specifies that natural processes must be documented to occur at the site or under similar site conditions. However, Ecology continues to believe that active treatment measures should be employed whenever practicable.

Extended Time Frames: Ecology intends to prepare guidance on the implementation of subsection (8)(e).

Issue #21: How will Ecology handle situations where off-site background concentrations are higher than cleanup levels?

Ecology proposed that where area background concentrations are elevated and might result in recontamination of a site, cleanup actions would be phased in and coordinated with off-site control efforts. One commentor requested clarification of this provision:

> Some clarification is needed regarding the Washington State Department of Ecology intent and authority to require control of offsite sources which are contributing to the area background. Does Ecology intend to require such facilities to halt discharges, even if such discharges are in compliance with all regulatory requirements? If not, does this mean that site cleanup may remain in "interim action" status for an extremely long period of time? (Izatt, p. 2)

Ecology's Response: Ecology believes that in heavily industrialized areas, such as Commencement Bay or Harbor Island, successful cleanup actions are often dependent upon source control measures on adjacent sites. In such situations, Ecology would look at the whole industrial area and develop a coordinated approach to cleanup. This approach utilizes a wide range of statutory authorities, including the MTCA, and may involve regulatory actions by other agencies or Ecology programs. This approach is currently being utilized to address problems in Commencement Bay and Harbor Island.

Issue #22: How will Ecology handle situations where cleanup levels are more stringent than technically feasible levels?

Ecology proposed that where it is not feasible to attain conditional cleanup levels, the remedial action would be considered an interim action. Mr. Daniel Syrdal expressed the opinion that this was unreasonable:

> Subsection (8)(d) provides a good example of where there needs to be additional flexibility in determining the cleanup standard levels. If a PLP is to reduce concentrations of contaminants to those that are technically feasible, which by definition is irrespective of cost, it should not be required to deem the actions simply an interim action unless the remaining risks are substantial or at least significant. If technology is not capable of reaching the conditional cleanup levels, which given the parameters in Method B may occur in several instances,

> either the PLP should not be required to conduct the cleanup until such levels are achievable, or it should be considered a final remedial action. Leaving the technically feasible alternative as only an interim action would likely result in the refusal of many PRPs to conduct the action in the first place if they are doing all that is technically feasible but still gain no potential for release from liability. Furthermore, what they do in the way of technically feasible response actions could end up being counterproductive with respect to any new technologies that may be developed far into the future to do more. (Syrdal, p. 5-6)

Ecology's Response: Ecology recognizes that cleanup levels for some hazardous substances may be difficult to achieve. The final rule contains several provisions which provide some flexibility to deal with these situations: Method C cleanup levels; conditional points of compliance; and selection of cleanup actions. However, as discussed in Section III, Ecology does not believe it would be appropriate to routinely "redefine" cleanup levels based on what is technically feasible at a particular point in time.

Issue #23: What is the relationship between determinations under the MTCA and regulatory decisionmaking under other state and federal laws?

Mr. Kenneth Weiner recommended that Ecology incorporate the following provision into the rule:

> The fact that a draft or final cleanup action plan selects a preferred alternative based on a remedial investigation/feasibility study or comparable document that contains more than one feasible alternative shall not preclude a determination that there are no feasible, reasonable, or practicable alternatives if such a determination is required under another applicable law, regulation or policy. (Weiner, p. 19)

Ecology's Response: Ecology recognizes that the terms used in the final rule are similar and/or identical to those in other environmental statutes. Although Ecology believes that it would be inappropriate to automatically translate a finding of "feasibility" or "practicability" under the MTCA to findings under other statutes, the department does not believe it can preclude such actions through this rulemaking.

Issue #24: What is the relationship between this process and decisionmaking process under the federal cleanup law?

In the proposed rule, Ecology specified that a record of decision may be used to meet the requirements for preparing a cleanup action plan. Mr. Leonard Butler (Waste Management) questioned the use of the word "may":

> The conditional provision under subsection (12) wherein the Department may use a record of decision under the Federal cleanup law to meet the requirements of this section should be changed to

an absolute proviso. Cleanups performed pursuant to CERCLA and RCRA already incorporate the spirit of the requirements of DOE's proposal (eg., including stipulations for public comment on the cleanup action, and attainment of all Federal and state ARARs). Needless duplication and redundancy should be avoided by changing the conditional "may" to "shall." (Butler, p. 7)

Ecology's Response: Ecology believes the use of the federal record of decision should be contingent upon the three factors specified in the rule. Ecology has also revised the rule to clarify that cleanups performed pursuant to CERCLA may be performed as result of an order or consent decree.

XI. PERIODIC REVIEW (WAC 173-340-420)

A. Background

Section 121(c) of CERCLA/SARA provides that if EPA "selects a remedial action that results in any hazardous substances, pollutants or contaminants remaining at the site, [EPA] shall review such remedial action no less often than each five years after the initiation of such remedial action to assure that human health and the environment are being protected by the remedial action being implemented."

B. Ecology's Proposal

Ecology proposed requirements similar to those in Section 121(c). The proposed rule specified:

> If the department selects or approves a cleanup action that results in hazardous substances remaining at a site at concentrations which exceed compliance cleanup levels established under WAC 173-340-700 through 173-340-760 or if conditional points of compliance have been established, the department shall review the cleanup action no less frequently than every five years after the initiation of such cleanup action to assure that human health and the environment are being protected.

C. The Public's Response

The department received one written comment on the periodic review provisions asking this question:

Issue #1: What procedures will the department utilize to perform periodic reviews?

D. Ecology's Evaluation and Response

Mr. Wishart raised this conern in his comment:

> When we wrote Initiative 97, we did so with the intent of eliminating the need of secondary cleanups. The department, by its rulemaking, has almost assured that we will indeed require secondary cleanups on a wide variety of sites. For this reason, the site review process becomes far more important.
>
> As it now stands, this section contains little information on how the review will be conducted. We strongly suggest that you make public monitoring data and other pertinent information at the time of the review (and at all times) and provide for some type of process to allow for public comment. Without this component, you can not expect the public to have any confidence in your program. (Wishart, p. 5)

Ecology's Response: Ecology recognizes the concerns regarding "secondary cleanups." However, as described in the Draft Environmental Impact Statement, there are practical as well as environmental constraints on Ecology's ability to completely eliminate the need for periodic reviews of

ongoing cleanup actions. The rule has been revised to provide additional details on the nature and procedures for those reviews.

First, with respect to public notification, Ecology will notify the general public through the site register. Ecology's evaluation and the data used to perform that evaluation will be available for public review and comment.

Second, this section has been expanded to clarify the types of information Ecology will consider during the review. In evaluating whether a cleanup action is still protecting human health and the environment, Ecology will consider the following:

- Monitoring data to assess the effectiveness of ongoing or completed cleanup actions;
- New scientific information and/or applicable state and federal laws for hazardous substances at the site;
- Current and projected site and/or resource uses;
- The availability and practicability of higher preference technologies (if any).
- The availability of improved analytical methods with lower practical quantitation limits (in situations where cleanup level is below the PQL).

It is important to recognize that the periodic review is designed to determine whether the cleanup action is still protecting human health and the environment. The availability of new toxicological information/applicable state and federal laws/new treatment technologies or other factors will not automatically trigger requirements for new or additional cleanup measures.

Third, Ecology has clarified that in instances where the five-year review results in a substantial change in the cleanup action, a revised Cleanup Action Plan will be prepared and opportunities for public review and comment provided, consistent with the provisions of WAC 173-340-600.

XII. INSTITUTIONAL CONTROLS (WAC 173-340-440)

A. Ecology's Proposal

In the proposed rule, Ecology specified the following:

> Institutional controls that restrict the use of the site and natural resources affected by releases of hazardous substances from the site shall be required to assure continued protection of human health and the environment or integrity of an interim action or cleanup action in the following circumstances:
>
> (a) When a cleanup action results in residual concentrations of hazardous substances which exceed compliance cleanup levels established under WAC 173-340-700 through 173-340-750;
>
> (b) If conditional points of compliance have been established; or
>
> (c) When the department determines they are required to assure continued protection to human health and the environment and integrity of the cleanup action.
>
> The proposed rule specified that the restrictions on the use of the site and natural resources affected by the site must be "described in a restrictive covenant executed by the property owner and recorded with the register of deeds for the county in which the site is located.

B. The Public's Response

Several individuals provided comments on the institutional control provisions. The principal issues raised during the rulemaking proceedings were the following:

Issue #1: **Does the MTCA authorize Ecology to require institutional controls?**

Issue #2: **What is the distinction between institutional controls and site use restrictions?**

Issue #3 **Will the administrative problems associated with institutional controls preclude their use in certain situations?**

Issue #4 **Does Ecology have the authority and administrative mechanisms to require institutional controls in areas beyond the site boundary?**

Issue #5: **Under what circumstances should Ecology require financial assurances?**

Issue #6: **Does the Economic Impact Statement adequately address the potential costs associated with the use of institutional controls?**

C. Ecology's Evaluation and Response

Issue #1: Does the MTCA authorize Ecology to require institutional controls?

Several individuals appeared to agree there were situations where institutional controls would be needed to supplement other cleanup measures. For example, Mr. Butler stated:

> "The DOE is to be commended for including the provision for institutional controls as part of an overall site remedy that protects human health and the environment." (Butler, p. 7)

However, Ms. Brothers questioned whether Ecology has the statutory authority to require the use of institutional controls:

> Nowhere in the Model Toxics Control Act ("MTCA") is DOE granted authority to require restrictive covenants or to require the recordation with the county. Absent such delegation of authority by statute proposed WAC 173-340-440 exceeds DOE's authority and should be deleted from the proposed regulation. See e.g., Kaiser Aluminum v. Pollution Control Hearings Board, 33 Wn. App 352 (1982). We recognize that under certain circumstances DOE may seek to place limitations of the use of property, however such limitations can be accomplished through the use of existing administrative procedures. (Brothers, p. 2)

Ecology's Response: Although the Department agrees that the Initiative does not explicitly grant the Department the right to require the use of institutional controls, the Department believes that RCW 70.105D.030(1)(b) provides the authority to do so. This section authorizes the Department to "conduct, provide for conducting, or require PLP's to conduct remedial actions" (emphasis added). The term "remedial action" is broadly defined to include "any action or expenditure consistent with the purpose of this chapter to identify, eliminate, or minimize any threat or potential threat posed by hazardous substances to human health or the environment..." (emphasis added). Ecology believes these provisions authorize the Department to impose institutional controls where such controls (and the resulting site use restrictions) are necessary to protect human health and the environment.

Issue #2: What is the distinction between institutional controls and site use restrictions?

Mr. Findley stated that Ecology should clearly distinguish between the terms "institutional controls", "site use restrictions" and "under restricted site use conditions":

> The terms "institutional controls", "site use restrictions" and "under restricted site use conditions" are inconsistently defined. According to the proposed regulation, institutional controls will require a deed restriction. These deed restrictions would run with the land and include many desirable items. According to the defini- tion of site use restrictions, fences and similar barriers would be required, but there is no mention of the deed restrictions required under Institutional Controls (WAC 173-340-440). (Findley, p.4)

Ecology's Response: Ecology intends to revise the rule to clarify that the term "institutional controls" refers to both (1) the physical actions undertaken to restrict the use of a site and/or limit exposure to hazardous substances (fences, signs, etc.) and (2) the legal and administrative mechanisms used to ensure that those restrictions are maintained over time (restrictive covenants, health advisories, well-drilling prohibitions, etc.). This appears to be consistent with the terminology utilized in the National Contingency Plan (EPA, 1990a). The terms "site use restrictions" and "restricted site use" have been deleted from the final rule.

Issue #3: Will the administrative problems associated with institutional controls preclude their use in certain situations?

Several individuals expressed the opinion that the mandatory nature of the institutional controls might be a problem and recommended that Ecology provide some flexibility to determine when to impose institutional controls. For example:

> Ecology should revise this section to give itself some flexibility on the imposition of institutional controls. As currently drafted, this section would require the institution of such controls in the circumstances set forth in WAC 173-340-440(1). This would be satisfactory if the regulation applied only to the standard hazardous substance release site, such as an industrial facility. Ecology should keep in mind, however, that it is likely that these regulations will apply to large scale residential cleanups and other situations involving off-site contamination. In such cases, Ecology may want to consider some form of institutional controls other than deed restrictions. Imposing deed restrictions on hundreds of homeowners with the attendant Ecology oversight may not be satisfactory to either Ecology or the homeowners. As this section is currently written, Ecology would have no flexibility under such circumstances. (Syrdal, p. 6)
>
> **********
>
> There may be an additional problem if Ecology or EPA is undertaking the action and the property owner is unwilling to put a deed restriction on the property. Would this mean that if the property was unwilling to accept a deed restriction, Ecology and EPA could not apply the conditional cleanup levels or conditional points of compliance? (Findley, p. 4)

Ecology's Response: Ecology agrees that the rule should provide the flexibility to utilize administrative mechanisms other than restrictive covenants for those properties that are adjacent to the property(s) containing the original source of hazardous substances. Ecology intends to revise the rule to incorporate the flexibility to utilize other administrative mechanisms in situations where the Office of the Attorney General and Ecology determine that a property owner is not liable under RCW 70.105D.040(3).

Issue #4: Does Ecology have the authority and administrative mechanisms to require institutional controls in areas beyond the property boundary?

Mr. Jones questioned the applicability of institutional controls as it relates to restrictive covenants and site boundaries:

> We understood that institutional controls would apply only to the site itself, not to areas outside the site boundaries. We feel this needs to be clarified, especially concerning the use of restrictive covenants. In addition, we believe that institutional controls should be allowed outside the site boundaries. Not to do so leaves Ecology with little flexibility in certain situations where off-site institutional controls may be a very necessary, though temporary, part of a cleanup action. (Jones, p. 1)

Ecology's Response: Ecology agrees that there may be situations where some type of institutional controls will be necessary in areas outside the property boundaries. As discussed under Issue #3, Ecology intends to revise the rule to provide more flexibility in selecting the types of institutional controls to be used in these off-property areas.

Issue #5: Under what circumstances should Ecology require financial assurances?

In the proposed rule, Ecology specified that "[t]he department may require the potentially liable person to provide financial assurances through a trust fund or equivalent financial mechanism approved by the Department, sufficient to cover all costs of operation and maintenance including compliance monitoring, and undertaking appropriate corrective measures." Ms. Cellarius was critical of Ecology's proposal in that "the department only "may" require the PLP to provide financial assurances for maintenance ... and even if required, they would not help an exposed individual once exposed." Mr. Johnson expressed the opinion that public entities should be exempt from the financial responsibility requirements (see p. 1 of comments on March 9, 1990 draft).

Ecology's Response: Ecology has revised the rule to incorporate the expectation that financial assurances will be required where the cleanup action involves onsite containment, isolation or disposal of hazardous substances at levels which exceed Method A or Method B cleanup levels, as applicable. This expectation would apply to both public and private entities. The Department does, however, recognize that public entities may be able to utilize financial mechanisms that are not routinely available to smaller private entities (i.e., self insurance).

Issue #6: Does the Economic Impact Statement adequately address the potential costs associated with the use of institutional controls?

Ms. Brothers commented that the Economic Impact Statement fails to address the costs associated with the imposition of institutional controls.

Ecology's Response: Institutional controls were identified as a partial mitigating measure in the Small Business Economic Impact Statement (ICF, 1990). Such controls could be used to supplement containment-types of cleanup actions and would serve to reduce the economic impacts of more expensive removal or treatment options. However, these short-term economic benefits would have to be weighed against the long-term operation and maintenance requirements and possible impacts on property transactions. The latter, impacts on property transactions, was evaluated in the Environmental Impact Statement (Ecology, 1990a). It was concluded that the cleanup regulations will likely have impacts on property transaction but those impacts will be similar to those under the current situation.

XIII. RELEASES FROM UNDERGROUND STORAGE TANKS (WAC 173-340-450)

A. Background

Washington State's Underground Storage Tank Act, Chapter 90.76 RCW, directs Ecology to establish an underground storage tank program which meets the federal requirements for program delegation. Ecology must adopt rules which are at least as stringent as the federal underground storage tank regulations (40 CFR Part 280 Subpart F).

Corrective action at petroleum and other hazardous waste sites in Washington State falls within the jurisdiction of the Model Toxics Control Act. Ecology is adopting Section 450 of Chapter 173-340 WAC to address the requirements of Chapter 70.105D RCW, Chapter 90.76 RCW and 40 CFR Part 280 regarding releases from underground storage tanks.

B. Ecology's Proposal

WAC 173-340-450 addresses the federal rules for corrective action of underground storage tank releases. These include requirements to: report a release to Ecology within 24 hours of confirming the release, immediately begin actions to stop the spread of the release and reduce the threat to human health and the environment, characterize the site and report to Ecology on corrective actions planned and taken.

C. Ecology's Evaluation and Response

Comment #1: Ms. Cabreza commented that the absence of language under WAC 173-340-450(5)(a) comparable to the federal requirement for investigations when there is evidence that contaminated soils may be in contact with ground water would mean that the state regulations would not meet the "no less stringent" requirement.

Ecology's Response: The regulation would require further investigations when soils are in contact with ground water under WAC 173-340-450(3)(a)(iii). If ground water exceeds the ground water standards, which are more conservative than the cleanup standards, WAC 173-340-450(5)(a)(i) requires a state remedial investigation/feasibility study. WAC 173-340-450(5)(a)(iii) allows the department to require a state remedial investigation/ feasibility study under other circumstances.

Comment #2: Ms. Cabreza recommended that Ecology remove the phrase, "Unless the department requires otherwise" from WAC 173-340-450(1)(b), and insert the phrase into individual subsections as in the federal rule.

Ecology's Response: The Department has considered the comment but will retain the current placement of the phrase. The intent is to provide flexibility when Ecology determines that the requirements of this section are unnecessary for a particular site.

Comment #3: Ms. Cabreza commented that the language, "Reduce the threat to human health and the environment posed by contaminated soils" in WAC 173-340-450(3)(a)(ii) does not convey the same meaning as the federal language, "Remedy hazards posed by contaminated soils."

Ecology's Response: The Department believes that Section 450 will "remedy hazards posed by contaminated soils." In WAC 173-340-450(3) the regulation requires owners and operators to reduce the threat posed by contaminated soils within twenty days of confirming the release. WAC 173-340-450(7) requires owners and operators to clean up sites to cleanup standards. Those two elements should address the concern.

Comment #4: Ms. Cabreza noted that, unlike the federal regulations, WAC 173-340-450(4)(b)(iii) does not require data on climatological conditions.

Ecology's Response: WAC 173-340-450(4)(b)(viii) allows the department to require additional information, including data on climatological conditions when appropriate.

Comment #5: Ms. Cabreza commented that WAC 173-340-600, public notice and participation, does not appear to include language similar to the federal requirement for public notice when an approved corrective action plan is unsuccessful and the agency is considering terminating it.

Ecology's Response: The department will add language to WAC 173-340-360 requiring public notice when a cleanup action plan is unsuccessful.

Comment #6: Mr. Izatt commented that WAC 173-340-450 did not appear to incorporate the federal requirements for corrective action plans, including plan submittal, approval considerations, and submission of plans pursuant to voluntary corrective actions.

Ecology's Response: WAC 173-340-450(6) states that the Department may require the UST owner or UST operator to submit engineering documents as described in WAC 173-340-400. WAC 173-340-400(4) gives requirements for "plans describing the cleanup action." The Department would review and approve plans or reports prepared under section 400 under an order or decree in accordance with WAC 173-340-400(9). UST owners and operators conducting independent cleanup actions are still required to submit a description of cleanup actions or compliance monitoring which are planned or underway, under WAC 173-340-450(4)(b)(vi).

Comment #7: Mr. Syrdal commented that the requirement to remove as much of a hazardous substance from an UST as is necessary to prevent further release may not always be possible within 24 hours.

Ecology's Response: The federal UST rule requires owners and operators to take immediate action to prevent any further release of the regulated substance into the environment. However, Ecology will change WAC 173-340-450(2)(b) to "Remove as much of the hazardous substance from the UST as is possible and necessary to prevent further release to the environment."

Comment #8: Mr. Syrdal expressed the opinion that the requirement that the UST owner or operator must "comply with any conditions imposed by the department;" is not justified.

Ecology's Response: The federal rules contain similar language to WAC 173-340-450(8)(b). However, Ecology will qualify the requirement by adding "to assure adequate protection of human health and the environment."

XIV. GENERAL PROCEDURES (WAC 173-340-700)

A. Ecology's Proposal

The purpose of this section was to define the overall decision-making process for establishing cleanup levels under the MTCA and how that process related to the selection of cleanup actions. Ecology proposed that cleanup levels would be based on the reasonable maximum exposure scenario or the highest beneficial use of a site. The proposed rule included a two-tiered approach for establishing cleanup levels:

> Compliance Cleanup Levels were defined as environmental concentrations which are protective of human health and the environment with no restrictions on future site use or access. The proposed rule provided two methods for establishing compliance cleanup levels:
>
> > Method A could be utilized at sites (1) undergoing routine cleanup actions or (2) sites where numerical standards are available for all hazardous substances of concern. Under this method, cleanup levels would have to be at least as stringent as concentrations specified in applicable state and federal laws and concentrations specified in Tables 1, 2, and/or 3.
> >
> > Method B could be utilized at all sites. Under this method, cleanup levels would have to be at least as stringent as concentrations specified in applicable state and federal laws, cleanup levels for noncarcinogens and carcinogens estimated using risk assessment procedures specified in the regulation, and concentrations necessary for the protection and propagation of aquatic and terrestrial organisms.
>
> Conditional Cleanup Levels would be established at a site when one of several conditions was demonstrated to exist: (1) Compliance cleanup levels are below area background concentrations; (2) attainment of compliance cleanup levels would result in a net adverse environmental impact; (3) attainment of compliance cleanup levels is technically infeasible; (4) attainment of compliance cleanup levels is technically impracticable. The proposed rule specified minimum requirements for cleanup levels including concentrations specified in applicable state and federal laws and risk-based values.

The proposed section also described how to adjust the cleanup level to take into account multiple hazardous substances and multiple pathways of exposure.

B. The Public's Response

The Department received numerous comments on this section. Many of the issues raised in those comments are addressed elsewhere in this Responsiveness Summary. For example:

- Comments pertaining to the degree of protection including the use of natural background as a cleanup goal and acceptable risk are addressed in Section IV;

- Comments on the use of reasonable maximum exposure are addressed under Issue #3 in Section V;

- Comments on the use of indicator hazardous substances are found under Issue #19 in Section V; and

- Comments on the role of cost in establishing cleanup levels for state-funded actions are addressed in Section VIII.

The principal issues addressed in this section include the following:

Issue #1: **Does this section provide an easily understandable description of the decisionmaking process for establishing cleanup levels?**

Issue #2: **Should all cleanup levels be considered both compliance and conditional?**

Issue #3: **What is the relationship between Method A and Method B?**

Issue #4: **Are there circumstances which justify modifying compliance cleanup levels to conditional cleanup levels?**

Issue #5: **Is it appropriate to consider concentrations of hazardous substances in areas adjacent to the cleanup site when establishing cleanup levels?**

Issue #6: **Is it appropriate to consider "net environmental impacts" when establishing cleanup levels?**

Issue #7: **Is it appropriate for the Department to consider the cost of cleanup when establishing cleanup levels?**

Issue #8: **Is it appropriate to consider a person's ability to respond to other environmental threats when establishing cleanup levels?**

Issue #9: **What is the relationship between site use restrictions and conditional cleanup levels?**

Issue #10: **Are there circumstances where it is appropriate for the department to consider establishing conditional points of compliance?**

Issue #11: **How will Ecology establish points of compliance in cases of cross-media contamination?**

C. Ecology's Evaluation and Response

Issue #1: Does this section provide an easily understandable description of the decisionmaking process for establishing cleanup levels?

Mr. Weiner expressed concern that Sections 700 and 705 were very complicated and did not provide an easily understandable description of the overall process for establishing cleanup standards. This opinion was shared by a number of other individuals (see Section III, Issue #2). Mr. Weiner recommended that the

two sections be divided into a number of smaller sections and he submitted draft regulatory language with his written comments.

Ecology's Response: Ecology agrees with Mr. Weiner's comments and intends to incorporate most of the recommendations included in his written testimony. In particular, Ecology has divided sections 700 and 705 into seven sections:

Overview of Cleanup Standards - WAC 173-340-700 provides an overview of the methods for establishing cleanup standards. This involves specifying hazardous substance concentrations that protect human health and the environment ("cleanup levels"), and the location on the site where cleanup levels must be attained ("points of compliance"), and additional regulatory requirements that apply because of the type of cleanup action and/or site location. This section also describes key administrative principles which underlie the cleanup standards.
General Policies - WAC 173-340-702 summarizes several policies the Department will use to ensure cleanup standards are established and implemented in a scientific and technically sound manner.

Use of Method A - WAC 173-340-704 describes the basic requirements for establishing cleanup levels using Method A (Tables).

Use of Method B - WAC 173-340-705 describes the basic requirements for establishing cleanup levels using Method B.

Use of Method C - WAC 173-340-706 describes the basic requirements for establishing cleanup levels using Method C.

Analytical Considerations - WAC 173-340-707 defines the procedures for addressing analytical limitations when evaluating compliance with cleanup standards.

Human Health Risk Assessment Procedures - WAC 173-340-708 defines the basic risk assessment framework that the Department will utilize to establish cleanup levels.

Issue #2: Should all cleanup levels be considered both compliance and conditional?

Ecology proposed a two-tiered approach for establishing cleanup levels: compliance cleanup levels and conditional cleanup levels. Mr. Weiner expressed the opinion that this distinction was somewhat artificial in that all remedial actions that qualify as cleanups are both conditional and compliance. He recommended:

> Keep it simple and consistent. The proposed rule already uses "Method A" and "Method B". Simply use "Method C", and get rid of the modifiers "compliance and conditional." Each method is an alternate method, depending on which is appropriate to use, as substantively defined in the rules. Under each method, there is an additional safety net because a cleanup is also required to be protective of human health and the environment and meet applicable state and federal laws. (Weiner, p. 4)

Ecology's Response: Ecology believes that Mr. Weiner's suggestion has considerable merit and has revised the regulation based on the concepts outlined in his written comments. However, Ecology remains somewhat concerned that the original constraints associated with the use of Conditional Cleanup Levels are somewhat obscured under the approach proposed by Mr. Weiner.

Issue #3: What is the relationship between Method A and Method B?

In the proposed rule, compliance cleanup levels were defined as those environmental concentrations which are protective of human health and the environment with no restrictions on future site use or access. Under the rule, compliance cleanup levels could be established using one of two methods:

> Method A could be utilized at sites (1) undergoing routine cleanup actions or (2) at sites where numerical standards are available for all hazardous substances of concern in all media of concern.
>
> Method B could be utilized to establish compliance cleanup levels at all other sites.

Several individuals urged Ecology to clarify the relationship between Method A and Method B:

> Ecology should explain the rationale for selecting Method A values.... [I]t was unclear whether Method A and Method B values could be `mixed and matched.' We recommend that a clear statement clarifying the use of and relationship between Method A and Method B values be inserted. (Patmont and Wineman, p. 2)
>
> **********
>
> The tables were supposed to be conservative numbers that one could ensure would always be safe, with the calculations of Method B designated to allow more flexibility. For many contaminants this situation is now reversed, in that Method B would produce more conservative cleanup levels than Table A. (Srydal, p.8)

Other individuals providing similar comments included the following: Mr. Aldrich, p 7; Mr. Dobratz, p.1; and Mr. Fortier, p.1.

Ecology's Response: Method A was designed for sites involving routine actions (as defined in the regulation). The decision to utilize this approach rests with the person undertaking the cleanup action (i.e. the person performing a routine cleanup may elect to utilize Method B). However, the two methods cannot be "mixed and matched" as suggested by one commentor. Indeed, if all of the hazardous substances of concern are not included in the Method A tables or applicable state and federal laws, then the person undertaking the cleanup action does not have the option of utilizing Method A unless the cleanup level for all other hazardous substances are established at levels equal to natural background.

A contaminant concentration may be the same in both methods because a chosen level must be at least as stringent as applicable state and federal rules. A single Method B cleanup level may be more stringent than Method A if it is

modified to account for the affects of multiple contaminants and pathways found at a complex site.

Ecology agrees that it is important to explain the rationale behind Method A tables. The rationale for the Method A cleanup levels for individual hazardous substances is provided in Sections XVII, XIX and XX of this responsiveness summary.

Issue #4: Are there circumstances which justify modifying compliance cleanup levels to conditional cleanup levels?

In the proposed rule, Ecology provided the flexibility to modify compliance cleanup levels if one of five situations arose. The resulting cleanup levels, labelled conditional cleanup levels in the proposed rule, would be established at concentrations that are protective of human health and the environment in combination with appropriate site use restrictions. The proposed rule defined five situations which might justify the selection and/or approval of conditional cleanup levels:

- Compliance cleanup levels are below area background concentrations;
- Attainment of compliance cleanup levels would result in a net adverse environmental impact;
- Attainment of compliance cleanup levels is shown to be technically infeasible;
- Attainment of compliance cleanup levels is shown to be technically impracticable; and
- Attainment of compliance cleanup levels would limit a person's ability to respond to other environmental threats.

A broad range of individuals supported Ecology's proposal to provide some flexibility when establishing cleanup levels: Srydal, p.2; Burgess and Dunster, p.3; Science Advisory Board, p.3: Izatt, p.2; Jones, p.1; and Sacha, p.2.

However, some participants expressed concerns that Ecology's proposal provided too much flexibility. For example:

> "The use of conditional cleanup levels has such general application that it will provide a "loophole" that will be difficult to control." (Cellarius, p. 1)
>
> **********
>
> [W]e feel that this section should be narrowly drawn so as to limit the number of cleanups which fail to meet that standard. With the exception of a few select situations, we do not accept the 1 in 100,000 level as an acceptable alternative. (Wishart, p. 2)

In contrast to the above comments, a number of participants expressed the concern that the proposed rule provided an insufficient amount of flexibility. For example:

> This entire section needs to be rewritten. It currently contains so many caveats and limitations on the use and levels that must be attained for conditional cleanups that one wonders whether they could ever be employed. In addition, the conditional cleanup levels specified in 700 (8) and throughout Sections 720 through 750 do not provide for significantly different cleanup levels than is provided by Method B. (Burgess and Dunster, p.3)

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> While the concept [of conditional cleanup levels] is critical to a workable program and to ensuring cleanup progress, the qualifying criteria are so restrictive that the likelihood that they can be used is limited. Also, as written, regardless of method used (Method A, Method B, and methods for computing conditional cleanup levels) compliance with ARAR's is required. It is thus intuitively unclear how alternate cleanup levels can be justified. (Sacha, p. 2)

Individuals expressing similar concerns included the following: Johnson; Syrdal; and Jones, p.1.

Ecology's Response: Ecology believes the proposed approach provides an appropriate amount of flexibility to take into account site-specific circumstances without jeopardizing human health and environmental protection. The department recognizes that the proposed approach does provide less flexibility than the federal approach for establishing cleanup levels. For further discussion, see Section III (Issue #3) and Section IV (Issue #4).

Issue #5: Is it appropriate to consider concentrations of hazardous substances in areas adjacent to the cleanup site when establishing cleanup levels?

In WAC 173-340-700(5)(d)(i) of the proposed rule, Ecology stated that conditional cleanup levels may be appropriate in situations where compliance cleanup levels are below area background concentrations.

Several people supported this concept, but expressed the opinion that the conditional cleanup level should be established at a level equal to area background concentrations independent of whether those levels were higher or lower than a 10^{-5} cancer risk level. (See comments of: Aldrich; Burgess and Dunster; Thomson; and Srydal)

Sacha noted that "[t]he proposed method of proving a background level will be very difficult in large industrial areas with multiple sources and many separate properties." (p.2)

Other individuals expressed concerns that the use of this provision would simply serve to reward companies for locating their facility in areas with

other sources of hazardous substances. For example, Wishart provided several recommendations for modifying this section:

> We urge you to substitute "natural background" for "area background." There can be no justification for deviating from acceptable cleanup levels simply due to the fact that a neighboring property is also contaminated with the same toxic compounds (e.g., two oil refineries on adjacent properties). A possible exception might be carved out for situations in which recontamination is an issue. The exception, however, should be narrowly drawn, with the burden on the responsible party to demonstrate that recontamination is likely. The exception should only be applied to an interim cleanup. (Wishart, p.3)

Ecology's Response: Ecology agrees that it makes little sense to require a site to clean up to a level that would become recontaminated due to nearby contamination. Consequently, the rule provides some flexibility to modify site-specific cleanup levels on the basis of area background concentrations. However, the process for modifying cleanup levels is constrained by applicable state and federal laws and the risk levels incorporated into the regulation. If a cleanup action does not attain these levels it will be considered an interim action.

Issue #6: Is it appropriate to consider "net environmental impacts" when establishing cleanup levels?

Ecology proposed that conditional cleanup levels may be appropriate in situations where attainment of compliance cleanup levels has the potential for creating a significantly greater overall threat to human health or the environment. (WAC 173-340-700(5)(d)(ii))

Concerns similar to those voiced above were expressed on this issue. Several individuals suggested that the current provisions provided insufficient flexibility. For example:

> Although it is possible that complying with a conditional cleanup level may require selection of a cleanup method that causes a greater threat to human health (this may be the only method that can achieve the required cleanup level), this is not a consideration in establishing the conditional levels. A good example might be worker exposure or offsite treatment of wastes which are a result of the cleanup remedy. Consider revising WAC 173-340-700(8) to state that "conditional cleanup levels shall be established in accordance with the following procedures except where it will cause the establishment of a cleanup level that would require a treatment method which would cause greater overall threat to human health and the environment." (Izatt, p. 3)
>
> **********
>
> It does not make sense to require compliance with the conditional cleanup level specified in subsection (8) if it results in creating a significantly greater overall threat to human health and the

> environment as required by paragraph (ii). (Burgess and Dunster, p. 3)

Individuals providing similar comments included the following: Aldrich; Belfiglio; and Thomson.

Ecology's Response: Ecology believes the rule contains sufficient flexibility to consider "net environmental impacts" when establishing conditional cleanup levels. Site-specific considerations include both short-term and long-term impacts, with more emphasis being placed on long-term impacts to nearby residents than short-term impacts to workers. It is also important to recognize that the proposed rule provides the flexibility to consider net environmental impacts when selecting the type of cleanup action, the time frame for implementing the action and the point of compliance. For additional discussion, see Section IV (Issue #9).

Issue #7: Is it appropriate for the Department to consider the cost of cleanup when establishing cleanup levels?

Ecology proposed to consider the use of conditional cleanup levels when a person could demonstrate that the incremental cost of attaining the compliance cleanup level were substantial and disproportionate to the incremental reduction in the threat to human health and the environment. The Department received a number of comments on this provision. Those comments and Ecology's response are found in Section VII (Issue #1).

Issue #8: Is it appropriate to consider a person's ability to respond to other environmental threats when establishing cleanup levels?

This issue is discussed in Section VII (Issue #4).

Issue #9: What is the relationship between site use restrictions and conditional cleanup levels?

Mr. Izatt urged Ecology to clearly indicate where conditional cleanup levels apply and how site use restrictions factor into the development of the levels. He stated:

> The intended use of conditional cleanup levels is unclear. The definition in WAC 173-340-200 indicates that site use restrictions are a part of conditional cleanup levels. The discussion in WAC 173-340-700(8) seems to rely solely upon specified criteria resulting in concentration-based limits, with no exposure pathway which would allow for site use restrictions. Additionally, no statement is made regarding where the cleanup standard applies. The minimum criteria seem to imply that the conditional cleanup levels would have to be met at the most contaminated area. This approach does not provide any real latitude for site use restrictions if the conditional cleanup levels must meet the criteria throughout a site. There appears to be no allowance for

> site use restrictions for non-carcinogen constituents. Consider revising WAC 173-340-700 (8) to clearly indicate where the conditional cleanup levesl apply and how site use restrictions factor into the development of levels. (Izatt, p.4)

Mr. Findley commented that the term "institutional controls," "site use restrictions" and "under restricted site use conditions" are inconsistently defined.

Ecology's Response: Conditional cleanup levels (Method C) are intended to be protective of human health under certain situations (for example, industrial sites). Consequently, site use restrictions/institutional controls are required to ensure that the site is not used for other purposes (such as residential).

Under the final rule, Method C cleanup levels (as well as cleanup levels developed under Methods A and B) must be met throughout the site unless the Department established a conditional point of compliance.

The point of compliance is the location where cleanup levels need to be attained. The rule specifies the default parameter as throughout the site. Site-specific determinations of a conditional point of compliance are described in Sections 720 through 750.

Issue #10: Are there circumstances where it is appropriate for the department to consider establishing conditional points of compliance?

Ecology proposed several general requirements for establishing points of compliance:

> (a) The point of compliance is the point or points where cleanup levels established in accordance with WAC 173-340-720 through WAC 173-340-750 shall be attained.
>
> (b) The point of compliance under this chapter shall be established throughout the site. Under certain circumstances a conditional point of compliance may be established under WAC 173-340-720 through WAC 173-340-750.
>
> (c) A conditional point of compliance shall not be established unless the person undertaking the cleanup action can demonstrate that all practicable methods of treatment shall be or have been utilized at the site.

Several individuals expressed concerns with the concept of "conditional points of compliance." They recommended that this provision either be eliminated or its use greatly restricted:

> The determination of the point of compliance is, without a doubt, one of the most significant decisions made in the process. As you know, the Sierra Club has maintained that the point of compliance should be throughout the site; we do not support the use of a "conditional point of compliance."

> If you should choose to adopt a conditional point of compliance procedure, then the cost effectiveness analysis approach described above should be utilized. In addition, we would strongly recommend that, in instances in which a conditional point of compliance is utilized, the Department issue findings which demonstrate that the cost is clearly substantial and disproportionate to the benefits of adopting a point of compliance throughout the site.
>
> In short, we believe that the use of the conditional point of compliance should be limited to sites in which there is no other real option. Despite the fact that these sites will be dealt with as "final" cleanups, they will not be clean. The rule should work to severely limit this approach. (Wishart, p. 2)

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> The point of compliance should be throughout the site if it is technically feasible, if there is no shift or increase in risk and if the "practicable" test is met. Language should be added to require a finding that these criteria cannot be met if the department is to allow a conditional point of compliance. (Tabbutt, p.4)

Other individuals underscore the importance of providing some flexibility in establishing points of compliance. For example:

> [I]n the case of multiple sites that may share a common pathway (e.g., ground water, surface water) it has also been implied that these sites would undergo "interim cleanups" and not "final cleanups." We understood that the goal of MTCA was to expedite cleanups and particularly final cleanups. If the point of compliance is not reasonable, it will impact the number of cleanups that will be initiated by PLPs. In addition, it will greatly impact property transfer transactions in this state. (Fortier, p. 2)

However, several individuals expressed the opinion that the proposed rule provided an insufficient amount of flexibility to establish conditional points of compliance. For example:

> Points of Compliance: As written, the regulation penalizes smaller sites, sites where low to moderate exceedances [sic] exist, and sites where off-site contamination contributes to or causes contamination. Regulations are too rigid with regard to number of samples and percentage of samples for indicating compliance. The general requirement (173-340-700(11)(b) that the point of compliance be demonstrated "throughout the site" conflicts with more media specific guidance and conflicts with logical monitoring requirements should remediation include containment, isolation, or barriers. The confusion is in part semantic. The regulation speaks to "point of compliance" in the context of "throughout the site."
>
> How will point of compliance be determined in cases of cross media contamination? Concurrent application of specific media point of compliance requirements will be very restrictive.

What happens if a contamination source from neighboring property meets federal program standards (for example, RCRA) but doesn't meet MTCA standards? This situation is fairly routine in Commencement Bay. (Sacha,p.2-3)

Ecology's Response: Ecology believes there will be situations where it is appropriate to establish conditional points of compliance. A discussion of specific comments on this issue and Ecology's responses are located in Section XVII (Ground Water Cleanup Standards), Section XVIII (Surface Water Cleanup Standards) and Section XIX (Soil and Industrial Soil Cleanup Standards).

Issue #11: How will Ecology establish points of compliance in cases of cross-media contamination?

Ms. Sacha requested clarification on how the Department will establish points of compliance in cases of cross-media contamination. (p.2)

Ecology's Response: Points of compliance for cross-media contamination will generally be established on a case-by-case basis. However, several sections of the cleanup standards provide general criteria, for example WAC 173-340-720 specifies:

- Ground water cleanup levels shall be attained in all ground waters from the point of compliance to the outer boundary of the hazardous substance plume;
- The point of compliance shall be established throughout the site from the uppermost level of the saturated zone extending vertically to the lowest most depth which could potentially be affected by the site;
- The Department may approve a conditional point of compliance which shall be as close as possible to the source of hazardous substances, not to exceed the property boundary, when hazardous substances remain on-site as part of the cleanup action;
- At sites where the affected ground water flows into nearby surface water, the cleanup level may be based on protection of the surface water; and
- Parameters for establishing conditional points of compliance.

WAC 173-340-740 specifies that:

- For soil cleanup levels based on the protection of ground water, the point of compliance shall be established in the soils throught the site;
- For soil cleanup levels based on human exposure via direct contact, the point of compliance shall be established in

the soils throughout the site from the ground surface to fifteen feet below ground surface; and

- For those cleanup actions selected under WAC 173-340-360 that involve containment of hazardous substances, the compliance monitoring program shall be designed to ensure the long-term integrity of the containment system. Institutional controls shall specify appropriate operation and maintenance procedures for the containment system.

XV. GENERAL PRINCIPLES (WAC 173-340-705)

A. The Public's Response

The purpose of WAC 173-340-705, General Principles, was to define the policies and principles that Ecology would utilize to ensure that cleanup standards were established and implemented in a scientifically and technically sound manner.

A considerable number of participants provided comments on this section and a wide range of opinions were expressed. Most of the principal issues are discussed in other sections of the responsiveness summary. These include the following:

Relationship to the Federal Cleanup Law: This subsection stated that Ecology considered WAC 173-340-360 and WAC 173-340-700 through 173-340-750 applicable requirements under the federal cleanup law. Comments on this subsection are addressed in Section III of this responsiveness summary.

Regulation Update: The proposed rule specified that the regulation would be reviewed and, as appropriate, revised at least once every five years. Comments on this subsection are addressed in Section V of this responsiveness summary.

Site Use Restrictions: This subsection stated that site use restrictions would be required when the Department approved conditional cleanup levels or conditional points of compliance. Comments on this subsection are addressed in Sections XII and XIV of this responsiveness summary.

Burden of Proof: This subsection provides general guidance on who has the burden of proof to demonstrate the appropriateness of conditional cleanup levels or points of compliance.

New Scientific Information: This subsection stated Ecology's commitment to consider new scientific information when establishing cleanup levels for individual sites. Comments on issues related to this subsection are addressed in Section V of this responsiveness summary.

Reference Doses: This subsection defined the procedures for developing reference doses for use in establishing cleanup levels. Comments on issues related to this subsection are addressed in Section V of this responsiveness summary.

Carcinogenic Potency Factors: This subsection defined the procedures for developing carcinogenic potency factors for use in establishing cleanup levels. Comments on issues related to this subsection are addressed in Section V of this responsiveness summary.

Bioconcentration Factors: This subsection defined the procedures for developing bioconcentration factors for use in establishing cleanup levels. Comments on issues related to this subsection are addressed in Section XVIII of this responsiveness summary.

Exposure Parameters: This subsection defined the requirements for modifying several exposure parameters. Comments on issues related to this subsection are addressed in Section V of this responsiveness summary.

Methods for Defining Background: This section defined minimum requirements for defining background concentrations. Comments on this subsection are addressed below.

Analytical Considerations: This subsection provided general guidance on procedures for evaluating the effectiveness of cleanup actions. Comments on issues related to this subsection are addressed in Section VIII of this responsiveness summary.

The principal issues addressed in this section include the following:

Issue #1: **What is the technical basis for the minimum sample sizes specified in the procedures for defining background concentrations?**

Issue #2: **Should the minimum sample size vary depending on the media being sampled?**

Issue #3: **Is the regulatory definition of the null hypothesis appropriate for background-based standards?**

Issue #4: **What are appropriate methods for handling non-detected values?**

B. Ecology's Evaluation and Response

Issue #1: What is the technical basis for the minimum sample sizes specified in the procedures for defining background concentrations?

In the proposed rule, Ecology specified that when determining natural background and area background concentrations, minimum sample sizes of ten and twenty samples, respectively, would be required. Two commentors questioned the technical basis for the minimum sample sizes:

> It is not clear what are the justifications of suggesting a sample size of 10 or more and "20 or more" for determination of natural background concentrations and area background concentrations, respectively (See WAC 173-340-705 (11)(d)). When the measurements from the background area are not normally or log-normally distributed, an upper one-sided nonparametric tolerance limit with 95% coverage and a tolerance coefficient of 95% requires 59 background samples. (Conover, 1980, Practical Nonparametric Statistics, Second Edition, John Wiley and Sons, Inc., New York, New York, pages 117-121 and Table A5, page 447) Hence, the recommended background sample size(s) may not be adequate. (Chou, p. 2)

****

> We do not understand the rationale and there is no statistical basis specified for requiring 10 or more samples for determining natural background and 20 or more for area background. While some statistical tests, such as the Chi-Squared Test for distribution, require as much as 20 samples, in many situations assumption of a normal distribution is acceptable and will be conservative. When using the tolerance interval approach as specified in the

> regulations, increasing the sample size from 10 to 20 will only modify the test statistic or tolerance factor (K) from 2.911 to 2.396, respectively, while doubling the cost of determining area background. We suggest that the regulations not include specific sample numbers for determining background. This should be determined by qualified scientists. (Burgess and Dunster, p. 3)

Ecology's Response: The minimum sample sizes were selected following consideration of environmental distributions, sample costs and the level of confidence in sample results. The department recognizes that there are many site-specific and contaminant-specific variables which will influence this determination. The selected values represent a reasonable balance between the need for regulatory efficiency and the practical aspects of collecting and analyzing large numbers of samples.

Issue #2: Should the minimum sample size vary depending on the media being sampled?

Dr. Burgess and Mr. Dunster questioned whether it was practicable to specify a minimum sample size that applied to all media:

> In addition, this number of samples may be impracticable to attain for certain media at some sites. For example, how would these requirements be applied to determining background for ground water. Would it require 10 or 20 background wells. Fewer wells sampled several times would not be true independent samples and would violate basic statistical assumptions. (Burgess and Dunster, p. 3)

Ecology's Response: Ecology agrees and the final rule has been revised to clarify that sample sizes for media other than soil will be established on a case-by-case basis. Ecology intends to develop sampling guidance in 1991.

Issue #3: Is the regulatory definition of the null hypothesis appropriate for background-based standards?

One individual stated that the null hypothesis for background-based standards should be the reverse of that for a risk-based standard:

> The null hypothesis as stated is that the site is contaminated at concentrations which exceed cleanup levels (see definition on page 6). That is, the null hypothesis is that the cleanup unit is "dirty" and the alternative hypothesis is that the cleanup unit is "clean". These hypotheses are appropriate for a comparison with a risk-based standard (i.e., one-sample test). However, when the cleanup standards are background-based standards (i.e., two-sample case), the hypotheses should be the reverse of those given (in page 6). (Chou, p. 1)

Ecology's Response: Ecology agrees and the final rule has been revised to clarify that the stated null hypothesis only applies to comparison

with risk-based standards. Similar recommendations are provided in EPA (1989h).

Issue #4: What are appropriate methods for handling non-detected values?

One individual noted that there are other non-parametric statistical tests to detect different types of contamination:

> There are other non-parametric statistical tests to detect different types of contamination. The Wilcoxon Rank Sum Test (Conover, 1980) may be used to test uniform contamination above background. The Quantile test may be used to test spotty contamination (i.e., whether a small portion of a cleanup unit has concentrations larger than background) (Johnson, R.A., S.Verrill, and D.H. Moore II, 1987, "Two-Sample Rank Tests for Detecting Changes That Occur in a Small Proportion of the Treated Population," Biometrics 43:641-655). These tests can be conducted (without assigning an arbitrary value for less than detection limit datum) even when a large proportion of the data is below the detection limit. (Chou, p. 3)

Ecology's Response: The final rule has been revised to incorporate the flexibility to utilize alternate procedures for handling non-detected values. This issue is discussed in greater detail in Section XVII (Issue #14).

XVI. APPLICABLE STATE AND FEDERAL LAWS (WAC 173-340-710)

A. Background

Under RCW 70.105D.030(2)(d), the Department is required to "[p]ublish and periodically update minimum cleanup standards for remedial actions at least as stringent as the cleanup standards under section 121 of the federal cleanup law (CERCLA) and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law."

Section 121(d) specifies that remedial actions must "attain a degree of cleanup ... at a minimum which assures protection of human health and the environment." Protection of human health and the environment is to be achieved, at least in part, by identification and compliance with the "applicable or relevant and appropriate standard, requirement, or criteria, or limitation" (ARARS) for the hazardous substances, pollutants or contaminants that will remain at the site. Section 121(d)(4) specifies six conditions where it may be appropriate to waive compliance with ARARs.

Applicable requirements are defined by EPA as those cleanup standards, standards of control and other substantive environmental protection requirements, criteria, or limitations promulgated under Federal or State law that specifically address a hazardous substance, pollutant, contaminant, remedial action, location or other circumstances at a CERCLA site...." (EPA, 1990a) Relevant and appropriate requirements are defined by EPA as those "cleanup standards, standards of control, and other substantive environmental requirements, criteria or limitations promulgated under Federal and State law that, while not legally applicable to a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance at a CERCLA site, address problems or situations sufficiently similar to those encountered at the CERCLA site that their use is well suited to the particular site...." (EPA, 1990a)

B. Ecology's Proposal

RCW 70.105D.030(2)(d) requires that the cleanup standards be at least as stringent as Section 121 of SARA and all applicable state and federal laws, including health-based standards, under state and federal law. Two primary issues are associated with this requirement. First, there is the issue of what constitutes an applicable state and federal law. Ecology proposed to define the term "applicable state and federal laws" to include both "legally applicable" and those requirements that the department determines are "relevant and appropriate" requirements. Ecology has proposed to adopt the federal definitions for these terms as specified in the National Contingency Plan (U.S. EPA 1990a). Second, there is the issue of whether Ecology should provide the flexibility to waive compliance with applicable state and federal laws on a site-specific basis. Although such provisions appear in the federal cleanup law and the previous state law, the MTCA is silent on this issue. Given the explicit provisions in the previous state law and the lack of such provisions in MTCA, provisions for waiving compliance with applicable state and federal laws were not incorporated into the proposed amendments.

C. The Public's Response

A considerable number of individuals provided comments on the issue of applicable state and federal laws. The principal issues raised during the rulemaking were the following:

Issue #1: **Should the term "applicable state and federal laws" be defined to include both "legally applicable" and "relevant and appropriate" requirements?**

Issue #2: **Does the proposed rule incorporate a sufficient amount of flexibility when defining "relevant and appropriate" requirements?**

Issue #3: **Should Ecology require cleanup levels to be at least as stringent as non-promulgated, health-based guidelines?**

Issue #4: **Is the department required to incorporate the CERCLA waiver provisions?**

Issue #5: **Should Ecology consider and incorporate provisions for waiving compliance with applicable state and federal laws?**

Issue #6: **Does the term "applicable state and federal law" include local requirements?**

Issue #7: **Can Ecology consider variance provisions within certain "applicable state and federal laws" when establishing cleanup requirements for individual sites?**

Issue #8: **Will the promulgation of new ARARs require additional cleanup measures?**

Issue #9: **Are environmental laws and regulations of Indian Tribes considered applicable state and federal laws?**

D. Ecology's Evaluation and Response

Issue #1: Should the term "applicable state and federal laws" be defined to include both "legally applicable" and "relevant and appropriate" requirements?

The Department proposed to define the term "applicable state and federal laws" to include both "legally applicable" requirements and those requirements that the Department determines are "relevant and appropriate." Ecology received a broad range of comments on this issue. Some individuals expressed concerns about the proposed definition and its application to sites in Washington. For example:

> "The definition of `applicable state and federal laws' should not include relevant and appropriate requirements. WAC 173-340-200. This is an unwarranted and confusing departure from the federal Superfund program...." (Thomson, p. 5)
>
> **********
>
> In this section, Ecology attempts to define "all applicable state and federal laws" to include those which are only relevant and

> appropriate, as opposed to legally applicable. Not only should these remain separate and distinct for reasons outlined above, but the MTCA may not allow requirements which are merely relevant and appropriate as defined in these proposed regulations. (Syrdal, p. 11)

Individuals expressing similar concerns during the rulemaking include: Burgess and Dunster, p. 1; and Sacha, p. 2.

However, in contrast to the above comments, several participants suggested that Ecology had misinterpreted the MTCA requirements and urged the department to adopt a broader definition of this term. For example:

> The ARAR "relevant and appropriate requirements" should be broader, i.e., it should include such things as federal guidance and health advisories. These are not law, but are often the best you have to go with in setting requirements. (Peterson, p. 1)

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> The Technical Summary [in the draft environmental impact statement] discusses the definition of "applicable or relevant and appropriate requirements." This section does not directly address the relevant laws in other states. The impact statement should include a review of laws in other states and provide evidence that the standards being proposed are at least as stringent as the 'applicable' laws in other states. In this meaning "relevant" for purposes of Washington State rules under Chapter 173-340 WAC.
>
> Thus, the proposed definition of "applicable state and federal laws" incorrectly and/or ambiguously delimits consideration of any other state's law or requirement through the use of "and" instead of the word "or". As indicated above, there are no "legally applicable" laws for residents of Washington in other state's statutes. The following words are suggested to correct this ambiguity:
>
> "Applicable state and federal laws" as used in context of the specification of cleanup standards means all relevant current laws and corresponding implementation rules and requirements, any of which reasonably could apply to sites in Washington, promulgated by any federal or state authority or state citizenry.... (Cook, p. 3)

Ecology's Response: RCW 70.105D.030(2)(d) requires Ecology to adopt cleanup standards that are at least as stringent as Section 121 of CERCLA and other "applicable state and federal laws." The department believes that the reference to Section 121 requires publication of standards that are at least as stringent as both "legally applicable" and "relevant and appropriate" requirements. (Manning, 1989)

While recognizing the difficulties in performing ARAR analyses, the department does not believe these rules represent "an unwarranted and confusing departure from the Federal Superfund program...." A side-by-side comparison of the National Contingency Plan (EPA, 1990) and this rule reveals that the two rules include virtually identical definitions and evaluation criteria.

Finally, the suggestion that Ecology must adopt standards at least as stringent as those in all 50 states, while an interesting concept, goes beyond what is normally considered applicable to sites in the State of Washington. Exceptions to this statement may include situations where releases from a site in Washington have the potential to impact resources in other states. For example, in evaluating requirements for dischargers to the Columbia River, it may be necessary to consider the water quality standards for both Washington and Oregon.

Requirements under other states' laws may also be handled as "to be considered" (TBC) requirements. In these situations, Ecology would evaluate the technical bases for such standards and determine whether similar conditions apply at a particular cleanup site.

Issue #2: Does the proposed rule incorporate a sufficient amount of flexibility when defining "relevant and appropriate" requirements?

Several individuals stated the opinion that the proposed rule did not contain sufficient flexibility when defining "relevant and appropriate" requirements. For example:

> Another example of the failure in necessary flexibility for cleanup standards to be applied at particular sites is the approach taken by the regulations in deciding which ARARs should apply. Under the federal system, while legally applicable requirements may apply in all cases, the application of relevant and appropriate standards to a particular case is judged on a case by case basis. Unfortunately, the department in these regulations has chosen a substantially different path. Perhaps the primary example of this is the decision to apply MCLG's and secondary drinking water standards as cleanup standards for groundwater. (Syrdal, p. 3)

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> Applicable laws should be only those that meet the definition provided for "legally applicable requirements." As indicated in EPA's guidance on applicable or relevant and appropriate requirements (ARARs) in Cercla Compliance with other Laws Manual (OSWER Directive 9234.1-01), there is much more discretion in determining whether laws that are not legally applicable may be relevant and appropriate to the conditions of a specific site. We believe it is important to maintain this distinction and flexibility in the cleanup standards. (Burgess and Dunster, p. 1)

Other individuals suggested that the proposed rule contains too much flexibility. For example:

> "710 (1), page 172. It would appear that it is Ecology's responsibility to list applicable state and federal laws in the administrative rule." (Burch, p. 1)

Ecology's Response: Ecology believes that an appropriate level of flexibility has been provided for defining "relevant and appropriate"

requirements for individual sites. With the exception of drinking water standards, where a generic determination of "relevant and appropriate" has been made, the state rules provide the same case-by-case approach utilized under the Federal program. Specific comments on the use of MCLs, MCLGs, and SMCLs are addressed in the following section.

Issue #3: Should Ecology require cleanup levels to be at least as stringent as non-promulgated, health-based guidelines?

RCW 70.105D.030(2)(d) requires the department to adopt cleanup standards at least as stringent as those under "all applicable state and federal laws, including health-based standards under state and federal law." Some individuals interpreted this requirement to include health advisories and/or guidance. For example:

> "The ARAR `relevant and appropriate requirements' should be broader, i.e., it should include such things as federal guidance and health advisories." (Peterson, p. 1)

Ecology's Response: In general, the Department does not believe that policies or guidance can be interpreted as health-based "standards" or ARARs under the Model Toxics Control Act(see Manning, 1989). The two exceptions to this interpretation are Maximum Contaminant Level Goals (MCLGs) and Ambient Water Quality Criteria which are specifically identified in Section 121 of CERCLA.

However, Ecology has considered guidance and health advisories in developing the state rules and requirements. Indeed, many of the procedures and assumptions used to develop cleanup standards are identical to those used to prepare guidance and advisories. For individual sites, Ecology will also take into account such guidance and advisories when developing site cleanup levels. Such advisories would also be used in evaluating whether cleanup levels are protective of human health and the environment for individual sites.

Issue #4: Is the department required to incorporate the CERCLA waiver provisions?

Section 121 of CERCLA defines six conditions which may be used to justify a waiver from complying with ARARs under the federal program. Early in the rulemaking process, several individuals expressed the opinion that Ecology was required to incorporate similar provisions into the state rule.

Ecology's Response: Ecology does not believe it is required to incorporate the CERCLA waiver provisions into the state rule. Mr. Jay Manning of the Office of the Attorney General has stated:

> As mentioned previously, it is my opinion that the waiver provisions contained in Section 121 of CERCLA are not incorporated into the MTCA by the reference to Section 121 of CERCLA in Section 3(2)(d). It has been argued that the reference to Section 121 cleanup standards in the MTCA, by necessity, incorporates the waiver provisions of that section. In my view, this is an

> incorrect reading of Section 3(2)(d). There is simply no reference in Section 3(2)(d), or anywhere else in the MTCA, to the Section 121 waiver provisions or any other waivers, for that matter. (Manning, 1989, p. 6)

Issue #5: Should Ecology consider and incorporate provisions for waiving compliance with applicable state and federal laws?

Ecology's proposal does incorporate two exceptions to complying with applicable state and federal laws. First, interim actions would not be subject to automatic compliance with relevant and appropriate state and federal laws. Second, a cleanup level based on an applicable state and federal law may be modified upward where it can be demonstrated that the particular ARAR is below natural background levels.

Comments from environmental group representatives supported this proposal and argued that incorporation of broad waiver provisions would be inconsistent with the intent of Initiative 97. However, other participants argued that the failure to incorporate a broader range of waiver provisions would create considerable problems. For example:

> One important specific point is that Section 360 needs to have a provision for a waiver of compliance with applicable state and federal laws, where compliance is not practicable. In many shallow aquifer near shore areas, for example, compliance with groundwater standards will be extremely burdensome to PLPs, and the often remote potential for harm to human health results in expensive "treatment for treatment's sake." (Johnson, p. 2)

Individuals providing similar comments include the following: Burgess and Dunster, p. 2; and Findley, p. 4. In addition, the Department received numerous comments on earlier drafts of the regulation which supported an approach that provided some flexibility to waive compliance with ARARs.

Ecology's Response: Ecology believes that the broad use of waivers is inconsistent with the legislative history of MTCA. This was summarized by Manning (1989):

> In answering this question, it is important to review the legislative history of the MTCA and the circumstances surrounding its passage. As you know, the MTCA's predecessor, Chapter 70.105B RCW, did contain a waiver provision, 70.105B.060(C). That section allowed the Department to approve a remedial action alternative which did not meet cleanup levels established under the statute. The MTCA, on the other hand, contains no such waiver provision. Thus a statute which contained a cleanup standard waiver provision was replaced by one which does not. A legitimate inference to be drawn from this series of events is that the voters desired and intended to adopt a statute which does not allow cleanup standard waivers.
>
> Perhaps more importantly, the legislative history of the MTCA also illustrates that cleanup standard waivers are either disallowed or

extremely disfavored under the MTCA. One of the few legitimate sources of legislative history for an initiative is the voter's pamphlet. Washington Department of Revenue v. Hoppe, 82 Wn.2d 549 (1973). Two statements in the voter's pamphlet demonstrate that cleanup standard waivers were in fact intended to be disallowed or extremely limited under the MTCA.

In the rebuttal of the statement against Initiative 97, it is stated:

"...strong citizen's initiative eliminates polluters' loopholes. It forces polluters to clean up their own mess. No deals. No delays. No watered-down health standards..."

Emphasis added. Later, in the statement against Initiative 97B, it is stated that Initiative 97B "allows back room deals from tough cleanup standards."

Thus, both the circumstances surrounding the passage of Initiative 97 and the legislative history contained in the voter's pamphlet support a reading of the MTCA which either disallows completely or at least greatly limits the availability of cleanup standard waivers. (Manning, 1989, p. 7)

Issue #6: Does the term "applicable state and federal law" include local requirements?

Several individuals requested clarification on whether local requirements could be considered applicable state and federal laws.

Ecology's Response: The department recognizes this potential problem and concurs with the comment to a degree. Locally imposed standards or requirements constitute cleanup standards under Section 3(2)(d) of the MTCA where such standards are promulgated under state or federal law. In other words, a local government's shoreline master program that had been approved by Ecology and adopted as state regulation would need to be complied with. However, local requirements based on a government's general police powers would not be considered an applicable regulation.

In addition, the MTCA is silent on whether there is a categorical exemption from SEPA and permits for actions performed under this law. The department intends to pursue such permits on cleanup sites. Consequently, many local requirements will be addressed through these processes.

Issue #7: Can Ecology consider variance provisions within certain "applicable state and federal laws" when establishing cleanup requirements for individual sites?

Ecology proposed to provide the flexibility to consider the waiver provisions found in some state and federal laws when establishing cleanup requirements for individual sites (WAC 173-340-710). The few comments received on this issue were generally opposed to incorporating this provision into the rule. For example, Ms. Elizabeth Tabbutt noted in her comments dated December 6, 1989

that any variance, waiver or exemption available under an ARAR should not be available under this rule.

Ecology's Response: Ecology believes that if a variance could potentially apply to an action done outside of the MTCA, it would be unreasonable not to consider such provisions for similar actions done under the MTCA, [provided that the conditions for applying the variance are met]. The department believes that the flexibility provided by such variances reduces the need to incorporate additional waiver provisions under this rule (see Issue #5).

Issue #8: Will the promulgation of new ARARs require additional cleanup measures?

The proposed rule specified that laws and regulations promulgated in the future would be considered when evaluating cleanup actions during the five-year reviews.

Several individuals attending the public workshops expressed concerns about how newly promulgated ARARs might be applied retroactively to sites that had undergone cleanup.

Ecology's Response: The department acknowledges the unease among members of the regulated community regarding this subject. Ecology believes it must consider new scientific information and ARARs when evaluating whether a cleanup action continues to protect human health and the environment. However, as discussed in Section XI (Periodic Review), the overriding evaluation criteria will be protection of human health and the environment at that site and the promulgation of a new ARAR will not automatically trigger the need for new technologies or cleanup actions.

Issue #9: Are environmental laws and regulations of Indian Tribes considered applicable state and federal laws?

Mr. William Sullivan urged the department to clarify that requirements established by Indian Tribes were potentially applicable state and federal laws.

Ecology's Response: Ecology believes that Tribal requirements could be considered applicable requirements for those MTCA cleanup actions performed on tribal lands. Such tribal requirements would be evaluated using the criteria of WAC 173-340-710.

XVII. GROUND WATER CLEANUP STANDARDS (WAC 173-340-720)

A. The Public's Response

A considerable number of participants provided comments on the ground water requirements and a wide range of opinions were expressed. The principal issues raised during the rulemaking proceedings were the following:

Issue #1: **For the purpose of establishing groundwater cleanup requirements, should Ecology specify uniform requirements for all groundwater?**

Issue #2: **Is it appropriate to define "drinking water and other domestic uses" as the highest beneficial use of ground water?**

Issue #3: **What factors should Ecology consider in defining a potential future source of drinking water?**

Issue #4: **Should Maximum Contaminant Level Goals (MCLGs) be defined as "applicable state and federal laws"?**

Issue #5: **Should Secondary Maximum Contaminant Levels (SMCLs) be defined as "applicable state and federal laws"?**

Issue #6: **Is it appropriate to require ground water cleanup levels that are more stringent than MCLs?**

Issue #7: **What procedures were utilized to develop the cleanup levels in Table #1?**

Issue #8: **Has Ecology identified appropriate method A cleanup levels for radionuclides?**

Issue #9: **Has Ecology utilized reasonable drinking water consumption rates for establishing ground water cleanup levels?**

Issue #10: **What is an appropriate methodology for estimating potential inhalation exposure to ground water?**

Issue #11: **Does the proposed regulation provide Ecology with an appropriate amount of discretion in establishing ground water cleanup levels for individual sites?**

Issue #12: **What is an appropriate ground water point of compliance?**

Issue #13: **What is an appropriate point of compliance for ground water discharging to surface water?**

Issue #14: **Should compliance with ground water cleanup levels be based on filtered or unfiltered samples?**

Issue #15: **What is the appropriate way to evaluate the mean of ground water data sets with non-detectable values?**

Issue #16: **What statistical procedures are appropriate when the same location (monitoring well) is sampled repeatedly over a period of time?**

Issue #17: **Do the compliance monitoring requirements provide an incentive to collect additional data?**

Issue #18: **Is there a sound scientific basis for utilizing the same compliance monitoring procedures irrespective of the number of substances present?**

Issue #19: **What is the relationship between the proposed ground water cleanup standards and the proposed "Water Quality Standards" for Ground Waters of the State of Washington (Chapter 173-200 WAC)?**

In analyzing these issues, Ecology places primary weight on the comments of participants who documented their statements and have experience in performing or overseeing ground water cleanup actions. These included Landau, Patmont and Wineman, Burgess and Douglas, Fortier, and Brown.

B. Ecology's Evaluation and Response

Issue #1: For purposes of establishing ground water cleanup requirements, should Ecology specify uniform requirements for all ground water?

During the rulemaking process, several individuals recommended that Ecology distinguish between various ground water uses when establishing cleanup standards. For example:

> Ecology should consider modifying (c) to state "Where ground water is currently, or can reasonably be anticipated, to serve as a principal source of drinking water, concentrations which are..." This relates to the issue of the size and relative importance of an aquifer, and provides the WDOE with a way of relaxing a bit on a cleanup standard for a water supply that is of very limited value and would be extremely costly to clean up. (Eaton, Science Advisory Board, comments on October 16, 1989 draft)

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> Before any cleanup standards apply, there should be a clear link between the contaminant source and a receptor. The cleanup standards should not apply to aquifers with no chance of potential impact to human health and the environment. (Johnson, comments on October 16, 1989 draft)

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> Not all ground water should be considered to be drinking water. The reasons for deciding that ground water will not be used as drinking water should include that the ground water contains naturally occurring organic or inorganic constituents which make use of the water for drinking infeasible or uneconomic. Whether these naturally occurring constituents are economically recoverable is a separate issue. (Thomson, comments on October 16, 1989 draft)

Ecology's Response: In establishing cleanup requirements for contaminated ground water under MTCA, Ecology has adopted a "differential protection" approach, with the level of protection being linked to the current or potential future uses of the ground water. By adopting such an approach for cleanup actions, Ecology believes that such actions can be directed towards protecting human health and the environment.

However, in adopting this approach for cleanup sites, Ecology believes it is important to distinguish requirements for remediating historically contaminated ground water from requirements designed to prevent ongoing releases of hazardous substances into the ground water. In these situations, the state's antidegradation provisions as specified under Chapter 90.48 RCW and Chapter 90.54 RCW would apply.

The antidegradation policy is two-pronged. First, degradation of water quality which would either harm a beneficial use or violate the ground water quality standards is generally prohibited. However, some degradation of ground water may be allowed in situations where numeric criteria would not be exceeded and the activity causing the degradation serves the overriding public interest. Second, regardless of the quality of the water, all wastes must be provided with all known, available and reasonable methods of prevention, control and treatment (AKART) prior to entry into the state's waters. The numeric criteria in the state's surface water and ground water standards support AKART and the antidegradation policy, but do not substitute for them.

Issue #2: Is it appropriate to define "drinking water and other domestic uses" as the highest beneficial use of ground water?

Ecology proposed to establish groundwater cleanup levels on the basis of estimates of the highest beneficial use and reasonable maximum exposure and stated that "the department has determined that for most sites drinking water is the beneficial use requiring the highest quality of groundwater and that exposure to hazardous substances via ingestion of drinking water and other domestic uses represents the reasonable maximum exposure. (WAC 173-340-720(1)(a))

Several individuals expressed the opinion that this statement was inappropriate. For example, Cook stated:

> Drinking water for farm or domestic animals is a use that should be considered routinely and thus should be specified rather than left to the determination of DOE on a case basis. For example, the accumulation of hazardous substances in milk of cows and goats should be considered.
>
> The second sentence of paragraph (a) is unnecessary. It inappropriately suggests consideration of drinking water as the highest beneficial use in most cases. Such a suggestion adds nothing to the rule. (Cook, p. 9)

Ecology's Response: Ecology believes that by establishing ground water standards that protect drinking water use, the Department will also protect a variety of other beneficial uses. However, Ecology also recognizes that for some hazardous substances there may be beneficial uses that require more stringent cleanup levels than those based on drinking water. The rule requires Ecology to establish cleanup levels to protect other beneficial uses on a case-by-case basis.

Issue #3: What factors should Ecology consider in defining a potential future source of drinking water?

Ecology proposed to establish groundwater cleanup levels on the basis of ingestion of drinking water and other domestic uses unless the person undertaking the cleanup action can demonstrate the following:

(i) The ground water does not serve as a current source of drinking water;

(ii) The ground water is not a potential future source of drinking water for any of the following reasons:

(A) The ground water is present in insufficient quantity to yield greater than 0.5 gallon per minute on a sustainable basis to a well constructed in compliance with chapter 173-160 WAC and in accordance with normal domestic water well construction practices for the area in which the site is located;

(B) The ground water contains natural background concentrations of organic or inorganic constituents which make use of the water for drinking not technically practicable. Ground water containing total dissolved solids at concentrations greater than 10,000 mg/l shall normally be considered to have fulfilled this requirement; or

(C) The ground water is situated at a great depth or location which makes recovery of water for drinking water purposes technically infeasible; and

(iii) The department determines it is unlikely that hazardous substances will be transported from the contaminated ground water to ground water that is a current or potential future source of drinking water, as defined in subsection (ii) of this section, at concentrations which exceed ground water quality criteria published in Chapter 173-200 WAC; or

(iv) More stringent concentrations are necessary to protect human health or the environment (WAC 173-340-720(a).

Several individuals stated that the proposed criteria for defining potential future use of groundwater were inadequate, for example:

> "The criteria for determination of potential future use of groundwater are inadequate. Consideration of technological advancement in the capability to remove organic or specific inorganic constituents should be included in the analysis." (Cook, p. 9)

Several individuals expressed concerns over the use of 10,000 mg/l of total dissolved solids to define a potential source of drinking water. For example:

> "The definition of drinking water should not be based on the criteria of 10,000 mg/l of total dissolved solids." (Thomson, p. 4)

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> The definition of drinking water should not be dependent on the criteria of 10,000 milligrams per liter (mg/l) of total dissolved solids. Ground waters are often considered naturally, or with treatment, unfit for drinking water with much less than this amount of total dissolved solids. (Izatt, p. 5)

****

> In the proposed regulation, Ecology has made a distinction between the majority of ground waters of the state and those which produce less than 0.5 gpm or have high salinity (greater than 10,000 mg/L). A distinction should also be made for ground waters that are seasonal, isolated or of poor natural quality. This should be consistent with the proposed groundwater quality standards (e.g., TDS levels of 500 ppm) and is especially important for groundwater in selected industrial areas. (Patmont and Wineman, p. 4)

Other participants who expressed similar concerns include the following: Syrdal, p. 12; and Butler, p. 9.

Several individuals recommended that Ecology consider additional factors when defining potential future sources of drinking water. For example:

> The conditions under which drinking water is presumed to not be a current of likely potential future use of drinking water should included: Where ground water is not and will not be used based on location and availability of other sources of supply (e.g. it is extremely unlikely that ground water in the urban area of Seattle will ever be developed for drinking water supply). Ground water should not have to be remediated to drinking water standards if it is situated in a location where it is extremely unlikely that it will ever be used. (Burgess and Dunster, p. 5)

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> A new subsection (D) should be added. This subsection should make it clear that the use of groundwater as a source of drinking water will not be considered with regard to groundwater present in a man-made aquifer. For example, there are situations in which filling activity is at such a depth that groundwater has permeated portions of the fill. By its very nature as fill, usually industrial, it is not suitable as a source of drinking water. Therefore, there should be another category which automatically excludes that groundwater from consideration of drinking water purposes. Drinking water should be limited to natural aquifers. (Syrdal, p. 12)

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> Furthermore, Ecology should recognize an alternative compliance cleanup level for ground water that, while useable, it is extremely unlikely to ever be used as drinking water. For example, certainly this applies in various tidal areas where alternative water

supplies are well established and the drinking water aquifer is truly marginal at best. (Thomson, p. 4)

Ecology's Response: Ecology has reviewed approaches used by other state and federal agencies and determined the definition of "potential future source" is generally consistent with what is being done in other areas of the country. For example, under EPA's Ground Water Classification Guidelines (EPA 1986a), ground water may be categorized as:

> Class I - Special ground waters that are vulnerable to contamination and are irreplaceable sources of drinking water or are ecologically vital;
>
> Class II - Current (IIA) and potential (IIB) sources of drinking water or for other beneficial use (i.e., sources with less than 10,000 mg/l total dissolved solids (TDS), or that can be treated to drinking water quality using methods reasonably employed in a public water supply system, and which yield at least 150 gallons/day; and
>
> Class III - Ground water not considered potential sources of drinking water and of limited beneficial use. These ground waters also must not migrate to Class I or II ground waters.

These guidelines are utilized by EPA when establishing ground water cleanup requirements for Superfund sites, RCRA hazardous waste management facilities, and Subtitle D solid waste management units.

Ecology has historically considered all ground waters in the state to be identical when establishing regulatory requirements. The cleanup rule represents a departure from that approach and consequently the criteria for defining "potential future sources of drinking water" were carefully scrutinized. The rationale for the criteria are provided below:

A. The ground water is present in insufficient quantity to yield greater than 0.5 gallon per minute (gpm) on a sustainable basis to a well constructed in compliance with Chapter 173-160 WAC. The value of 0.5 gpm (720 gallons per day) was selected based on available water use statistics and the technical feasibility of measuring ground water yields less than 1-5 gpm. Water use statistics for Washington indicate that the average per capita water use for public and rural supplies is 143 and 48 gallons per day, respectively (National Water Well Assoc. 1990). For a family of four, this represents 672 and 192 gallons per day in urban and rural areas, respectively. Although these values are somewhat lower than the 0.5 gpm standard, it has been Ecology's experience that it is difficult to measure ground water yields below a rate of 0.5 gpm.

B. The ground water contains natural background concentrations of organic or inorganic constituents which make use of the water for drinking not technically practicable. Ground water containing total dissolved solids at concentrations greater than 10,000 mg/l shall normally be considered to have fulfilled this requirement. As noted above, the value of 10,000 mg/l is utilized by numerous other state and federal agencies to define ground water that may be used for drinking water.

C. The ground water is situated at a great depth or location which makes recovery of water for drinking water purposes technically impossible. As recommended by Mr. Cook, Ecology will consider whether technologies exist which will allow ground water to be recovered.

Ecology does recognize that the use of the above criteria may lead to the application of drinking water standards to situations where it is very unlikely that ground water will be used for drinking water. Of particular concern are situations where the shallow ground water is discharging to nearby surface waters and is very unlikely to be used as a future source of drinking water (i.e., shallow ground water in the Commencement Bay and Harbor Island areas). In these cases, the ground water rarely represents a current source of drinking water and the primary ongoing concern is reducing the release of hazardous substances to nearby surface waters. To address these situations, Ecology has added the following provision to WAC 173-340-720(1):

(c) The department recognizes that there may be sites where there is an extremely low probability that ground water classified as a potential future source of drinking water under (b) of this subsection will actually be used for that purpose (i.e., the shallow ground water on Harbor Island). At such sites, the department may approve ground water cleanup levels that are based on protecting beneficial uses of adjacent surface water if the person undertaking the cleanup action can demonstrate all of the following:

(i) There are known or projected points of entry of the ground water into the surface water;

(ii) The surface water is not classified as a suitable domestic water supply source under chapter 173-201 WAC;

(iii) Ground water flows into surface waters will result in no exceedances of surface water cleanup levels at the point of entry or at any downstream location where it is reasonable to believe that hazardous substances may accumulate;

(iv) The cleanup action includes institutional controls that will prevent the use of contaminated ground water at any point between the source of hazardous substances and the point(s) of entry of the ground water into the surface water; and

(v) The department determines it is unlikely that hazardous substances will be transported from the contaminated ground water to ground water that is a current or potential future source of drinking water, as defined in (b) of this subsection, at concentrations which exceed ground water quality criteria published in chapter 173-200 WAC.

Issue #4: Should Maximum Contaminant Level Goals (MCLGs) be defined as "applicable state and federal laws"?

Ecology proposed to define MCLGs as "applicable state and federal law" for ground water that is classified as a current or potential future source of drinking water. (See WAC 173-340-720(2)(a)(ii)) Several individuals expressed concerns with this approach and recommended that Ecology either delete this

requirement or provide more flexibility in assessing the "relevance and appropriateness" of MCLGs on a "case-by-case" basis. For example:

> "Requiring cleanups to comply with MCLGs and secondary maximum contaminant levels, may result in an unwarranted commitment of resources and should not be required unless, perhaps, if the MCLGs or secondary standards qualify as relevant and appropriate." (Syrdal, p. 11)

Other individuals providing similar comments include: Aldrich, p. 11; Burgess and Dunster, p. 7.

Ecology's Response: It is Ecology's opinion that where an MCLG establishes a contaminant level above zero it is appropriate to consider that MCLG as an "applicable state and federal law" for purposes of establishing cleanup levels for ground waters and surface waters that represent a current or potential future source of drinking water. In order to understand the rationale for this approach, it is necessary to trace the relationship between requirements under the Safe Drinking Water Act, the federal cleanup law, and the MTCA.

First, Section 1412 of the Safe Drinking Water Act (SDWA) as amended in 1986 requires EPA to publish Maximum Contaminant Level Goals (MCLGs) and promulgate National Primary Drinking Water Regulations which specify Maximum Contaminant Levels (MCLs). EPA is required to establish MCLGs at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety. When establishing MCLGs, EPA utilizes a two-tiered approach: MCLGs for carcinogens are generally set at zero; and non-carcinogens are set at protective levels. MCLGs are non-enforceable health goals. EPA is also required to establish enforceable standards, MCLs, which EPA must set as close as feasible to the MCLG. To date, EPA has established MCLs for carcinogens at levels equal to the "practical quantitation limit." MCLs for non-carcinogens have generally been set at levels equal to the MCLG.

Section 121(d) of CERCLA states that a remedial action must attain a level or standard of control established under the SDWA, among other statutes, where such level or control is applicable or relevant and appropriate. Section 121(d) also states that remedial actions shall attain MCLGs where such goals are relevant and appropriate. Under the National Contingency Plan (EPA, 1990a), EPA has concluded that non-zero MCLGs are ARARs.

Finally, Section 70.105D.030(2)(d) states that cleanup standards must be at least as stringent as Section 121(d). Consistent with the approach taken by EPA, Ecology has concluded that MCLGs for noncarcinogens (non-zero values) are "applicable state and federal laws." If the MCLG is equal to zero, Ecology agrees with EPA's position that the MCLG is not appropriate for establishing cleanup levels and the MCL or risk-based level should be used. Consequently, where the ground water in question represents a current or potential future source of drinking water, cleanup levels must be at least as stringent as non-zero MCLGs.

Issue #5: Should Secondary Maximum Contaminant Levels (SMCLs) be defined as "applicable state and federal laws"?

Ecology proposed to define SMCLs as "applicable state and federal laws" (See WAC 173-340-720(2)(a)(ii). A number of participants expressed concerns with this approach. For example:

> Requiring cleanups to comply with MCLGs and secondary maximum contaminant levels may also result in an unwarranted commitment of resources and should not be required unless, perhaps, if the MCLGs or secondary standards qualify as relevant and appropriate. In fact, it is doubtful that 2^0 standards are legally appropriate under MTCA since, in general, compliance with 2^0 standards is not necessary to protect human health or the environment. (Syrdal, p. 11)
>
> **********
>
> "In addition, always requiring cleanup to a secondary maximum contaminant level may also result in the unwise use of resources, particularly for those ground waters that are not current sources of drinking water." (Izatt, p. 5)

Participants providing similar comments include the following: Burgess and Dunster, p. 7; and Aldrich, p.11.

Several participants provided recommendations for addressing the above concerns. In general, most recommended providing more flexibility in applying MCLGs and SMCLs at particular sites. For example, Mr. Izatt recommended the following:

> Add wording that allows cleanup levels for secondary maximum contaminant levels to be established on a case-by-case basis giving consideration to the current use of ground water, the availability of point of use or point of source treatment, and the effects of the elevated secondary contaminants on the useability of the drinking water supply. (p. 5)

Other participants who provided similar recommendations include the following: Syrdal, p. 12; Burgess and Dunster, p. 2.

Ecology's Response: Ecology believes that protection of beneficial uses of ground water requires that SMCLs be considered when establishing ground water cleanup levels. From a philosophical standpoint, the department would find it difficult to rationalize an approach that authorizes the differential protection of drinking water resources based on the type of contaminants present at a site. This approach has been rejected by the department in promulgating ground water standards (Chapter 173-200 WAC).

From a statutory and legal perspective, a differential approach would also be difficult to justify. RCW 70.105D.030(2)(d) specifies that cleanup standards must be at least as stringent as applicable state and federal laws. For ground water and surface waters that represent current and potential sources of

drinking water, the state's drinking water regulation (Chapter 248-54 WAC), which include SMCLs, are considered applicable state and federal laws.

Issue #6: Is it appropriate to require ground water cleanup levels that are more stringent than MCLs?

Ecology proposed to establish ground water cleanup levels that are more stringent than primary MCLs when:

(1) the total site cancer risk exceeds 1 in 100,000;
(2) the site Hazard Index exceeds 1.0;
(3) cleanup levels established at the MCL would result in violations of cleanup levels for other media such as surface water; or
(4) the Secondary MCLs is lower than the Primary Drinking Water Standard.

Several participants stated that it was inappropriate to require ground water cleanup levels that are more stringent than MCLs. For example:

> "Cleanup to more stringent levels than health-based drinking water standards leads to imprudent use of resources." (Thomson, p. 4)

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> "Cleanup levels which meet or exceed health-based MCLs will be protective of the highest beneficial use of ground water and the regulation must state that cleanup in excess of such levels is not required." (Syrdal, p. 12)

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> "A cleanup level should not be required to ever be set below a maximum contaminant level (MCLs). Cleaning up ground water to more stringent levels than a health-based drinking water standard will only result in less cleanups due to the unwise use of limited resources." (Izatt, p. 5)

Similar comments were provided by the following individuals: Butler, p. 9; Izatt, p. 5; and Science Advisory Board, p. 3.

Ecology's Response: Ecology believes there are situations where cleanup levels, more stringent than individual MCLs, are required. The rationale for this position is discussed in Section IV - Issue #2.

Issue #7: What procedures were utilized to develop cleanup levels in Table #1?

The proposed rule included a list of Method A Compliance Cleanup Levels for ground water (Table #1). Several individuals requested clarification on how those values were derived.

Ecology's Response: In general, the procedures specified in the regulation were utilized to develop the cleanup levels for individual substances. Consequently, the values were derived from one of several sources.

The following paragraphs provide a summary of the technical bases for the Method A values. Ecology is preparing guidance which provides greater detail on the underlying studies and factors that may be considered under Methods B and C:

Maximum Contaminant Levels (MCLs): Method A cleanup levels for eleven of the twenty-six substances are based on final MCLs published in 40 CFR 141. These include the following: Benzene; Chromium; 1,2 Dichloroethene; Gross Alpha Particle Activity; Gross Beta Particle Activity; Mercury; Radium 226 and 228; Tetrachloroethylene; 1,1,1 Trichloroethane, and Trichloroethylene.

Maximum Contaminant Level Goals (MCLGs): The Method A cleanup level for lead is based on the proposed MCLG (EPA 1988).

Secondary Maximum Contaminant Levels (SMCLs): The Method A cleanup levels for three of the twenty six substances are based on proposed or final SMCLs: Ethylbenzene; Toluene; and Xylenes. (See EPA 1989d)

Risk-Based Cleanup Levels: The Method A cleanup levels for seven of the twenty-six substances were based on the risk equations in WAC 173-340-720. These include the following: DDT; Ethylene Dibromide; Lindane; Methylene Chloride; PAHs (carcinogenic); PCB mixtures; and vinyl chloride. The risk-based concentrations for EDB, PAHs, PCB mixtures, and vinyl chloride were modified based on analytical considerations consistent with the provisions of WAC 173-340-707.

Background: The Method A cleanup level for arsenic was based on the background concentrations of arsenic in ground water as reported in PTI (1989a).

Issue #8: Has Ecology identified appropriate Method A cleanup levels for radionuclides?

Two individuals provided comments on the radionuclide values in Table 1:

> Table 1: These numbers come from drinking water standards. the following changes should be made: (1) the gross alpha particle activity should exclude uranium; (2) gross beta activity should include photon (gamma) activity. This makes it equivalent to the Board of Health radionuclide primary standards for radionuclides contained in WAC 248-54. (Peterson, p. 1)

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> Table 1: Gross Beta Particle Activity. A mrem/yr dose cannot be calculated for gross beta radiation; a specific beta emitting radionuclide must be known. We suggest that the cleanup level of gross beta particle activity be set based on the MCL in 40 CFR 141 of 50 pCi/L [as long as H-3 and Sr-90 do not in combination exceed 20,000 pCi/L (H-3) + 8 pCi/L (Sr-90) $\leq$ 1]. (Burgess and Dunster, p. 4)

Ecology's Response: Comments noted. Ecology will prepare rulemaking guidance to ensure that these provisions are implemented consistently with state and federal drinking water standards.

Issue #9: **Has Ecology utilized reasonable drinking water consumption rates for establishing ground water cleanup levels?**

Ecology proposed to utilize drinking water consumption rates of 1 and 2 liters/day for children and adults, respectively. One commentor, Mr. Leonard Butler (Waste Management) expressed the opinion that such values may be too high:

> The DOE may be unaware that the standard 2 liter per day water ingestion assumption is nearly double the actual adult average value [U.S. EPA "Exposure factors handbook", EPA/600/8-89/043, March 1989]. Thus the conservatism built into the MCL derivation process already incorporates an additional margin of safety for potential inhalation exposure of drinking water volatile organic compounds. (Butler, p. 10)

Ecology's Response: Ecology agrees that available data suggest that average adult drinking water consumption rate may on the order of 1.2 to 1.63 liter/day (EPA, 1989b). Indeed, EPA (1989b) concluded:

> Thus the average drinking water consumption rate would be somewhat less than the 2.0 L/day commonly used. Policy or precedent reasons may support the continued use of the 2.0 L/day as the average adult drinking water consumption rate; however, the data from the scientific literature suggest a rate of 1.4 L/day as the average. (EPA 1989b, p. 2-9)

However, as noted in Section V, cleanup levels are established on the basis of reasonable maximum exposures (not averages). This is consistent with EPA (1989a) which recommends that the following approach be utilized when selecting contact rates (i.e. ingestion rates) for use in calculating reasonable maximum exposure levels:

> Contact rate reflects the amount of contaminated medium contacted per unit time or event. If statistical data are available for a contact rate, use the 95th percentile value for this variable. In this case and throughout this chapter, the 90th percentile value can be used if the 95th percentile value is not available). If statistical data are not available, professional judgment should be used to estimate a value which approximates the 95th percentile value. (It is recognized that such estimates will not be precise. They should, however, reflect a reasonable estimate of an upper bound value). (EPA 1989a, p. 6-22)

EPA (1989a) identifies 2.0 liters/day as the 90th percentile value. This is based on information in the Exposure Factors Handbook (1989b) which concludes:

> Very little data are available upon which to recommend a reasonable worst case rate. The 90th percentile value reported by Gillies and Paulin (1983), 1.90 L/day suggests that a rate of 2.0 L/day may be a reasonable approximation. In addition, the approximate 90th percentile value suggested by Cantor et al. (1987) is 2.0 L/day. Based on these studies, a value of 2.0 L/day is recommended as the reasonable worst-case drinking water consumption rate for adults. (EPA 1989b, pp. 2-9 through 2-10)

It is also important to recognize that 2 liters/day is used by a number of other scientific and regulatory bodies to establish standards or guidelines. These include the following:

- Establishing cleanup levels under the EPA Superfund Program (EPA, 1989a; EPA, 1990b);
- Establishing drinking water standards under the state and federal drinking water programs (EPA 1989d);
- Establishing drinking water guidelines (NAS 1977, 1980, 1986); and
- Establishing ground water quality standards in Washington.

Issue #10: What is an appropriate methodology for estimating potential inhalation exposure to ground water?

For purposes of estimating exposure and health risks associated with the inhalation of contaminated ground water, Ecology proposed to utilize a correction factor of 2 for volatile organic hazardous substances unless data were available to support an alternate value for a particular hazardous substance. Implicit in this approach were the assumptions that:

(1) A person would receive an equivalent amount of exposure from inhalation as that received from ingesting two liters of water per day; and

(2) Hazardous substances presented similar risks by both routes of exposure.

Several participants expressed reservations with the proposed methodology. For example:

> "It would seem more appropriate to assess the amount of exposure via inhalation of volatiles using the inhalation reference dose and not the oral reference dose as shown in the cleanup equation." (Tsuji, p. 6)

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> The DOE may be unaware that the standard 2 liter per day water ingestion assumption is nearly double the actual adult average value [U.S. EPA "Exposure factors handbook", EPA/600/8-89/043, March 1989]. Thus the conservatism built into the MCL derivation process already incorporates an additional margin of safety for potential inhalation exposure of drinking water volatile organic compounds. (Butler, p. 10)

Dr. David Monroe expressed the opinion that inhalation exposures were frequently greater than exposures from drinking water. He provided the example of trichloroethylene and suggested that Ecology's use of an inhalation correction factor of two would underestimate health risks.

Ecology's Response: Ecology has considered the above comments and adopted the following approach:

- Inhalation of compounds volatilized from tap water is a significant exposure pathway and must be considered in establishing cleanup levels. This is consistent with the conclusions of NAS (1986), EPA (1990a) and others.

- This requirement will apply to volatile organic compounds (VOCs) and to compounds with molecular weights, diffusion, constants and Henry's Law constants similar to VOCs.

- It should be assumed that inhalation exposure to volatile chemicals during showering and bathing is equivalent to exposure from ingesting two liters of the same water per day, unless data is available to perform contaminant-specific evaluations. This is consistent with the conclusions of NAS (1986) and EPA (1990a).

- Inhalation-based risks should be calculated using appropriate inhalation reference doses and potency factors (where available).

Issue #11: Does the proposed regulation provide Ecology with an appropriate amount of discretion in establishing ground water cleanup levels for individual sites?

In the proposed rule, Ecology specified various procedures for developing ground water cleanup levels. Ecology also reserved the right to establish more stringent cleanup levels for individual sites at "[a]ny other concentration which the department determines are necessary to protect human health and the environment."

Several participants expressed the opinion that this provision represented an "impermissively" broad delegation of authority to Ecology (see Syrdal, p. 11; Burch, p. 2; Thomson p. 5). Others such as Mr. Izatt urged Ecology to clarify that concentrations protective of the environment will be established on a case-by-case basis (p. 6). This issue, along with Ecology's response is discussed in greater detail in Section III.

Issue #12: What is an appropriate ground water point of compliance?

In the proposed rule, Ecology specified that the ground water cleanup levels would generally need to be attained throughout the site (WAC 173-340-720). However, the proposed rule also provided the department with the flexibility to establish "conditional points of compliance" in situations where hazardous substances remain on-site as part of the cleanup action. Ecology proposed conditional points of compliance:

> A conditional point of compliance which shall be as close as practicable to the source of hazardous substances, not to exceed the property boundary. Where a conditional point of compliance is proposed, the

person responsible for undertaking the cleanup action shall demonstrate that all practicable methods of treatment are to be utilized in the site cleanup. (WAC 173-340-720(6)(c))

[The department also proposed procedures for establishing conditional points of compliance in situations where ground water discharges to surface water. These are discussed in the following section.]

Several individuals expressed the opinion that conditional points of compliance were inappropriate. (See Tabbutt, p. 4; and Wishart, p. 2)

Other participants expressed the opinion that Ecology should provide additional flexibility to establish points of compliance beyond the property boundary:

> WAC 173-340-720(6)(c) The limitation of the point of compliance to the property boundary could create a substantial problem in many cases. For example, if hazardous substances are left on the cleanup site, but beyond the property boundary, in a contained position, the point of compliance would have to be within or underneath the contained substances. This could prove to be totally unworkable. There are certainly instances where the neighboring property owners will not sell the property so as to move the property boundary to alleviate this problem. (Syrdal, p.13)
>
> **********
>
> Section 173-340-720 - Point of Compliance. WAC 173-160-205 states that wells shall not be located within one thousand feet of solid waste landfills. Thus, for a solid waste landfill, the point of compliance for the groundwater pathway should be a thousand feet from the boundary of the site. (Jones, p. 2)

Ecology's Response: Ecology believes it is appropriate that ground water cleanup levels be achieved throughout the area of contaminated ground water. This would require that the entire plume be cleaned up to concentrations at or below clean up levels. While this is the general requirement, Ecology recognizes that there may be situations where it will be impractical to cleanup ground water throughout the site. Consequently, the department has provided some flexibility to establish "conditional points of compliance" as close as practicable to the source of contamination, not to exceed the property boundary. Similar approaches are specified in the National Contingency Plan (EPA 1990a), the proposed corrective action requirements for hazardous waste management facilities (EPA 1990h), and state rules for ground water, hazardous waste management and solid waste.

With respect to conditional points of compliance, Ecology considered two primary options:

- As close as practicable to the edge of contamination not to exceed the property boundary: and
- At the point of actual exposure

Incorporating the flexibility to select the wellhead as the point of compliance was recommended by several individuals on the grounds that it is the most cost-

effective alternative. Ecology believes this option is inappropriate in that it:

(1) Overlooks the technical uncertainties associated with the accurate prediction of ground water movement and the costs associated with contaminating future water supplies;

(2) Is only applicable to sites with contaminated public water supplies;
(3) The actual cost-effectiveness is questionable given the dilution that occurs between the source and the drinking water well. [Such cleanups may have low annual costs, but generally have to be operated for longer periods of time than a cleanup that addresses the source of contamination in an expedited manner.]; and

(4) The option requires the greatest reliance on institutional controls.

Issue #13: What is an appropriate point of compliance for ground water discharging to surface water?

Ecology proposed:

> At sites where affected ground water discharges to nearby surface water, the cleanup level may often be based on protection of the surface water. If a conditional point of compliance is approved at such a site, it shall be located within the ground water and at an upland location that is as close as practicable to the interface between the ground water and surface water. At these sites use of a dilution zone under WAC 173-201-035 to demonstrate compliance with surface water cleanup levels shall not be allowed.

Several participants expressed concerns that this provision was inconsistent with procedures for point source discharges and urged Ecology to incorporate the flexibility to consider "dilution zones" for non-point sources. For example:

> Boeing opposes the failure of the proposed rules to recognize dilution when applying surface water standards to groundwater cleanups. WAC 173-340-720(6)(d). We believe this position is indefensible on numerous grounds. Even in a permit context, the use of a dilution zone is done on a case by case basis depending upon parameters such as flow volume, receiving water volume and receiving water flow. (Thomson, p. 5)

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> Groundwater: Dilution zones should be permitted where groundwater discharges to surface waters. A dilution zone concept acknowledges the change in media, the disparate concentrations between and within the two media and increased natural recovery processes. The regulation implies the extremely conservative and incorrect assumption that groundwater concentrations are indicative of receiving water concentrations. Point of compliance will be very difficult to prove in situations where separate aquifers at various depths are interactive, particularly if background levels or

> sources vary by aquifer as happens in Commencement Bay. (Sacha, p. 2)

Other participants who recommended similar approaches include the following: Ryan p. 2; Syrdal, pp. 13-15; Burgess and Dunster, p. 6; and Schadt, p. 1 of his comments attached to the statement of Aldrich.

Several participants identified potential technical and regulatory issues that should be considered by Ecology:

> The issue of the point of compliance for groundwater discharging to surface water may require additional clarification. The effect of such influences as tides or lateral infiltration from adjacent waterways results in a de facto dilution zone as the premodient component of the sampled water is provided by the surface water feature. If the intent of the standard is to obtain mixed water samples, the language is suitable. However, if the intent is to obtain uninfluenced groundwater samples, the compliance point may be substantially removed from the groundwater/surface water interface. (Findley, p. 3)

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Finally, Mr. Syrdal submitted lengthy comments providing his rationale for incorporating language authorizing dilution zones for ground water discharges to surface water. He stated:

> To require meeting surface water criteria within the groundwater would result in needlessly expensive cleanup actions with no overall benefit to human health or the aquatic environment. These changes are also necessary to meet several of the other objectives for cleanup standards, including the preservation of the integrity of existing programs in a scientifically and legally defensible system. Comments regarding these other objectives are as follows:
>
> 1. The mixing zone regulation being developed by the state is acknowledging that even stormwater will not have to meet acute criteria at the end of pipe and will be eligible for a dilution zone.
>
> 2. Fresh water flows into salt water bodies both by surface flow and by ground water seep. Fresh water is acutely toxic to marine organisms due to the lack of salt, yet somehow marine organisms survive these events. The toxicity is naturally reduced (salt is added) by dilution.
>
> 3. WAC 173-201-035(2) notes that "[i]n brackish waters of estuaries, where the fresh and marine water quality criteria differ within the same classification, the criteria shall be interpolated on the basis of salinity." Salinity changes happen only with dilution, so interpolation of standards imply some dilution whether or not a formal dilution zone has been assigned in a permit.
>
> 4. The determination of whether a dilution zone may be permitted is usually done in a permit on a case-by-case basis considering such things as the volume of flow and the volume of a receiving water, or the flow in the receiving water. The problem is that dilution

zones are only allowed for authorized discharges under the NPDES system and ground water flow doesn't fit that neat category.

5. In the case of ground water flows into surface waters, the flow that would be associated with a contaminated site will (in most cases) be small relative to the total ground water flow to the surface water body. The flow in the surface water past the site may be quite large by comparison. The volume of the receiving water may be considerable. If the surface water is tidally influenced, the ground water may be diluted by tidal action in the water table before it even emerges. The hardness may change. Dissolved metals may bind to organic particles or precipitate out due to chemical changes as the ground water nears the point at which it will emerge. Once ground water emerges to a salt water body, it will very briefly be fresh water and then be diluted with the salt water. Hence, the fresh water standard would apply, at the hardness of the water when it emerged, and then the standard would change to a salt water standard, requiring interpolation over a salinity gradient. Such interpolation between standards, already required by WAC 173-201-035(2), carries with it a de facto consideration of dilution. A comparable dilution consideration is appropriate for a discharge to fresh water. (Syrdal, p. 13-15)

Ecology's Response: Ecology finds the above arguments very persuasive and intends to revise the rule to specify that where cleanup levels are based on protecting nearby surface waters, compliance with those standards will generally be based on surface water monitoring performed as close as possible to the ground water/surface water interface. Although this provision will not provide for approval of an explicit dilution zone, Ecology believes that this approach will provide for a "de facto" dilution zone because of the relatively low ground water flows. The rule will provide several constraints on the use of this provision:

(1) Ground water discharges must be provided with AKART prior to release;

(2) Ground water discharges must not result in violations of sediment quality values; and

(3) Ecology may require ground water monitoring to be performed to determine contaminant flux rates and to address concerns regarding potential bioaccumulation of hazardous substances at surface water concentrations below detection limits. Should this monitoring indicate a potential problem, the point of compliance may be moved back up into the ground water system.

Issue #14: Should compliance with groundwater cleanup levels be based on filtered or unfiltered samples?

Ecology proposed that:

> Compliance with groundwater cleanup levels shall be determined by analyses of unfiltered groundwater samples, unless it can be demonstrated that a filtered sample provides a more representative measure of groundwater quality. (WAC 173-340-720(8)(a))

Several participants expressed concerns with this approach. for example:

It is extremely difficult in many shallow Puget Sound aquifers comprised of silt and sand to construct a well that is sediment free. Our concern in such aquifers is that concentrations of metals, for example, are often erroneously elevated due to the detection of sediment associated metals. We recommend that Ecology include in the regulations an allowance for filtering metal samples under such conditions. In addition, in sediment-laden groundwater samples, compounds such s PAHs are often not detectable at concentrations which MTCA has indicated to be detection limits. Thus, we recommend the inclusion of specific language to address this commonly occurring situation. (Patmont and Wineman, p. 5)

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Use of unfiltered ground water samples is not appropriate in most cases for determining compliance with the ground water standards. One of the principle data quality objectives for an environmental investigation is to ensure that samples are representative. In many situations unfiltered samples from monitoring wells (particularly in low yield monitoring intervals) will not provide samples that are representative of contaminants that are mobile in the ground water flow system. A representative sample of ground water should contain only those constituents that are mobile in the ground water flow system under natural gradients or what would enter a water supply well. Groundwater flow systems contain dissolved constituents and suspended colloids, but do not contain settleable solids.

There are fundamental differences between the construction and operation of a water supply well and a monitoring well. When initially drilled, a drinking water well produces water that may contain particulates in substantial amounts. Suspended solid particles in a water sample is called turbidity. Such wells are developed or stabilized by running sufficient water through the system to ensure that the sediments are exhausted. As a result, the turbidity of water supply wells usually stabilizes at extremely low levels. Many contaminants are extremely sensitive to turbidity as a result of high absorption to soil particles in the aquifer matrix due to high soil-water partition coefficients. EPA recognizes the importance of turbidity in the analysis of ground water and generally requires a turbidity of less than 5 N.T.U. when the analytical method is sensitive to turbidity.

Ideally the same well development procedure should be followed for monitoring wells to ensure that samples are representative of those that would be obtained from a supply well. However, this is not normally feasible with a monitoring well. Extremely large quantities of water, potentially requiring collection and treatment, would be produced to develop a monitoring well to the degree a supply well is developed.

Many monitoring wells are installed in low yield fine-grained formations where such development is not possible. In addition, monitoring wells are normally only used periodically for sampling and are not in continual use like a supply well. This allows the buildup of sediments and precipitates that would require

redevelopment each time the well is sampled to ensure a representative ground water sample is obtained.

We recommend that unfiltered ground water samples only be required if it is feasible to obtain samples having a turbidity less than 5 N.T.U., or it can be demonstrated that the parameters being analyzed are not sensitive to turbidity. Filtered samples should be allowed (without having to make a demonstration) for certain parameters sensitive to turbidity (i.e., metals) when turbidity exceeds 5 N.T.U. Other methods such as settling centrifugation, and decanting may be required for certain parameters (i.e., semi-volatile organic compounds) for which filtering may not be appropriate. (Burgess and Dunster, p. 7)

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This subsection requires analysis of unfiltered groundwater samples to demonstrate compliance, but allows (as a less preferred choice) filtered samples where it provides a more representative measure of ground water quality. Unfiltered samples do not properly characterize what is bio-available in groundwater and are not, in most cases, representative of contaminants that are mobile in the groundwater system. Filtered samples should be the preferred method for analysis. (Syrdal, p. 15)

Similar comments were provided by the following individuals: Butler, p. 3; and Izatt, p. 6.

Ecology's Response: The department recognizes there is no universal agreement on the issue of whether filtered vs. unfiltered ground water samples should be used when evaluating metal contamination. However, Ecology believes the use of unfiltered samples is consistent with a number of other regulatory programs who are currently requiring analysis of unfiltered samples. For example, both the RCRA Technical Enforcement Guidance (EPA, 1989e) and Superfund guidance recommend analysis of both filtered and unfiltered samples.

This approach is also consistent with the recent findings and recommendations of EPA's Regional Superfund Ground Water Forum. The Forum, which is composed of ground water experts from EPA's regional offices, concluded:

> The findings and recommendations of the committee were that use of a 0.45 micron filter was not useful, appropriate, or reproducible in providing information on metals mobility in ground water systems, nor was it appropriate for determination of truly "dissolved" constituents in ground water. A dual sampling approach was recommended, with collection of both filtered and unfiltered samples. If the purpose of the sampling is to determine possible mobile contaminant species, the unfiltered samples should be given priority. This means that added emphasis is placed on appropriate well construction methods, materials and ground water sampling procedures. For accurate estimations of truly "dissolved" species concentrations, filtration with a nominal pore size smaller than 0.45 microns was recommended. It was further concluded that filtration could not compensate for inadequate construction or sampling procedures. (Puls and Barcelona, 1989)

The department recognizes that there may be practical problems in interpreting metals data from unfiltered samples. Results can be highly variable making statistical comparisons less sensitive to small changes in water quality. This problem is often traceable to the fact that metals occur naturally in soils. When a silty sample is placed in a bottle and acidified (as per lab requirements) this brings some of the naturally occurring metals on the soil particles into solution. Depending on the amount of silt in the water, the same well can yield vastly different results.

Organic contaminants represent a difficult problem. Filtering of organically contaminated waters is generally not recommended since much of the organics can be lost during the filtering process due to volatization and absorption on the filling apparatus. The suggestion to use non-standard techniques such as centrifugation and/or decanting, while it has merit, is not sufficiently developed as a standard protocol to include as an option. There is also a concern that if the soil matrix is so contaminated with sorbed organics, it is inappropriate to consider the ground water clean.

In many cases, this problem can be eliminated with proper well development. However, monitoring wells are sometimes screened in silty formations. When this is the case, it is very difficult, if not impossible, to develop the monitoring well to the point that truly clear samples can be obtained (as in a production well).

Ecology believes the cleanup rules provide sufficient flexibility in that it is specified that compliance will be based on unfiltered samples "unless it can be demonstrated that a filtered sample provides a more representative measure of ground water quality." The Department has added clarifying language to reflect our expectations that filtering will generally be allowed for naturally-occurring inorganics and that unfiltered samples will be required where colloidal transport is a potential problem, and organic contaminants are being analyzed for.

Issue #15: What is the appropriate way to evaluate the mean of groundwater data sets with non-detectable valves?

It is generally recognized that trace levels (parts per billion or lower) may pose a risk to human health and the environment. Evaluating compliance with standards is frequently complicated by hazardous substance concentrations that are below detection limits established by analytical laboratories. To address this problem, Ecology proposed:

> (g) For purposes of demonstrating compliance with ground water cleanup levels, measurements below the method detection limit shall generally be assigned a value equal to one half the method detection limit. Measurement above the method detection limit but below the practical quantitation limit shall generally be assigned a value equal to the method detection limit. The department may approve alternate statistical procedures for handling non-detected values or values below the practical quantitation limit. (WAC 173-340-720(8)(g))

Several participants stated that there may be situations where assigning a value of less than one-half the method detection limit would be appropriate and

urged the Department to provide sufficient flexibility in the rules to address such situations. For example:

> Depending on the specific site, the method in which values below the detection limit are handled may have a significant effect on determining compliance. At sites with numerous monitoring wells and a site-averaging approach to determining compliance, more lenient language should be used for values below detection limit. In certain situations it may be appropriate to use less than one half the detection limit and the regulation should reflect this. (Schadt, p. 1)

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> The U.S. EPA recognizes that assuming non-detectable samples are one-half the detection limit can result in problems and artificially high estimates of exposure concentrations. For example, because of potential sample-specific problem such as matrix interferences, detection limits from some samples may be unusually high and can greatly exceed the positive results reported for the same chemical in other samples in the data set. Consequently, U.S. EPA (1989b p. 5-10) recommends that one "exclude the samples from the quantitative risk assessment if they cause the calculated exposure concentration...to exceed the maximum detected concentration for a particular sample set." U.S. EPA also indicates that zero could be assigned to non-detected values in the case where site-specific information indicates that a chemical is not likely to be present in a sample. (Tsuji, p. 6)

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> The first of these are the methods for handling environmental samples with concentrations at or below the detection limit. It appears quite likely that the accepted procedures for such samples will change significantly over the next few years, and it would be desirable to maintain flexibility in the wording of the regulation. This could be done by listing several different methods for handling censored data. (Science Advisory Board, p. 5)

Similar comments were provided by Burch, p. 2; and Chou, p. 3.

Ecology's Response: Ecology is expanding this section to identify other procedures for handling environmental samples with concentrations at or below the detection limit. These include log-probit analysis (Travis and Land, 1990), parameter estimation, goodness of fit and regression (Porter, et al, 1988).

Issue #16: What statistical procedures are appropriate when the same location (monitoring well) is sampled repeatedly over a period of time?

The Science Advisory Board urged Ecology to distinguish between several types of monitoring situations. Specifically they stated:

> With regard to sampling procedures, the Board believes that it is important to distinguish between cases in which the same location is to be sampled repeatedly over a period of time (e.g., a monitoring well) and cases in which a set of samples is to be taken at the same time from selected representative locations. The justification for applying the same statistical tests in both situations is not evident. For example, the confidence interval approach, which assumes random sampling of a normally distributed population, does not appear to be applicable to multiple samples taken from the same monitoring well. (Science Advisory Board, p. 5)

Ecology's Response: Ecology recognizes that it may be inappropriate to use the upper 95% confidence limit of the mean as the compliance criterion where data are obtained from a monitoring well over a period of time. Specifically, this method is inappropriate where measured concentrations are time-dependent or deviate significantly from normality. In such cases, WAC 173-340-720(8)(d)(iii) provides for "other statistical methods approved by the department."

Examples of other methods which could be used include:

(1) Calculation of a nonparametric 95% confidence interval; or

(2) Use of regression analysis to calculate the 95% confidence limit for the predicted concentration at the latest sampling time. In this case, the standard error of the predicted concentration, rather than the standard error of the mean, can be used to calculate the upper 95% confidence limit. Alternatively, if it becomes evident that concentration measurements are time-dependent, Ecology may require that repeated sampling over a short period of time be conducted to provide data for statistical analysis.

As an example, replicated measurements could be made on each sample and an analysis of variance could be used to compare within and between-sample components of variance. If the within-sample component is high, it may be appropriate to use the between-sample variance for statistical tests of compliance.

Issue #17: Do the compliance monitoring requirements provide an incentive to collect additional data?

The Science Advisory Board stated:

> The requirements of WAC 173-340-720(7)(e)(ii) and (iii) and (7)(f), in contrast to those of (7)(e)(i), may under certain circumstances provide a disincentive to adequate sampling. The confidence interval approach should tend to lead to extensive sampling, since taking a greater number of samples will reduce the error in the sample statistics. However, it would also be expected that for measurements near the MDL (or PQL), and near the compliance cleanup level, the analysis will be more difficult and the error unavoidably larger. In such a circumstance, it will not be uncommon for a single sample to have a concentration two times the

cleanup level or for 10% of samples to exceed the cleanup level by a small amount. Specific numerical factors such as these should be based on experience from prior successful cleanups or should be set on a case-by-case basis, taking into account both the characteristics of the site and those of the contaminant. (p. 5)

Ecology's Response: Ecology acknowledges that problems in demonstrating compliance may arise where the cleanup level is close to the MDL (or PQL). Two ways to reduce the error due to laboratory analysis problems are:

(1) To use a more precise analytical method that has a smaller measurement error; and

(2) Perform multiple laboratory measurements on each sample and use the average or median measurement in statistical analyses. In addition, the provision for "other statistical methods approved by the department" provides for flexibility in dealing with such problems.

WAC 173-340-720(7)(f) provides that "if a method to test the proportion of ground water samples is used to evaluate compliance with a ground water cleanup level, compliance shall be determined using the following criteria:

(i) Less than 5% of the sample concentrations shall exceed the ground water cleanup level; and

(ii) The mean of the ground water concentrations which are above the ground water cleanup level shall be less than twice the ground water cleanup level."

These requirements provide no incentive to conduct adequate sampling, and (ii) provides a disincentive. A similar problem arises for this method when applied to soils (WAC 173-340-740(f)). It is not obvious from the current wording that the criterion in (i) deals with population, rather than sample, parameters and is therefore a requirement for statistical inference.

The proposed solution would be to change (i) to read:

(i) The true proportion of samples that do not exceed the ground water cleanup level shall not be less than 95%. Statistical tests shall be performed with a Type I error level of 0.05.

The same modification should be applied to the wording in the soil cleanup level.

Issue #18: Is there a sound scientific basis for utilizing the same compliance monitoring procedures irrespective of the number of substances present?

The Science Advisory Board expressed concern "that the effect of the regulation will be to apply the same procedures described for individual substances to all sites irrespective of the number of contaminants present. It is not evident where there is a scientific basis for this approach." (p. 5-6)

Ecology's Response: Ecology believes that the language regarding statistical analyses requirements provides flexibility for site-specific conditions. It does not necessarily require the same compliance procedures irrespective of the number of substances present.

When statistical tests are conducted for a number of contaminants, the risk of a Type I error (i.e., falsely concluding the site is clean) may increase. Ecology believes the use of indicator hazardous substances reduces the potential for these types of problems. However, Ecology is considering the option of specifying a lower Type I error rate for each test (e.g., 0.01 instead of 0.05). On the other hand, analyses of other contaminants can serve as a safeguard against accepting a false conclusion that the site is clean simply on the basis of chance significance for one particular contaminant.

Issue #19: What is the relationship between the proposed groundwater cleanup standards and the proposed "Water Quality Standards" for groundwaters of the State of Washington (Chapter 173-200 WAC)?

The Department of Ecology is concurrently developing groundwater requirements under both the Model Toxics Control Act and the Water Pollution Control Act. Several participants expressed concerns about the relationship between the two sets of requirements. For example:

> Assuming that the overall intent of groundwater standards under WAC 173-340-720 of MTCA and WAC 173-200 (Water Quality Standards for Groundwaters of the State of Washington) is similar, we recommend Ecology address the differences between these two proposed sets of standards. Although different standards may apply to different sites, we envision numerous difficulties arising from the application of two different sets of groundwater quality standards to groundwaters of the State of Washington. Furthermore, federal drinking water standards for maximum contaminant levels under 40 CFR 141 also differ for several constituents. We feel that a consensus should be reached with the agency on a groundwater concentration adequately protective of human health and the environment on a compound-by-compound basis. If no consensus can be reached due to different objectives, we recommend clarification of site specific application. (Patmont and Wineman, p. 4)

Ecology's Response: Ecology intends to utilize the cleanup standards developed under the Model Toxics Control Act to establish cleanup levels at contaminated sites. To clarify that point, the final ground water standards (Chapter 173-200 WAC) specify that such standards are not applicable requirements for actions taken under MTCA and CERCLA.

XVIII. SURFACE WATER CLEANUP STANDARDS (WAC 173-340-730)

A. Background

Surface water has been identified as a potentially affected medium at approximately 50% of Washington cleanup sites (Ecology 1990a). When establishing cleanup levels for these types of sites, Ecology has traditionally utilized an approach similar to that used in the federal Superfund program and based cleanup levels on applicable or relevant and appropriate requirements (ARARs) under other state and federal laws. These requirements include:

(1) Federal water quality criteria developed under Section 304 of the Clean Water Act (EPA 1986g) and;

(2) Water quality standards for surface water (Chapter 173-201 WAC).

B. Ecology's Proposal

Ecology proposed that surface water cleanup standards would be based on estimates of the highest beneficial use that a body of surface water could be expected to sustain, either currently or in the future. These standards would be applicable to bodies of water that are threatened or potentially threatened by sites defined in the MTCA. The proposed rule identified:

(1) Applicable state and federal laws;

(2) Procedures for establishing cleanup levels for substances not addressed under applicable state and federal laws; and

(3) Procedures for establishing points of compliance.

In the proposed rule, Ecology identified the following applicable state and federal laws:

(1) Water Quality Standards for Waters of the State of Washington (Chapter 173-201 WAC); and

(2) The Federal Water Quality Criteria developed under Section 304 of the Clean Water Act.

These requirements formed the basis for the Method A cleanup levels. Ecology also defined the risk assessment procedures to be utilized to supplement those requirements (Methods B and C).

Ecology proposed that these standards would generally have to be met throughout the cleanup site. Ecology provided the flexibility to establish dilution zones for point source discharges on a case-by-case basis consistent with the requirements in Chapter 173-201 WAC ("conditional point of compliance"). The proposed rule also specified that such dilution zones would not be authorized for ground water discharges to surface waters.

C. The Public Response

A considerable number of participants provided comments on the surface water requirements and a wide range of opinions were expressed. The principal issues raised during the rulemaking proceedings were the following:

Issue #1: **Is it appropriate to include procedures for establishing surface water cleanup levels in this regulation?**

Issue #2: **What surface waters are subject to the proposed regulations?**

Issue #3: **Should the federal water quality criteria be defined as "applicable state and federal laws?"**

Issue #4: **What are reasonable estimates of average and upper limit fish consumption rates?**

Issue #5: **What are reasonable estimates for fish diet fractions?**

Issue #6: **What is an appropriate methodology for estimating surface water concentrations which will prevent unacceptable levels of hazardous substances in fish and shellfish?**

Issue #7: **Does Ecology have the discretionary authority to establish surface water cleanup levels more stringent than those in the proposed rule on a case-by-case basis?**

Issue #8: **Has Ecology provided an appropriate amount of flexibility in the procedures for establishing surface water cleanup levels?**

Issue #9: **Should Ecology adopt regulations which provide the flexibility to establish dilution zones for point and nonpoint sources of hazardous substances?**

Issue #10: **What is the appropriate way to evaluate the mean of ground water data sets with non-detectable or non-quantifiable values?**

Issue #11: **How would the surface water cleanup standards be applied to a discharge from a contaminated site where the background surface water quality already exceeds cleanup standards as a result of discharges from other point or nonpoint sources?**

Issue #12: **Under what circumstances would sampling of fish provide information that could be used to evaluate compliance with surface water cleanup standards?**

D. Ecology's Evaluation and Response

Issue #1: Is it appropriate to include procedures for establishing surface water cleanup levels in this regulation?

During the rulemaking process, several individuals questioned the need to develop requirements for surface waters. For example, Mr. Syrdal, in his general comments on WAC 173-340-730, stated:

> This entire section should be deleted. Cleanups of surface waters are accomplished by source controls. If the sources are point sources, they are dealt with under the NPDES system and do not belong here. If the source of concern is a contaminated groundwater flow, that is handled under the cleanup of the affected groundwater and soils. With surface waters, dispersion and replacement is far more rapid than with ground water or soils. (Syrdal, p. 16)

Aldrich, p. 16, provided similar comments.

Ecology's Response: Ecology agrees that the majority of cleanup actions addressing surface water problems are source control actions that will often require some type of discharge permit. In recognition of that fact, Ecology has specified that the state's water quality standards will be used to establish surface water cleanup levels, and discharges must be provided with "all known available and reasonable methods of treatment" (AKART) [see WAC 173-340-710]. However, given the wide range of contaminants found at cleanup sites, Ecology believes that additional procedures are needed to supplement the water quality regulations in order to:

> (1) establish cleanup requirements for hazardous substances not adequately addressed under the state and federal water quality programs;
>
> (2) establish cleanup requirements where multiple hazardous substances are present; and
>
> (3) integrate surface water requirements with those for other media such as soil where there is the potential for exposure via more than one exposure pathway.

Issue #2: What surface waters are subject to the proposed regulations?

During the rulemaking, several participants, including Syrdal (p. 8 of comments on October 16, 1987 draft), stated it was unclear what surface waters were addressed by this regulation.

Ecology's Response: The definition of surface water utilized in this chapter is the same definition utilized in the water quality laws and regulations. Under this definition, surface water is broadly defined to include:

(1) Water bodies such as lakes, rivers, ponds, streams and the Sound which have traditionally been recognized as surface water bodies; and

(2) Water bodies such as wetlands and storm water runoff.

WAC 173-340-730(1) has been revised to clarify that surface water cleanup standards only apply to those surface waters that are affected or potentially affected by hazardous substances released from a facility addressed under this chapter.

Ecology has also reviewed how this section would be applied to stormwater runoff. On the one hand, Ecology is concerned that if the water quality standards are not applied to runoff from a contaminated site, compliance with cleanup standards could be easily demonstrated without taking actions to prevent stormwater contact with contaminated soils. On the other hand, Ecology does recognize that a strict application of water quality standards to stormwater runoff would not be practicable for many sites, especially those with ongoing operations. Based on these considerations, Ecology has revised the rule to provide a mechanism for a person to demonstrate that surface water cleanup levels (independent of whether they are based upon water quality standards [Chapter 173-201], water quality criteria or the risk equations) are not relevant and appropriate under some site-specific circumstances. For example, Ecology does not expect that cleanup levels will be applied to storm water runoff that is in the process of being conveyed to a treatment system, provided that runoff from other areas was kept separate from the on-site runoff.

Issue #3: Should the federal water quality criteria be defined as "applicable state and federal laws?"

In the proposed rule, Ecology listed federal water quality criteria as "applicable state and federal laws." Several participants recommended that Ecology provide more flexibility to evaluate whether the federal criteria should be applied to a specific site. For example:

> WAC 173-340-730(2)(a)(ii). This subsection should be revised to indicate that federal water quality criteria are not automatically applicable, but should be required only as relevant and appropriate on a site-by-site basis depending on the nature of the organisms found at the site and the type of organisms upon which the water quality criteria were based. (Syrdal, p. 16)

Aldrich, p. 16, provided similar comments.

Ecology's Response: Ecology believes that the Federal Water Quality Criteria are generally applicable to cleanup sites, but agrees that the regulation should provide the flexibility to demonstrate that certain values are not relevant and appropriate for specific sites. The rule will be revised to incorporate an approach similar to the provisions in Section 121 of CERCLA, the National Contingency Plan (NCP 1990a), and the Water Quality Standards for Waters of the State of Washington (Chapter 173-201-047(2-4) WAC).

This revision is directed towards providing a mechanism to review the human health criteria values in light of new information and new assessment

procedures. When making a determination that a particular human health criterion is not relevant and appropriate, Ecology will consider:

(1) The use of the receiving water body;

(2) Purposes of the criterion; and

(3) New scientific information.

The Department believes that the water quality criteria for protecting aquatic organisms are relevant and appropriate for cleanup sites. However, the revised rule will also provide the flexibility to develop site-specific water quality criteria using essentially the same procedures used to develop the national criteria (EPA 1983). EPA (1983) describes three methods for deriving site-specific water quality criteria:

> Recalculation procedure: Calculation of criteria based on modification of the national database to exclude species that are not resident at the site. This approach accounts for differences in the sensitivity of resident species to a chemical relative to species represented in the national database.
>
> Indicator species procedure: Calculation of criteria based on the results of bioassays of site water using indicator (non-resident) species. This approach accounts for differences in the bioavailability and toxicity of a chemical related to physical or chemical characteristics of site water.
>
> Resident species procedure: Calculation of criteria based on the results of bioassays of site water using resident species. This approach accounts for differences in species sensitivity to chemicals and differences in bioavailability and toxicity related to physical or chemical characteristics of site water. (EPA 1983, as summarized by PTI, 1990)

In general, when comparing the nature of the organisms at the site and the type of organisms upon which the water quality criteria were based, Ecology will consider that results from similar organisms found in other parts of the country to be relevant and appropriate indicators of potential threats to organisms in Washington.

Issue #4: What are reasonable estimates of average and upper limit fish consumption rates?

Ecology proposed using a fish consumption rate of 30 g/day when establishing surface water cleanup levels that address human health concerns related to the consumption of contaminated fish and shellfish.

During the rulemaking process, a number of participants provided comments on what Ecology should consider to be a reasonable fish consumption rate. For example:

> The use of 13 grams/day as the fish consumption rate is probably too high. The US EPA Superfund Public Health Evaluation Manual uses a figure of 6.5 grams/day for surface water fish. Fish consumption over this

amount is due primarily to deep sea and imported fish. (Merrit, p. 6 of comments on October 16, 1989 draft)

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The 30 grams/day fish consumption rate proposed for the Method A cleanup calculation is not supportable on a site specific basis, particularly when used in conjunction with EPA's conservative cancer potency factor. Consumption rates may vary depending on several site related factors such as the type of waterbody involved (fresh vs. marine). The cleanup level calculations should allow for the development of fish consumption rates based on applicable variables for a particular site. If the EPA cancer potency factors are used, EPA's 6.5 grams/day consumption rate should also be retained to avoid calculating an excessively conservative level. (Holm, p. 2 of comments on December 29, 1989 draft)

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"The risk assessment clean up based methodology utilizes fish consumption rates that may not accurately reflect the diet of Tribal members." (Sullivan, p. 2)

Ecology's Response: Ecology has reviewed the comments on this issue and approaches being utilized by other regulatory agencies and determined that a fish consumption rate of 54 grams/day is a more appropriate value for estimating reasonable maximum exposure levels than the proposed value of 30 grams/day. The value of 54 grams/day is based on the results of a study conducted in Washington (Pierce et al, 1981) and appears to be consistent with approaches utilized by other regulatory programs:

- Exposure Factors Handbook: EPA (1989b) has recently reassessed the information on fish consumption rates and concluded:

  The consumption rate data from Puffer (1981) and Pierce et al. (1981) studies are considered representative of actual annual consumption rates for recreational fisherman. Although these studies were limited to the west coast, it is recommended that these values be used to represent consumption rates for recreational fisherman [sic] in any area where there is a large body of water present and widespread contamination is evident. The values to use under these conditions are the average of the 50th and 90th percentile values reported by Puffer (1981) and Pierce et al. (1981):

50th Percentile	90th Percentile	Reference
36.9 gram/day	224.8 gram/day	Puffer (1981)
23.0 gram/day	54.0 gram/day	Pierce et al. (1981)
30.0 gram/day	140.0 gram/day	Average

  Additional factors to consider when using data derived from these studies include location, climate and ethnic makeup of the fishing population...." (EPA 1989b)

- EPA Risk Assessment Guidelines: EPA (1989a) specifies values of 132 gram/day (95th percentile daily intakes averaged over three days for consumers of fin fish), 38 grams/day (50th percentile daily intake,

averaged over three days for fin fish), and 6.5 grams/day (daily intake averaged over a year).

- EPA Region X Scope of Work: EPA (1990b) utilizes a fish consumption rate of 140 grams/day to estimate reasonable maximum exposure levels.

- EPA Draft National Guidelines: EPA is currently in the process of developing national exposure assessment guidelines for Superfund. The current draft recommends the use of a fish consumption rate of 54 grams/day (HMCRI 1990).

- The Puget Sound Estuary Program: The Puget Sound Estuary Program (EPA, 1988) reviewed fish consumption data from five surveys in the Puget Sound area and estimated average and upper 95th percentile values of 12.3 and 95.1 grams/day, respectively.

The Department recognizes that there may be areas where site-specific considerations would require the use of a higher fish consumption rate. Under section 173-340-705(10)(b), Ecology may utilize a higher site-specific value in order to protect populations that are at greater risk than the general population (e.g., Indian tribes consuming large quantities of local fish).

Finally, several individuals recommended that Ecology continue to utilize a fish consumption rate of 6.5 grams/day. This value was used to establish the federal water quality criteria (EPA 1980) and was based upon the results of a nationwide survey of nearly 25,000 persons performed by Javitz (1980). In that study it was estimated that the average rate of consumption of fish and shellfish in the U.S. is 14.3 gm/day; average consumption of fish alone was estimated as 6.5 grams/day. Ecology believes that continued reliance on these values for purposes of establishing cleanup levels suffers from two primary shortcomings. First, as summarized above, more recent information supports the use of higher consumption rates. Second, the values reported by Javitz (1980) are average values; an upper percentile value is more appropriate for estimating reasonable maximum exposure rates. Finally, estimates from Javitz (1980) are based on the general population. More recent studies have focused on recreational anglers which tend to be a higher risk than the general population.

Issue #5: What are reasonable estimates for fish diet fraction?

The "fish diet fraction" or "exposure frequency" is the ratio of the weight of fish/shellfish tissue consumed from a contaminated source to the total weight of fish/shellfish tissue consumed. Ecology proposed to utilize a fish diet fraction of 50% when establishing surface water cleanup levels with some flexibility to lower that value to 20% on a case-by-case basis. In establishing the proposed values, Ecology has taken into account the wide range of comments received during the rulemaking. For example:

> "The diet factor for fish consumption is unrealistically high. Who in the world would expect to have their fish diet come from the same contaminated source. The use of 50%, while still conservative, is more reasonable." (Eaton, comments on October 16, 1989 draft)

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"Using a diet fraction of 50% is not protective of sports fishing, subsistence fishing or sensitive subpopulations." (Cirone and Schwartz, p. 4 of comments on December 29, 1989 draft)

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"If the site is to have restricted use, it is hard to imagine that a person would eat 20% of their fish diet fraction (30 grams/day) at the site. Recreational fishing at a restricted site should be very limited to non-existent." (Tsuji, p. 7)

Ecology's Response: Several factors were considered in selecting an appropriate fish diet fraction. These include:

- Seasonal fishing patterns: EPA (1989b) summarized seasonal variations in the amount of fish caught in Washington. Based on these results, it appears that 80 to 85 percent of the fish are caught during a six month period from March to August.

- Regulatory approaches by other agencies: EPA (1989b) recommends the use of diet fraction of 20 percent and 20 to 75 percent for average and upperbound estimates. EPA (1990b) recommends the use of 100 percent for estimating reasonable maximum exposures, but notes that 75 percent may be appropriate in some instances. The EPA Water Program has considered the use of diet fractions as low as 0.013 percent. (PTI, 1989)

- Public Comment: Individuals provided a wide range of comments on this issue. Ecology's approach appears to be in the middle of the recommended values.

Based on a review of the above comments and approaches being used by other regulatory programs, Ecology believes that the use of 50 percent and 20 percent fish diet fractions represent a reasonable basis for establishing cleanup levels. The Department recognizes that higher values may be necessary in localized areas. The regulation provides the flexibility to utilize a higher fish diet fraction where site-specific considerations warrant such an approach.

Issue #6: What is an appropriate methodology for estimating surface water concentrations which will prevent unacceptable levels of hazardous substances in fish and shellfish?

Ecology proposed to utilize fish bioconcentration factors to establish surface water cleanup levels that prevent accumulation of unacceptable levels of hazardous substances in fish and shellfish.

Several participants urged Ecology to provide more detail and flexibility for establishing bioconcentration factors. For example:

> WDOE should recognize that these factors are for the most part out of date and often based on laboratory data which have little relevance for the field because of differences in conditions, environmental factors, and organisms at a specific site. In addition, the chemical form that is accumulated in tissues may not be toxicologically the same as the form in the environment. A good example is inorganic arsenic which fish convert to the relatively non-toxic organic form (USEPA 1988, Battelle, 1989). (Tsuji, p. 1)

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> In our comments on the March draft, we commented upon the use of a bioconcentration factor (BCF). The bioconcentration factor (BCF) should be at least a site and species-specific value when one is proposing cleanup levels on the basis of human health protection. That is, the BCF should be derived from either empirical field measurements, or from a properly conducted laboratory study. The BCF used should come from measured contaminant concentrations in the edible portion of the fish, and of an indigenous species that is actually consumed by people of the State of Washington. (Butler, p. 3)

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> The absence of a specific fish bioconcentration factor (BCF) is confusing. BCFs may vary considerably depending upon the assumptions used. For example, EPA's BCF for dioxin is currently set at 5000 while other regulators are using or proposing to use numbers ranging from 5000 to 500,000. The responsible party should be allowed to develop BCFs or bioaccumulation factors based on site specific considerations and the characteristics of the particular toxicant. (Holm, p. 2 of comments on December 29, 1989 draft)

However, Mr. Burch expressed the opinion that:

> "Ecology must provide greater details on what constitutes "clear and convincing scientific data" which would justify use of a BCF value other than values published by EPA. (Burch, p. 3)

Ecology's Response: Ecology recognizes the difficulties involved in determining and utilizing bioconcentration factors (BCFs) for the calculation of surface water cleanup levels. BCFs are often quite variable between species. Further, in contrast to oral reference doses and slope factors, there is not currently an EPA administered database of bioconcentration factors, though some technical assistance and guidance is available.

Ecology believes that the BCF values established during the development of water quality criteria provide reasonable "default" values to be used in establishing surface water cleanup levels. However, the Department recognizes that more current data may support the use of different values and the rule provides the flexibility to utilize such BCF values.

Ecology will prepare rulemaking guidance which defines criteria for evaluating BCF values. However, in general, when evaluating the use of alternate BCF values, Ecology intends to consider values in the following order of preference:

1. For substances where data is available on bioconcentration factors, Ecology will select a specific BCF value or an arithmetic mean BCF value that reflects the BCF of edible species. Deference will be given to EPA approved research wherever possible.

2. For organic chemicals where no data is available on bioconcentration factors, the log octanol-water partition coefficient will be used to derive a bioconcentration factor assuming a linear correlation. Strong linear correlations have been demonstrated between the log octanol-water partition coefficient and the log bioconcentration factor by several researchers (McBrien, et al, 1987).

3. For organic chemicals, where neither the bioconcentration factor nor the log octanol-water partition coefficient are available, Ecology will assume a linear correlation between the log water solubility and the log bioconcentration factor. A strong linear correlation has been demonstrated between the log water solubility and the log bioconcentration factor.

The use of octanol-water partition coefficients and water solubilities to estimate BCFs is expected to produce conservative estimates of bioconcentration factors (McBrien, et al, 1987). Ecology will consider new scientific data on bioconcentration factors as well as the limitations of methods (2) and (3) in developing bioconcentration factors and will review and update the bioconcentration factors it uses at a time interval not to exceed five years.

Issue #7: Does Ecology have the discretionary authority to establish surface water cleanup levels more stringent than those in the proposed rule on a case-by-case basis?

Several participants recommended that Ecology delete the phrase that would allow the department to establish cleanup levels at "any other concentrations that are necessary to protect human health and the environment...." (see Aldrich, p. 16; Syrdal, p. 16; and Burch, p. 3) This issue, along with Ecology's response, is discussed in greater detail in Section III.

Issue #8: Has Ecology provided an appropriate amount of flexibility in the procedures for establishing surface water cleanup levels?

A number of individuals also urged the department to provide greater flexibility in defining individual exposure parameters. For example:

> WAC 173-340-705(10) This provision indicates that as a matter of policy the Department defines various exposure parameters to be used when estimating cleanup levels under this chapter. This is far too limiting in that the standard exposure assumptions may be totally inappropriate for various site-specific conditions. For example, surface water cleanup standards require certain assumptions regarding fish consumption rates. These assumptions could be extremely far off base for given streams where there are not edible fish populations. (Syrdal, p. 10-11)

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> Section 705(10) This section states that exposure parameters cannot be modified with the exception of the exposure parameters specified in (b). This is too limiting. For example, the surface water cleanup standard requires use of a fish consumption rate of 30 grams/day and a fish diet fraction of 0.5. These exposure assumptions may be totally inappropriate for site specific conditions. There are probably only very isolated conditions where these assumptions would be valid as "reasonable maximum exposure." We understand the desire to establish consistent levels of cleanup, while reducing areas of potential dispute. However, there should be more flexibility to allow realistic RME parameters to be developed for determining the site specific cleanup levels. (Burgess and Dunster, p. 14-15)

Aldrich, p. 10-11, provided similar comments.

Ecology's Response: See discussion in Section V - Issue # 22.

Issue #9: Should Ecology adopt regulations which provide the flexibility to establish dilution zones for point and nonpoint sources of hazardous substances?

The proposed surface water cleanup requirements specified that:

> (a) The point of compliance shall be the point or points at which hazardous substances are released to surface waters of the state unless the department has authorized a dilution zone in accordance with WAC 173-201-035.
>
> (b) Where hazardous substances are released to the surface water by a ground water discharge to the surface water no dilution zone shall be allowed to demonstrate compliance with surface water cleanup levels. See WAC 173-340-720(6)(d) for additional requirements in this situation. (WAC 173-340-730(6))

Several participants expressed support for an approach that provided the flexibility to develop dilution zones for point sources and urged that this concept be extended to include nonpoint sources:

> Surface Water: Point of compliance must take into account surrounding contributions and not penalize the targeted site for contributions from neighbors or upstream properties. Chronic marine standards are frequently too restrictive relative to typical urban stormwater runoff. (Sacha, p. 2)

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WAC 173-340-730(6) This subsection should be changed to read:

(b) Where hazardous substances are released to the surface water by a ground water ~~discharge~~ flow to the surface water ~~no dilution zone shall be allowed to demonstrate~~ compliance with surface water cleanup levels shall be demonstrated by receiving water monitoring. See WAC 173-340-720(6)(d) for additional discussion concerning ~~requirements in~~ this situation. (Syrdal, p. 16)

Ecology's Response: Ecology believes that the use of surface water "mixing" or "dilution" zones for ground water discharges from contaminated sites is inappropriate. We believe it would be inappropriate to allow such mixing zones at contaminated sites for the following reasons:

- It is generally technically possible to eliminate ground water discharges to surface waters through the use of cutoff walls and/or ground water pumping;
- There appears to be no direct public benefit that will result from the approval of a dilution zone; and
- Ground water discharges are very difficult to measure and quantify due to the heterogeneous nature of ground water flow systems and the interface with the surface water body.

As noted in Section XVII (Ground Water Cleanup Standards), Ecology intends to modify the rule to clarify compliance with the cleanup standards to be demonstrated by monitoring in the receiving water body under certain circumstances. The Department believes that this approach, where applicable, will allow for a "defacto dilution zone" in that:

(1) Considerable dilution typically occurs as the groundwater from the site mixes with other ground waters discharging into the surface water; and

(2) The discharge is occurring over a portion of the surface water body instead of a single point.

Issue #10: What is the appropriate way to evaluate the mean of ground water data sets with non-detectable or non-quantifiable values?

It is generally recognized that trace levels (parts per billion or lower) may pose a risk to human health and the environment. Evaluating compliance with standards is frequently complicated by hazardous substance concentrations that are below detection limits established by analytical laboratories. To address this problem, Ecology proposed:

> For purposes of demonstrating compliance, measurements below the method detection limit shall generally be assigned a value equal to one half of the method detection limit. Measurements above the method detection limit but below the practical quantitation limit shall generally be assigned a value equal to the method detection limit. The department may approve alternate statistical procedures for handling non-detected values or values below the practical quantitation limit. (WAC 173-340-730(7)(d))

One individual, Mr. Syrdal, recommended that this provision be modified as follows:

> "WAC 173-340-730(7)(d) As set forth above, measurements above the method detection limit but below the practical quantification limit should be assigned a value equal to one-half the practical quantification limit." (Syrdal, p. 16)

Ecology's Response: See Section XVII (Ground Water Cleanup Standards).

Issue #11: How would the surface water cleanup standards be applied to a discharge from a contaminated site where the background surface water quality already exceeds cleanup standards as a result of discharges from other point or nonpoint sources?

Several individuals requested clarification on the procedures that would be utilized at sites where the background water quality already exceeds cleanup standards as a result of discharges from other point or non-point sources. For example:

> "Point of compliance must take into account surrounding contributions and not penalize the targeted site for contributions from neighbors or upstream properties." (Sacha, p. 2)

Ecology's Response: Under state and federal law, all discharges must be provided with "all known available and reasonable methods of treatment" (AKART). Section 303(d) of the Clean Water Act requires the state to implement water quality-based controls where such technology-based point source controls are insufficient to achieve water quality standards. To meet this requirement, a total maximum daily load (TMDL) must be established for each pollutant violating water quality standards. The TMDL is then apportioned between point and non-point sources as wasteload and load allocations (WLAs and LAs), respectively. Allocations are normally implemented through discharge permits, grant projects and nonpoint source controls.

Ecology recognizes that there are cleanup sites discharging to water bodies which currently exceed water quality standards and where technology-based controls are not expected to achieve water quality standards. In those instances, a TMDL would be established by Ecology's Water Quality Program and the cleanup site would be allocated a portion of the allowable discharge. Under the water quality law, Ecology has considered several allocation methods:

1. Requiring all sources to apply similar treatment technologies or similar load reductions.

2. Requiring all larger sources to bear a disproportionate share of the load allocation.

3. Basing load allocations on cost-effectiveness or sources' ability to pay for reduction.

Issue #12: Under what circumstances would sampling of fish provide information that could be used to evaluate compliance with surface water cleanup standards?

Ecology proposed that:

> "[S]ampling and analysis of fish tissue or shellfish may be required to supplement water column sampling during compliance monitoring."

While one individual, Dr. Lorenzana, expressed support for this approach, Dr. Burgess and Mr. Dunster noted that:

> Sampling of fish to supplement water column sampling is rarely prudent. Fish can be highly mobile and long-lived; therefore, controlled field experimentation to determine compliance with surface water cleanup standards would be quite difficult and likely inconclusive. (Burgess and Dunster, p. 8)

Ecology's Response: Ecology believes that fish sampling data may provide a valuable component of a compliance monitoring program for some hazardous substances. The State of Oregon Department of Environmental Quality (DEQ) has noted that detection of toxic pollutants in the water column is complicated by a number of factors and have proposed amending the state's water quality criteria to specify that fish tissue residue conconcentrations may be used as indicators for determining exceedances of water quality criteria. In support of that approach, the DEQ noted:

> Some states and federal agencies have adopted standards, criteria, or guidelines for evaluating fish tissue information for determining toxicity or have established standards for fish tissue concentrations which would indicate a violation of water quality standard (Appendix A). The state of Michigan and Maine have adopted or in the process of adopting protocols for evaluating fish tissue or adoption of standards for fish tissue.
>
> Benefits of using fish tissue concentrations as another tool for determining deleterious effects to water quality include a method which enables direct measurement of potential beneficial use effects and measurement in a media where these chemicals can be detected.
>
> The adverse effects of using fish tissue concentrations is the movement of fish from one area to another. Wild fish collected in an area may not have accumulated the chemical in that area. Wild fish collected from an area may not be representative of the conditions of water quality in that area, depending on species type and time of year collected.
>
> Caged fish or flow through systems containing fish may be utilized for determining point source affects to waterbodies. Wild fish may be used as a method of determining overall water quality. (DEQ, 1990, p. 6)

Fish sampling data may also be used to develop a scientific basis for modifying bioconcentration factors used by Ecology. Alternatively, such research might be used to demonstrate that a bioconcentration factor used by Ecology is not appropriate at a particular site. (WAC 173-340-708(9))

XIX. SOIL CLEANUP STANDARDS (WAC 173-340-740)

A. The Public's Response

Soil cleanup levels are usually the subject of considerable discussion when developing cleanup requirements for individual sites. Consequently, it is not surprising that there was a considerable amount of public comment on the proposed soil cleanup standards. The principal issues raised during the rulemaking proceedings were the following:

Issue #1: **Is it appropriate for Ecology to distinguish between various land uses when establishing soil cleanup levels?**

Issue #2: **What procedures were utilized to develop the cleanup levels in Table 2?**

Issue #3: **What procedures were utilized to establish the soil cleanup levels for lead?**

Issue #4: **What procedures were utilized to establish the soil cleanup levels for petroleum-related contaminants?**

Issue #5: **What procedures were utilized to establish the soil cleanup level for cadmium?**

Issue #6: **What procedures were utilized to establish the soil cleanup levels for pentachlorophenol?**

Issue #7: **What procedures were utilized to establish the soil cleanup levels for chromium?**

Issue #8: **What is the relationship between the health-based action levels developed under the RCRA Corrective Action program and cleanup levels under the Model Toxics Control Act?**

Issue #9: **What are appropriate procedures for establishing soil cleanup levels to protect ground water?**

Issue #10: **Should Ecology utilize soil leaching tests to establish soil cleanup levels that protect ground water?**

Issue #11: **What are appropriate soil ingestion rate assumptions for use in establishing soil cleanup levels for residential sites?**

Issue #12: **What is an appropriate duration of exposure for estimating soil cleanup levels for carcinogens based on direct contact?**

Issue #13: **What is an appropriate point of compliance for soils which pose a direct contact threat?**

Issue #14: **What is an appropriate point of compliance for soils which pose a threat to ground water?**

Issue #15: **Should Ecology distinguish between exposure concentrations and removal levels?**

Issue #16: **Should compliance with soil cleanup levels be based on total analyses of the soil fraction less than 2 mm in size?**

Issue #17: **What are appropriate statistical procedures for evaluating compliance with soil cleanup levels?**

Issue #18: **What is the appropriate way to evaluate the mean of soil data sets with non-detectable or non-quantifiable values?**

Issue #19: **Is it appropriate to establish soil cleanup levels at concentrations which exceed dangerous waste designation levels?**

Issue #20: **Has Ecology adequately addressed potential exposure to windblown dust or soils?**

B. Ecology's Evaluation and Response

Issue #1: Is it appropriate for Ecology to distinguish between various land uses when establishing soil cleanup levels?

For purposes of establishing soil cleanup levels, Ecology proposed to distinguish between residential and industrial sites and included specific procedures for establishing soil cleanup levels that are protective of those uses. The proposed rule also provided the flexibility to establish site specific cleanup levels for uses such as agriculture and recreation.

Several individuals were critical of this approach, expressing concerns about the potential for uncontrolled land use changes and the creation of "sacrifice zones." Of particular concern was the inclusion of "commercial" sites within the industrial category. For example:

> We do not believe the use of industrial or commercial soil standards is justified. This is not a narrow exemption; almost all sites will fit into either the industrial or commercial category.
>
> The pressure to convert industrial and commercial areas into residential and recreational areas has never been greater (e.g., Seattle's Gas Works Park). By allowing for a less stringent standard for industrial areas, the Department will create "sacrifice zones" which cannot be converted short of a second cleanup. (Wishart, p. 3)

Other individuals expressing similar concerns include the following: Tabbutt, and Connor.

However, a number of individuals expressed support for Ecology's approach and recommended that it be expanded to provide more detailed requirements for other site uses. For example:

> Boeing believes that establishment of soil cleanup standards for industrial sites is sound public policy. (WAC 173-340-745) However, it does not go far enough. Ecology can and should recognize other uses, such as agricultural and recreational, with alternative compliance levels. Appropriate safeguards can be included to protect against usage changes. (Thomson, p.4)
>
> **********
>
> The Board agrees that where appropriate, compliance cleanup levels for soil and air should be based on residential use, and for ground water should be based on drinking water use. The Board also supports the specific recognition of alternate compliance cleanup levels, such as industrial soil cleanup levels, for other site uses. Other site uses should be considered and may include, but are not limited to, recreational and agricultural uses. (Science Advisory Board, p. 4)
>
> **********
>
> Although the proposed standards make an important distinction between residential and industrial land uses for the soil cleanup standards, many land uses do not fall into these two categories. We believe that distinctly different types of exposure assumptions apply to other land use types (e.g. limited duration exposure in open space land uses) which result in different lifetime risks. Recognizing the complexity of addressing a variety of land uses, we recommend the addition of a section which specifically addresses open space and commercial land use types. (Patmont and Wineman, p. 4)

Other individuals providing similar comments include the following: Meyer (Seattle Hearing), Syrdal, Johnson and Izatt.

Ecology's Response: Ecology believes an approach which distinguishes between various site uses is appropriate and consistent with the "reasonable maximum exposure" approach used to establish cleanup levels. It also appears to be consistent with the approach utilized by the U.S. Environmental Protection Agency on federal Superfund sites:

> In considering land use, Superfund exposure assessments most often classify land into one of three categories: (1) residential, (2) commercial/industrial, and (3) recreational. EPA also considers the ecological use of the property and as appropriate, agricultural use. In general, the baseline risk assessment will look at a future land use that is both reasonable, from land use development patterns, and may be associated with the highest (most significant) risk, in order to be protective. These considerations will lead to the assumption of residential use as future land use in many cases. Residential land use assumptions generally result in the most conservative exposure estimates. The assumption of residential land use is not a requirement of the program, rather an assumption that may be made, based on conservative but realistic exposures to ensure that remedies that are ultimately selected for the site will be protective. An assumption of future residential land use may not be justifiable if the probability that the site will support residential use in the future is small. Where the likely future

> land use is unclear, risks assuming residential land use can be compared to risks associated with other land uses, such as industrial, to estimate the risk consequences if the land is used for something other than the expected future use. (EPA, 1990a, p. 8710)

However, Ecology does agree with comments that were critical of the proposal to consider commercial and industrial sites in the same manner. Consequently, Ecology intends to revise the final rule to limit the application of WAC 173-340-745 to industrial sites. Commercial sites, which are frequently located in or immediately adjacent to residential areas, will be considered potential future residential sites.

Finally, with respect to additional site categories, the rule continues to recognize the potential for establishing site-specific cleanup levels based on those uses. The Department believes that this provides sufficient flexibility to address health risks associated with these other uses. During the next year, Ecology will be developing guidance on the procedures to be used at these sites and will consider incorporating such procedures into the regulation when it is amended to address ecological hazards.

Issue #2: What procedures were utilized to develop the cleanup levels in Table 2?

The proposed rule included a list of Method A Compliance Cleanup Levels for soils (Table #2). Several individuals requested clarification on how those values were derived.

Ecology's Response: In general, the procedures specified in the regulation were utilized to develop the soil cleanup levels in Table 2. Consequently, the values were derived from one of several sources. The following paragraphs provide a summary of the technical bases for the Method A values. Ecology is preparing guidance which provides greater detail on the underlying studies and factors that may be considered under Methods B and C:

> Ground Water Protection: Method A Cleanup Levels for seven of the twenty-two hazardous substances have been established at 100 times the ground water standard in Table #1. These include the following hazardous substances: Benzene; Ethylene Dibromide; Methylene Chloride; Tetrachloroethylene; 1,1,1 Trichloroethane and Trichloroethylene. The Method A Cleanup Level for mercury was initially established at 100 times the ground water cleanup and then modified based on data in EPA (1985b), ATSDR (1989b), and Revis et al. (1990).
>
> Direct Contact Potential: Method A Cleanup Levels for five of the twenty-two hazardous substances were established on the basis of direct contact potential. Cleanup levels for five of those substances are based upon the direct contact formulae for carcinogens in WAC 173-340-740(3). These include the following hazardous substances: DDT; Lindane; Pentachlorophenol; PAHs (Carcinogenic); and PCB mixtures. In developing these values, the potential for biodegradation was also considered. The technical basis for the lead cleanup level is discussed under Issue #3 below.

Petroleum Contaminants: Method A Cleanup Levels for the seven hazardous substances associated with petroleum releases have been established at concentrations that protect ground water. These include the following substances: Benzene; Ethylbenzene; Toluene, TPH (gasoline); TPH (Diesel); TPH (Other); and Xylenes. The technical basis for those levels is described in greater detail under Issue #4 below.

Background: The Method A Cleanup Level for arsenic is based on preventing excess cancer risks. It was established at a concentration equal to the estimated background concentrations of arsenic in Washington soils as reported in Black and Veatch (1988).

Plant Protection: The Method A Cleanup Level for cadmium is based upon adverse effects in plants. The technical basis for that concentration is described under Issue #5 below.

Food-Chain Protection: The Method A Cleanup Level for pentachlorophenol was based in part on the potential for unacceptable risks resulting from foodchain exposure. The technical basis for that concentration is described under Issue #6 below. This value has been withdrawn from the table at this time.

Inhalation of Suspended Soil Particulates: The Method A Cleanup Level for chromium is based on preventing unacceptable risks associated with the inhalation of resuspended soil particulates. The technical basis for that concentration is described under Issue #7 below.

Issue #3: What procedures were utilized to establish the soil cleanup levels for lead?

Several individuals expressed opinions on the proposed soil cleanup levels for lead. For example:

> The value presented for lead, 250 ppm, is unnecessarily conservative given the actual data by the Centers for Disease Control (CDC, 1985) on lead exposure in children and the guidance of both the CDC and the U.S. EPA (1989a) that lead levels of 500 to 1000 ppm do not result in measurable increases in children's blood lead levels. The U.S. EPA has set an interim cleanup level at Superfund sites of 500 to 1000 ppm (USEPA, 1989a). (Tsuji, p. 7)

Ecology's Response: Evidence from human and animal studies indicate that exposure to elevated concentrations of lead compounds may result in a wide range of adverse effects (ATSDR, 1988a, 1990a). With respect to cleanup actions under the MTCA, the primary concerns are:

(1) Blood disorders resulting from lead's effects on heme synthesis;

(2) Central nervous system effects; and

(3) Carcinogenesis.

Several types of neurotoxic effects are associated with exposure to lead. Learning disabilities, encephalopathy and irreversible brain damage can result from blood lead levels greater than 80 ug/dl and 100 ug/dl in children and sensitive adults, respectively. Children and fetuses with blood lead levels greater than 10-20 ug/dl may also suffer neurotoxic effects resulting in decreased learning ability. Slowed nerve conduction has been observed in adults at 30-40 ug/dl (ATSDR, 1990a)

Lead and inorganic lead compounds have been shown to cause cancer in animals and EPA has classified lead in Group B2 - probable human carcinogen (EPA, 1990f). However, EPA has concluded that standard extrapolation methods would not adequately delineate the potential cancer risk (EPA, 1988). IARC has concluded that the evidence for carcinogenicity of lead is inadequate in humans and sufficient in animals and classified lead in IARC Group 2B- Possible Human Carcinogen.

The Method A cleanup level for lead was established at 250 ppm subsequent to considering alternate cleanup levels based upon a range of approaches. These include:

Correlation with Blood Lead Levels: The Agency for Toxic Substances and Disease Registry (ATSDR) currently considers that blood lead levels of 10 to 15 ug/dl may cause harm in children (ATSDR, 1990). The soil cleanup levels are based on correlations between soil levels and blood lead level. In order to ensure that the majority of a given population of children (99 percent) will have acceptable blood lead levels (below 15 ug/dl) the population mean level must be below 15 ug/dl by a factor of 2.3 standard deviations (15 ug/dl represents the 99th percentile confidence limit). Based on data collected by Roels, et al, (1980), the standard deviation of the mean for blood lead levels ranges from 2.0 to 3.1. Using a value of 3.1, it is estimated that a mean blood level of 7.8 ug/dl should ensure that at least 99 percent of a population of small children should have blood lead levels of less than 15 ug/dl.

ATSDR (1990a) reports that background exposure to lead in rural areas result in average blood lead levels of approximately 6.4 ug/dl. Using this value and a blood lead/soil lead ratio of 4.5 (ATSDR, 1990) reports that this slope factor ranges from 0.6 to 6.8ug/dl/1000 mg/kg, acceptable soil concentrations can be estimated using the following relationship:

$$7.8 = 6.4 \text{ ug/dl} + 4.5 \text{ ug/dl/1000 mg/kg} \times (Cs)$$

where Cs equals the soil cleanup level of approximately 300 mg/kg.

Correlation with Blood Lead Levels: The New Jersey Department of Environmental Protection has developed Interim Soil Action Levels for a number of contaminants including lead. The lead ISALs were based on observed correlations between ambient soil lead levels and blood lead levels (Madhaven, et al, 1989). The upper and lower range of values (1000 mg/kg and 250 mg/kg, respectively) are generally applied to industrial/commercial and residential properties, respectively.

EPA Interim Soil Guidance: EPA (1989c) has published interim soil cleanup levels for lead in residential areas (500 mg/kg) and industrial commercial areas (1000 mg/kg).

Ecology Dangerous Waste Levels: WAC 173-303-103 specifies that a person shall designate his/her waste as dangerous waste (DW) if the "concentration of any one [International Agency for Research on Cancer] positive (human or animal) carcinogen exceeds 0.01 percent [100 ppm] of the waste quantity."

Issue #4: What procedures were utilized to establish the soil cleanup levels for petroleum-related contaminants?

The Method A soil cleanup levels for benzene, ethylbenzene, toluene and xylenes (BETX) and total petroleum hydrocarbons (TPH) were based on preventing ground water contamination.

Benzene: Table 2 specified a Method A soil cleanup level of 0.5 mg/kg (ppm). This was based upon protecting ground water and was established at a level equal to 100 times the Method A ground water cleanup level of 5 ug/l. This concentration appears to be consistent with soil cleanup levels being used in other states. Bell, et al, (1990) have reviewed cleanup standards for petroleum contaminated soils utilized by 40 states. The eight reported values for benzene range from 0.025 ppm (Illinois) to 10 ppm (New Mexico). Particular weight was placed upon the State of California's levels which ranged from 0.3 to 1.0 ppm. This level is also consistent with current Ecology guidelines (.66 ppm) which several individuals experienced in performing petroleum cleanup actions indicated were readily attainable using current technologies (See Rattue and Smith, p. 1; and Miller, p. 2 of comments on March 9, 1990 draft)

Ethylbenzene: Table 2 specified a Method A soil cleanup level of 20 mg/kg (ppm) for ethylbenzene. This level was selected based on the following considerations:

Other State Programs: Bell, et al, (1990) have reviewed cleanup standards for petroleum contaminated soils in 40 states. The three reported values for ethylbenzene ranged from .7 ppm to 68 ppm. The eight reported values for total BETX ranged from 1 to 500 ppm.

Protection of Human Health: The proposed MCL for ethylbenzene is 700 ug/l (EPA, 1989). Soil cleanup levels that prevent exceedances of the proposed MCL can be estimated using the 100 fold multiplier specified in the regulation (70 ppm). Soil cleanup levels which prevent exceedances of the proposed MCL in ground water can also be estimated using the water partition equation (Cs = (foc)(koc)(Cgw)) where Cgw equals 700 ug/l, Koc is the contaminant-specific partition coefficient, and foc is the assumed organic carbon content. A soil cleanup level of 15 mg/kg is calculated using a Koc of 1100 and a foc of 2 percent.

Biodegradability: Ethylbenzene has been shown to degrade fairly rapidly in shallow soils and ground water. (Howard, 1990)

Toluene: Table 2 specified a Method A soil cleanup level of 40 mg/kg (ppm) for toluene. This level was selected based on the following considerations:

Other State Programs: Bell, et al, (1990) have reviewed cleanup standards for petroleum contaminated soils in 40 states. The three reported values for toluene ranged from .3 ppm to 200 ppm. The eight reported values for total BETX ranged from 0.3 to 50 ppm.

Protection of Human Health: The proposed MCL for toluene is 2000 ug/l (EPA, 1989). Soil cleanup levels that prevent exceedances of the proposed MCL can be estimated using the 100 fold multiplier specified in the regulation (200 ppm). Soil cleanup levels which prevent exceedances of the proposed MCL in ground water can also be estimated using the water partition equation (Cs = (foc)(koc)(Cgw)) where Cgw equals 2000 ug/l, Koc is the contaminant-specific partition coefficient, and foc is the assumed organic carbon content. A soil cleanup level of 12 mg/kg is calculated using a Koc of 300 (EPA, 1986) and a foc of 1 to 2 percent.

Biodegradability: Toluene has been shown to degrade fairly rapidly in shallow soils and ground water. (Howard, 1990)

Xylenes: Table 2 specified a Method A soil cleanup level of 20 mg/kg (ppm) for xylenes. This level was selected based on the following considerations:

Other State Programs: Bell et al. (1990) have reviewed cleanup standards for petroleum contaminated soils in 40 states. The three reported values for xylenes ranged from 1 ppm to 50 ppm. The eight reported values for total BETX ranged from 1 to 500 ppm.

Protection of Human Health: The proposed MCL for total xylenes is 10,000 ug/l. (EPA, 1989) Soil cleanup levels that prevent exceedances of the proposed MCL can be estimated using the 100 fold multiplier specified in the regulation (1000 ppm). Soil cleanup levels which prevent exceedances of the proposed MCL in ground water can also be estimated using the water partition equation (Cs = (foc)(koc)(Cgw)) where Cgw equals 10,000 ug/l, Koc is the contaminant-specific partition coefficient, and foc is the assumed organic carbon content. A soil cleanup level of 24 to 48 mg/kg is calculated using a Koc of 240 (EPA, 1986) and a foc of 1 to 2 percent.

Total Petroleum Hydrocarbons: Table 2 specified three method A cleanup levels for total petroleum hydrocarbons (TPH):

TPH (Gasoline) - 100 mg/kg (ppm)
TPH (Diesel) - 200 mg/kg (ppm)
TPH (Other) - 200 mg/kg (ppm)

For petroleum contaminated sites, Ecology requires that these levels be attained in addition to those for BETX because the greater mobility of BETX compounds may lead to low surface concentrations of these compounds even though extensive soil contamination remains. In this light, the TPH results provide a backup check on the degree of petroleum contamination.

The Method A values were selected based on the following considerations:

Other State Programs: Bell, et al, (1990) have reviewed TPH cleanup levels being used in other states. They observed that TPH cleanup levels range from 10 to 10,000 ppm with soil levels for gasoline being established at levels 2-10 times more stringent than those for diesel contamination.

Protection of Ground Water: Based on a review of the composition of gasoline and the relative cleanup levels for TPH and BETX compounds, it appears that a TPH cleanup level of 100 ppm provides a protective measure/indicator for all BETX compounds except benzene. For example, assuming xylene levels in gasoline range from 3-8 % (CWRCB, 1987), the 20 ppm cleanup level for xylene equates to 250 - 660 ppm TPH.

Treatability: Present technologies such as vapor extraction and aeration are able to attain a 100 ppm cleanup level (see Rattue and Smith, p. 1 of comments on March 9, 1990 draft rule; Miller, p. 4 of comments on March 9, 1990 draft; and Kostecki and Calabrese, 1990).

Issue #5: What procedures were utilized to establish the soil cleanup level for cadmium?

The Method A soil cleanup level was based on preventing concentrations which are toxic to plants. The level of 2.0 mg/kg was based on the Environmental Profile and Hazard Indices for Constituents of Municipal Sludge: Cadmium (EPA, 1985) which reported a soil concentration toxic to plants of 2.5 ug/g DW. EPA stated:

> "This value is the lowest, most conservative concentration associated with considerable reductions in yields for lettuce (40 percent) and moderate reductions in growth for wheat (21 percent) and soybeans (10 percent)." (EPA, 1985a, p. 3-5)

The Method A soil cleanup level of 2.0 mg/kg also reduces potential carcinogenic risks associated with the inhalation of windblown dust to risk levels below one-in-one million. Cadmium is classified by EPA in Group B1 - Probable Human Carcinogen and unit risks ranging from 1.8×10^{-3} ug/m3 to 5.5×10^{-2} have been calculated (EPA, 1990f, 1990g). The following exposure assumptions were used to evaluate the protectiveness of a soil cleanup level of 2.0 mg/kg:

(1) Concentrations in windblown dust are equal to soil concentrations;

(2) Average dust (Total Suspended Particulate) levels are 40 ug/m3;

(3) Duration of exposure is 30 years for a 70 kg person; and

(4) A person breathes 20 m3/day.

Issue #6: What procedures were utilized to establish the soil cleanup levels for pentachlorophenol?

Table 2 of the proposed rule specified a Method A soil cleanup level of 10 mg/kg (ppm) for pentachlorophenol. This was based on noncarcinogenic effects. However, pentachlorophenol (PCP) is also listed as a Group B2 carcinogen (Probable Human Carcinogen) and subsequent to Ecology's proposal, EPA established a carcinogenic potency factor of 0.12 kg-day/mg for the substance. (Bennett, 1990)

A revised Method A soil cleanup level of 1 mg/kg (ppm) for pentachlorophenol has been calculated based on carcinogenic effects (the technical bases for that value are summarized below). Due to the substantial reduction resulting from the use of the new toxicological information, Ecology has elected to repropose in a subsequent amendment the Method A pentachlorophenol values. In the interim, pentachlorophenol cleanup levels will be established using the Method B procedures.

Direct Contact: Using a carcinogenic potency factor of 0.12 and the direct contact equation in WAC 173-340-740(3)(c)(ii), a soil cleanup level of 8 mg/kg was derived.

Protection of Ground Water: A soil cleanup level of 0.1 ppm can be estimated using a ground water cleanup level of 1 ug/l (derived using the procedures and assumptions in WAC 173-340-720) and the 100 fold multiplier specified in the regulation. Alternately, soil cleanup levels which prevent exceedances of the proposed MCL in ground water can also be estimated using the water partition equation (Cs = (foc)(koc)(Cgw)) where Cgw equals 1 ug/l, Koc is the contaminant-specific partition coefficient, and foc is the assumed organic carbon content. A soil cleanup level of 1 mg/kg was calculated using a Koc of 53,000 (EPA, 1986) and a foc ranging from 1 to 2 percent.

Food-Chain Exposure: A risk based cleanup level consumption of root vegetables and was derived using the following relationship:

$$\text{Soil Cleanup Level (mg/kg)} = \frac{\text{Koc x foc x Cp}}{\text{RCF x EP}}$$

Where:

Koc = Soil Partition Coefficient
foc = Soil organic carbon content
Cp = Acceptable Plant Concentration
RCF = Root Concentration Factor
EP = Edible Portion of the Plant

A soil cleanup level of approximately 1 mg/kg (ppm) was developed using the following values:

Soil Partition Coefficient: The soil cleanup level was developed using a soil partition coefficient of 53,000 L/Kg (EPA, 1986).

Soil Organic Carbon Content: The soil cleanup level was developed using an organic carbon content of five percent. (Tasca, et al, 1989)

Root Concentration Factor: The root concentration factor (RCF) of 217 L/Kg was estimated using an approach developed by Briggs et al. (1982) which assumes that the degree to which a substance is concentrated in a plant is dependent upon the octanol/water partition coefficient (Kow). Using a Kow of 5.01 (Vershuren, 1983) and the relationship, (RCF = Antilog [0.7(log Kow) - 1.52] + 0.82), a RCF of 217 was estimated.

Acceptable Plant Concentration: An acceptable pentachlorophenol level of 0.04 ug/g in plants was estimated using the exposure assumptions in EPA (1989b), a carcinogenic potency factor of 0.12, and an acceptable risk of 10^{-6}. The exposure assumptions include a consumption rate of 80 g/day, an exposure duration of 5,500 days, a body weight of 70 kg, and a lifetime of 75 years.

Edible Portion of the Plant: A value of 50 percent (0.5) was used to account for the percentage of hazardous substance that is partitioned to the leaves and growing shoots of vegetation. (Heichel and Hankin, 1976)

Issue #7: What procedures were utilized to establish soil cleanup levels for chromium?

The Method A soil cleanup levels for chromium were based on preventing excess cancer risks associated with the inhalation of windblown dust. Chromium (VI) is classified by EPA in Group A - Human Carcinogen and a carcinogenic potency factor of 41 $(mg/kg/day)^{-1}$ (unit risk of 1.2 x 10^{-2} ug/m3) has been calculated (EPA, 1990). The following assumptions were utilized to calculate a soil cleanup level of 100 mg/kg:

(1) Concentrations in windblown dust are equal to soil concentrations;

(2) Average dust levels (Total Suspended Particulates) are 40 ug/m3 (Ecology, 1990);

(3) Duration of exposure is 30 years for a 70 kg person;

(4) A person breathes 20 m3/day;

(5) Twenty-five percent of inhaled chromium is absorbed (EPA, 1984); and

(6) One to hundred percent of the total chromium is chromium VI. Chromium VI is converted to Chromium III in soils (ATSDR, 1989; EPA, 1984)

Issue #8: What is the relationship between the health-based action levels developed under the RCRA Corrective Action program and cleanup levels under the Model Toxics Control Act?

In July 1990, the Environmental Protection Agency (EPA) issued proposed rules defining the corrective action requirements under the Resource Conservation and Recovery Act (RCRA). Mr. Fortier recommended that the health-based action

levels in the proposed rule be reviewed and evaluated for integration into the proposed rule. (Fortier, p. 2)

Ecology's Response: Ecology has reviewed the action levels in EPA (1990) and notes that there are a number of similarities in the approaches used to develop the action levels and the MTCA cleanup standards. Ecology has considered the proposed RCRA rules in developing the cleanup standards.

It is also important to recognize that the action levels were designed for additional purposes other than establishing cleanup standards for a particular facility. Under the RCRA program, the action levels are to be used to trigger further study of a site. However, the action levels are based upon a 1 in 1,000,000 cancer risk level and EPA has said that cleanup standards will be set within a range of 1 in 10,000 to 1 in 1,000,000. Consequently, EPA has tried to distinguished the values from cleanup levels:

> Action levels should be distinguished from cleanup standards, which are determined later in the corrective action process. Contamination exceeding action levels indicates a potential threat to human health or the environment which may require further study. Action levels also inform the permittee of the levels below which the Agency is unlikely to require active remediation of releases and provide a point of reference for suggesting and supporting alternative remedial levels. (EPA, 1990, p. 30814)

Issue #9: What are appropriate procedures for establishing soil cleanup levels to protect ground water?

Ecology proposed to establish soil cleanup levels at concentrations which will not result in ground water concentrations that exceed ground water cleanup levels. Ecology specified that this determination would be made using the following procedure:

> For individual hazardous substances or mixtures, concentrations that are equal to or less than one hundred (100) times the ground water compliance cleanup level established in accordance with WAC 173-340-720 unless it can be demonstrated that a higher concentration is protective of ground water at the site. (WAC 173-340-740(3)(b)(i)(A))

A number of individuals stated that the use of this approach was arbitrary and not scientifically sound. For example:

> The Board believes that there is little scientific foundation or justification for the use of the "100 times ground water cleanup level" in arriving at compliance cleanup levels for soil. Because there are many site specific factors that affect the relationship between soil contamination levels and the likelihood for future ground water contamination, the Board recommends that compound specific or at least chemical class specific factors be included in the derivation of soil cleanup levels that are based on potential for ground water contamination. The Board appreciates the difficulties in balancing regulatory simplicity and clarity against scientific justification to set soil cleanup levels, and is

> interested in working with Ecology to attain these objectives. (Science Advisory Board, p. 6)
>
> **********
>
> "Boeing is aware of little scientific basis for soil cleanup standards based upon one hundred times the groundwater compliance cleanup level. Such cross media guidelines are of dubious validity." (Thomson, p. 5)

Individuals expressing similar concerns included the following: Syrdal, and Fortier.

Several individuals provided suggestions for modifying this provision. For example, Mr. Findley and Mr. Fortier recommended that Ecology consider basing the soil standard on the leachability of various hazardous substances:

> The soil compliance level for the protection of groundwater are total soil concentrations 100 times the groundwater compliance level, unless it can be demonstrated that a higher concentration is protective of the groundwater at the site. This is probably based on some assumptions regarding the leaching of material from soil and the dilution of that leachate. It may be appropriate to change both this standard and the compliance monitoring section for soil so that both the standard and the required monitoring be in terms of a leaching test rather than in terms of total concentrations. At a minimum, this approach should be considered for certain categories of hazardous substances such as heavy metals. (Findley, p. 2)
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> **********

In addition to the Science Advisory Board, several other participants suggested that Ecology should consider distinguishing between certain categories of hazardous substances. For example:

> The use of a factor of 100 is arbitrary here. The use of a factor of 100 for metals and high molecular weight organic compounds is far too conservative as has been repeatedly demonstrated in many cleanup actions, governmental tests, etc. Just as a more realistic factor should have been used for developing the numbers in Table 2 which were based on such a factor, the presumption of the factor of 100 should not apply to those metals and high molecular weight organic compounds. (Syrdal, pp. 17-18)

Ecology's Response: Ecology agrees with individuals who stated that ground water cleanup levels should generally be established taking into account a number of site-specific features. However, the Department also believes it is important from a regulatory perspective to establish a series of cleanup levels which can be used as (1) screening criteria to identify soils which are "below regulatory concern" and (2) conservative soil cleanup levels that can be utilized at smaller routine cleanup actions.

The choice of a 100-fold multiplier was based on the following considerations:

Other State Programs: Several other states utilize approaches that involve multiplying ground water cleanup levels by a factor which accounts for environmental attentuation and bioavailability. These include:

Arizona: Soil cleanup levels are established at levels that are 100 times the ground water cleanup level.

California: The California Water Resource Control Board has developed procedures for establishing soil cleanup criteria based on threats to ground water. In general, multipliers of 100 and 1000 are used for organics and inorganics, respectively.

Michigan: The State of Michigan has promulgated regulations which utilize a multiplier of 20 to establish initial soil cleanup levels (MDNR, 1990).

RCRA Development Work: In developing the Toxicity Characteristics Leaching Potential (TCLP) test, EPA performed a series of computer modelling exercises and concluded that a dilution and attenuation factor (DAF) of 100 represents a conservative or upper-bound estimate on the reduction in concentrations that would occur between a source and receptor (EPA, 1990).

Science Advisory Board Followup: In followup meetings held with the Science Advisory Board in the Fall of 1990, several members of the Board supported the use of a 100-fold multiplier as long as there was flexibility to evaluate site-specific factors.

Ecology evaluated the potential for categorizing substances into several groups based on chemical characteristics (i.e. volatile organics, metals, acid base neutrals) with different multipliers applied to each. Although this intuitively appears to represent an attractive option, Ecology finds that there are often large overlaps in categories. Ecology believes such differences can be taken into account in a site-specific evaluation and is currently preparing guidance on acceptable approaches for performing such evaluations. This may include the use of fate and transport models and/or leaching tests.

Issue #10: Should Ecology utilize soil leaching tests to establish soil cleanup levels that protect ground water?

Several individuals recommended that Ecology consider basing the soil standard on the leachability of various hazardous substances. For example:

> The soil compliance level for the protection of groundwater are total soil concentrations 100 times the groundwater compliance level, unless it can be demonstrated that a higher concentration is protective of the groundwater at the site. This is probably based on some assumptions regarding the leaching of material from soil

and the dilution of that leachate. It may be appropriate to change both this standard and the compliance monitoring section for soil so that both the standard and the required monitoring be in terms of a leaching test rather than in terms of total concentrations. At a minimum, this approach should be considered for certain categories of hazardous substances such as heavy metals. (Findley, p.2)

Ecology's Response: Ecology believes the above proposal has merit, but has elected not to modify the rule at this time. However, the final rule provides the flexibility for persons performing cleanup actions to utilize soil leaching tests to demonstrate that soil cleanup levels greater than or less than 100 times the ground water are appropriate for a specific site. Such an approach is consistent with the waste delisting procedures under RCRA (EPA, 1988) and cleanup regulations recently issued by the Michigan Department of Natural Resources (MDNR, 1990). For example, the approach utilized by Michigan specifies the following:

> (2) To assure that soils do not pose a threat of aquifer contamination, the concentration of the hazardous substance in soil shall be below that which produces a concentration in leachate that is equal to the highest of the ground water criteria specified in R 299.5707, the ground water criteria specified in R 299.5709, or the leachate concentration generated by background soil. Leachate testing shall not be required to demonstrate compliance with this rule if the total concentration of a hazardous substance in soil does not exceed 20 times the criteria specified by R 299.5707 or R 299.5709. Leachate concentration shall be determined by a method which best represents in-situ conditions. For the purposes of this rule, the following test methods shall be acceptable:
>
> (a) The United States Environmental Protection Agency's toxicity characteristic leaching procedure (TCLP) as set forth in the provisions of 40 C.F.R. part 261 appendix II (revised as of March 29, 1990).
>
> (b) Other test methods accepted by the department to more accurately simulate conditions at the site than the test methods specified in subdivision (a) of this subrule. (MDNR, 1990, p. 31)

While the Michigan requirements are consistent with the approach in the final rule, Ecology has elected not to specify the use of specific leaching tests. Ecology remains concerned that the use of laboratory leaching tests to establish soil cleanup levels may underestimate potential ground water impacts:

- A short term laboratory test is not necessarily representative of the long-term leaching potential of a waste or contaminated soil. This is especially a problem when biological decomposition and/or chemical reactions occur in the field that cannot be simulated with a short-term laboratory test.
- Seemingly minor modifications in a leaching test procedure can yield considerably different test results.
- The liquid to solid ratio typically necessary in a laboratory leaching test to obtain sufficient elutriat to analyze is usually well in excess

of what occur in the field, resulting in considerable dilution of expected concentrations.

- The amount of contaminant leached from different soil samples with the same amount of contaminants in them could vary considerably in a laboratory test depending on the soil properties and micro conditions present prior to and at the time of sampling. This could lead to widely varying degrees of actual cleanup achieved/required at a given site.

Given these concerns, Ecology believes it is appropriate that total analyses remain the primary basis for evaluating compliance with cleanup standards. However, Ecology anticipates that leaching tests, in combination with total analyses and ground water monitoring data, could be used to establish soil cleanup levels on a site-specific basis. Ecology anticipates this will involve the use of a leaching test with a moderately aggressive elutriate (such as the TCLP test for metals) to compensate for the above shortcomings. Ecology will be preparing guidance on how leaching tests may be utilize in making site-specific determinations on ground water protection.

Issue #11: What are appropriate soil ingestion rate assumptions for use in establishing soil cleanup levels in residential areas?

Ecology proposed to establish soil cleanup levels for residential areas using a soil ingestion rate of 200 mg/day. Dr. Joyce Tsuji expressed the opinion that more recent studies suggested that soil ingestion rates of 10 - 80 mg/day were more appropriate. She stated:

> The assumption for soil ingestion rates in the soil cleanup calculations is based on U.S. EPA recommended levels. For the Reasonable Maximum Exposure (RME) scenario, U.S. EPA Region X uses 200 mg/day for children ages 0-6 and 100 mg/day for 6 years of age and older (USEPA, 1989a). These ingestion rates are equivalent to those presented in the Risk Assessment Guidance for Superfund (RAGS; USEPA, 1989b), which are derived from two tracer element studies conducted on children's fecal material (Clausing, et al, 1987; Binder, et al, 1986). These studies are described in more detail in the Exposure Factors Handbook (USEPA, 1989c). The Exposure Factors Handbook specifies that recommended soil ingestion rates are considered to be an average rate for each age group. Nevertheless, as noted in recent studies (Calabrese, et al, 1989; Davis, et al, 1990), neither of the two earlier studies accounted for the contribution of diet to the tracer element content of the fecal material studied. Thus, based on more recent information, the rates recommended by U.S. EPA may not be scientifically accurate. According to the up-to-date studies, more appropriate soil ingestion rates are on the order of 10 to 80 mg/day (Calabrese, et al, 1989; and Davis, et al, 1990); U.S. EPA is currently debating the merit of these studies. (Tsuji, p. 5-6)

Similar comments were provided by the following individuals: Fortier, from comments on March 9, 1990 draft rule; Fisher from comments on March 9, 1990 draft rule.

Ecology's Response: Under the cleanup rule, Ecology utilizes a soil ingestion rate of 200 mg/day to establish cleanup levels in residential and other unrestricted access areas. This value is consistent with findings from several studies and approaches used by other regulatory programs:

Risk Assessment Guidance for Superfund: EPA (1989a) states that the Reasonable Maximum Exposure (RME) generally requires 95th percentile intake rates, 90th or 95th percentile values for exposure duration and frequency, but average values for parameters such as body weight. For the RME scenario in unrestricted access areas, EPA (1989a) specifies the use of 200 mg/day for small children (ages 0-6 years and 100 mg/day for persons 6 years and older).

EPA Region X Guidance: For the RME in residential areas, EPA region X uses 200 mg/day for children ages 0 to 6 years of age and 100 mg/day for persons 6 years and older (EPA, 1990b). These ingestion rates are equivalent to those presented in the EPA Risk Assessment Guidance for Superfund which were derived from two tracer studies conducted on children's fecal material (Clausing et al. 1987; Binder et al. 1986).

National Guidelines: OSWER Directive 9850.4 (EPA, 1989) specifies 200 mg/day for children ages 1 through 6 (five years of exposure) and 100 mg/day for others.

Clausing et al.: Ecology's approach is consistent with the results of Clausing, et al, (1987) who examined soil ingestion rates among nursery school aged children. The average and upper 95th percentile soil ingestion rates based on their data are 130 mg/day and 610 mg/day, respectively.

Stanek, et al.: Stanek et al. (1990) utilized data collected from 64 preschool children in western Massachusetts to estimate soil ingestion rates. Using a mass balance approach for six elements (Al, Si, Ti, V, Y, and Zr), they estimated median values ranging from 10 to 89 mg/day depending on which element was studied. They also estimated that the upper 95th percentile soil ingestion rate ranged from 106 to 1903 mg/day.

Issue #12: What is an appropriate duration of exposure for estimating soil cleanup levels for carcinogens based on direct contact?

Several individuals expressed general concerns on the degree of conservatism associated with the procedures in the proposed rule. Specifically, Dr. Monroe and Mr. Wishart expressed concerns regarding the use of estimated exposure durations of less than a full lifetime.

Ecology's Response: Ecology recognizes that the use of a six year exposure duration is less than that utilized by EPA. However, Ecology believes that the use of a six year exposure duration, in combination with the other exposure parameters in the rule, results in a protective soil cleanup level:

- The use of Ecology's procedures results in exposure estimates that are 50 to 70 percent of the estimates derived using various EPA procedures (EPA, 1989a, 1990b)

- Ecology's procedures focus on the most highly exposed group (children). Over 50 percent of the total lifetime dose associated with direct contact is estimated to occur during the ages 1-6 years. Protection of susceptible subgroups is a basic public health practice.

- Ecology's rule provides tighter constraints on acceptable risk levels.

Issue #13: What is an appropriate point of compliance for soils which pose a direct contact threat?

Ecology proposed that soil cleanup levels would generally have to be attained throughout the site. However, Ecology proposed to provide some flexibility to establish conditional points of compliance for soils that present a direct contact hazard:

> (c) For soil cleanup levels based on human exposure via soil ingestion, the point of compliance shall be established in the soils throughout the site from the soil surface to the lowest depth which could potentially result in human exposure via soils ingestion.
>
> (d) In making the determination under subsection (6)(c) of this section, the presumption shall be that the point of compliance is fifteen (15) feet beneath the ground surface. This represents a reasonable estimate on the depth of soil that may contain hazardous substances that could be excavated and distributed at the soil surface as a result of site development activities.
>
> (e) The person undertaking the cleanup action may demonstrate that a conditional point of compliance for soil at a depth other than fifteen (15) feet is more appropriate for an individual site. In no case shall the depth be less than one (1) foot below the ground surface.

Several individuals expressed the opinion that the use of fifteen feet was arbitrary and unworkable. For example:

> WAC 173-340-740(6)(d) and (e) These subsections will render the cleanup of soils in large non-industrial sites virtually impossible. First, there is no basis for establishing that all sites must automatically be cleaned to a depth of one foot. Moreover, there is no basis for establishing a presumption that the point of compliance will be 15 feet deep throughout the site. The point of compliance should be established on a site-by-site basis and should take into account all of the factors associated with the site, including site use, nature of hazardous substance, toxicity of that substance, mobility of that substance, applicability and effectiveness of institutional restrictions and other relevant factors. The one foot/15 feet requirements of these sections are arbitrary, have no basis, and are unworkable...the proposed regulations regarding point of compliance for soil contamination do not take into account containment issues. (Syrdal, p. 18)

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> The use of 15 feet as a compliance point is arbitrary and assumes extensive excavation. Although Section (6)(e) allows for a variance based on individual sites, it still sets an arbitrary standard that will be used as a point of comparison. The regulation should delete Section (6)(d), and revise (6)(e) to reflect that each site should have an independent point of compliance determined based on site characteristics and potential future uses. Also, the regulation should reflect the potential for soil capping and deed restrictions that limit future excavation of the cap. This type of cleanup would eliminate and/or reduce the depth for the point of compliance and should be reflected in the regulations. (Schadt, p. 2)

Ecology's Response: In establishing a soil point of compliance for direct contact, Ecology's primary goal was to establish a soil depth where the potential for inadvertent excavation of contaminated soils was extremely low. The fifteen foot depth was chosen based on the maximum depth of excavation likely to be accomplished with a small backhoe (12 + feet). Ecology believes this depth is below the depth of a typical basement (8 + feet) and most utility lines (4 + feet). This consistent with the "rule of thumb" approach used in California (Reynolds, et al. 1990) where 10 feet is used.

The one foot depth was based upon the assumption that paving the area would represent a minimum requirement for eliminating direct contact exposures. The one-foot depth reflects the thickness of a clean base coarse material plus a surface consisting of asphalt or concrete. If a soil cover was utilized or substantial slopes were present, it was anticipated that a cover thickness similar to the minimum requirements typically specified for landfills (2 to 3 feet) would be utilized.

Ecology has reviewed the above comments and believes that further clarification is needed for sites where the cleanup action involves containment of contaminated soils. Consequently, Ecology has revised the rule to clarify that:

(1) Containment of contaminated soils is an acceptable cleanup action only in situations where treatment and/or removal is impracticable; and

(2) If containment is the preferred cleanup action, the soil is still contaminated and compliance will be based on maintaining the integrity of the containment system in a manner that eliminates the potential for direct contact with contaminated soils.

Ecology has also considered approaches for modifying surface soil cleanup levels for soil at depth. For example, Reynolds et al. (1990) have proposed an approach which takes into account potential dilution effects which occur following the excavation of soils. Ecology does not believe it is appropriate to incorporate such procedures into the rule, but may consider such measures when evaluating cleanup action options.

Issue #14: What is an appropriate point of compliance for soils which pose a threat to ground water?

Ecology proposed that, "for soil cleanup levels based on the protection of ground water, the point of compliance shall be established in the soils throughout the site...." (WAC 173-340-740(6)(b))

Several individuals recommended that Ecology provide the flexibility to develop soil conditional points of compliance for protection of ground water:

> A soil conditional point of compliance for the protection of groundwater should be permitted. Soil points of compliance for the protection of groundwater and for protection of direct contact hazards are specified. However, conditional points of compliance for soils are only allowed for direct contact hazards. Therefore, the soil cleanup level based on the protection of groundwater must be met throughout the site, even if wastes must be left on the site. This appears to be inconsistent with the provision for a conditional point of compliance in the groundwater when wastes are left on-site as is likely to be necessary for such sites as municipal landfills. (Syrdal, p.)

Ecology's Response: Ecology believes that contaminated soils throughout a site represent a potential threat to ground water resources. Consequently, remediation measures must address soils throughout the site. However, in establishing this requirement, Ecology recognizes that:

(1) Cleanup actions may involve containment of contaminated soils and

(2) Compliance monitoring provisions must take into account the variability in soil concentrations.

Issue #15: Should Ecology distinguish between exposure concentrations and removal levels?

Dr. Tsuji recommended that Ecology distinguish between "exposure concentration" and "removal levels." She stated:

> The proposed Amendments do not make a distinction between exposure concentrations and removal levels. The cleanup levels calculated by the equations provided are actually average exposure concentrations that would result in the target level given the exposure assumptions. The implication is that this concentration, which is achieved by back-calculation from the risk equations, should be used as a removal level at a site. In other words, all concentrations at the site must be below this level. If the goal of cleanup is to achieve a specified target risk level, the removal limit should be that which would result in a mean exposure concentration (target exposure level) that is associated with the target risk level. If the target exposure level is used as a removal level, then the actual mean exposure concentration at the site after cleanup will be considerably lower (i.e., by an order of magnitude or more) than the target goal.

Another way to look at this situation is to consider a site for which the risk assessment determines that exposure to site concentrations would not result in risks exceeding the target level. If cleanup levels were calculated as specified by the Proposed Amendments, this site would still have to be cleaned up because many of the levels on site will exceed the target exposure concentration. Because no one is exposed for a lifetime continuously to the maximum concentration at a site, there is no justified reason to use the exposure concentration as calculated by the risk assessment equations as the removal level.

The more scientifically justified approach is to set the cleanup level as a level above which concentrations are to be removed and replaced with background soil concentrations to result in an overall site mean that meets target risk levels. This upper limit could also be examined to ensure that no acute effects would result from short-term exposure to concentrations at the cleanup level. (Tsuji, p. 8)

Ecology's Response: Ecology believes the above comments reflect a general misunderstanding of the procedures included in the proposed rule. Indeed, Ecology considered many of the issues raised in Dr. Tsuji's comments when developing the proposed rule and believes the proposed approach already addresses many of the concerns raised by the above comments. Specifically:

(1) Compliance determinations are based on estimates of average concentrations - not maximum soil concentrations;

(2) Compliance determinations are made for each sample area (exposure unit) - not individual soil concentrations; and

(3) Risk based cleanup levels for carcinogens are based on 6-30 year exposure durations - not lifetime exposures.

Consequently, the proposed approach does not necessarily equate removal levels with achieving target exposure level in every single soil sample. It takes into account the variability in soil levels and activity patterns at a particular site.

Ecology's proposed approach for evaluating compliance with soil cleanup levels is based on procedures defined in EPA (1989h). For an individual site, compliance monitoring will involve the following steps:

Specification of Sample Areas: The waste site should generally be divided into several sample areas which will then be evaluated separately for compliance with cleanup standards. These areas should be defined so that they are as homogeneous as possible with respect to prior waste activities and contaminant levels. For example, if a PCB transformer disposal area and an open field are located on the same site, they should not be included in the same sample area. Specification of sample areas should also take into account the potential uses of the site and the areas over which particular activities are expected to occur. For example, EPA (1989a) specifies that "averaging soil data over an area the size of a residential backyard (e.g., an eighth of an acre) may be most appropriate for evaluating residential soil pathways...." (p. 6-28) For industrial sites, a sample area (or exposure unit) of approximately 2000 m3 (half an acre) has been estimated to represent the size of an area

where people would normally work on a given day. (Neptune, et al, 1990)

Data Collection: For purposes of evaluating compliance with cleanup standards, a sampling and analysis plan must be developed and implemented. The plan should specify the sample areas, sample collection and handling procedures, substances to be tested, etc.

Specification of Statistical Parameters: Soil cleanup levels are generally based on effects associated with long-term exposures. Consequently, cleanup levels are generally based on estimates of average exposure levels over a period of time. For purposes of evaluating compliance with soil cleanup levels, Ecology specified that the 95th percent upper confidence limit on the mean would be compared to the soil cleanup level. The proposed rule also specifies that for cleanup levels based on short term exposures, an upper percentile value would be used in place of the mean.

Compliance Determinations: The proposed rule specified multiple criteria for evaluating compliance with soil cleanup level. These are specified in WAC 173-340-740(7).

Under the approach suggested by Dr. Tsuji, it would appear that simply increasing the size of the site (thereby including relatively clean areas) may serve to "dilute" the contaminated areas and lead to an erroneous conclusion that a site is "clean" when it remains contaminated.

Issue #16: Should compliance with soil cleanup levels be based on total analyses of the soil fraction less than 2mm in size?

Ecology proposed:

> Compliance with soil cleanup levels shall be based on total analyses of the soil fraction less than two (2) millimeters in size. When it is reasonable to expect that larger soil particles could be reduced to two (2) millimeters or less during current or future site use and this reduction could cause an increase in the concentrations of hazardous substances in the soil, soil cleanup levels shall also apply to these larger soil particles. Compliance with soil cleanup levels shall be based on dry weight concentrations. (WAC 173-340-740(7)(a))

As noted above, several individuals expressed the opinion that compliance with soil cleanups developed to protect ground water should be based on leaching tests, not total analyses. The Environmental Protection Agency recommended that Ecology develop separate procedures for evaluating compliance with soil cleanup standards where immobilization technologies are used:

> Assessing compliance with the soil clean-up standards for immobilization remedies should be changed. For many sites, especially those contaminated with heavy metals, immobilization will be either the primary or secondary component of the remedy. However, WAC 173-340-740(7)(a) requires that compliance with soil cleanup levels be based on the total analysis of the soil fraction less than 2mm in size. If the Department

> decides that an immobilized material could be reduced to 2mm or less during future site use, no immobilized material could achieve the soil cleanup standards. On the other hand, if it is decided that the immobilized material would not be reduced to 2mm or less, then no compliance monitoring requirement would apply. This may not be adequately environmentally protective. (Findley, p. 2)

Ecology's Response: Ecology believes the concerns raised regarding stabilized materials are valid in that such materials will often contain essentially the same total amount of heavy metals as the parent material. Some of these cleanup methods do actually change the chemical form of the metal and thus would reduce the amount measured in a total (recoverable) analysis. If successfully applied, these methods would be able to demonstrate compliance with the cleanup standards. Other methods essentially encapsulate the heavy metals in a matrix and do not change the chemical form of the metal. In this latter case, the concern is that the physical and/or chemical breakdown of the encapsulating matrix could allow these metals to be remobilized. To accommodate these later cases, the rule will be revised to allow a demonstration that where stabilization is used, an alternate testing procedure may be used if it can be demonstrated that the stabilized material will be sufficiently resistant to breakdown by physical/chemical processes.

Issue #17: What are appropriate statistical procedures for evaluating compliance with soil cleanup levels?

Ecology proposed statistical procedures for evaluating compliance with soil cleanup levels. Dr. Tsuji questioned the use of a one-tailed test and whether Ecology had selected an appropriate null hypothesis:

> The authors of the Proposed Amendments have shot themselves in the foot by specifying that a one-tailed test of the null hypothesis should be used. In doing so they have increased the power to reject and made it more likely that the null hypothesis (that the site exceeds the cleanup levels) will be rejected. If the null hypothesis were correctly defined (see definitions above) and one had a prior reason to believe that the site were contaminated, then a one-tailed test would be appropriate. (This appears to be the result of wanting to have one's cake and eat it too!) (Tsuji, p. 7-8)

Ecology's Response: Ecology believes the approach in the proposed and final rule provides an appropriate methodology for evaluating attainment of soil cleanup standards. However, comments on this section and the definition of the "null hypothesis" appear to reflect some confusion on distinction between statistical methods for investigation/problem definition and procedures for evaluating whether a site known to have been contaminated is now clean. This distinction was summarized in by EPA in a recent guidance document Methods for Evaluating the Attainment of Cleanup Standards: Volume 1: Soils and Solid Media:

> When the results of an investigation are uncertain, the procedures in this guidance document favor protection of the environment and human health and conclude that the sample area does not attain the cleanup standard. In the statistical terminology applied in this document, the

null hypothesis is that the site does not attain the cleanup standard. The null hypothesis is assumed to be true unless substantial evidence shows that it is false. Let it represent the true (but unknown) value of a particular soil property, such as the mean concentration of a specified chemical over the entire site. The null hypothesis is:

Ho: $\geq$ cleanup standard (CONTAMINATED or DIRTY)

and the alternate hypothesis is:

H1: < Cleanup standard (CLEAN)

This document describes how to gather and analyze data that will provide evidence necessary to contradict the null hypothesis and demonstrate the site indeed attains the cleanup standard. Figure 2.1 shows how the null and alternative hypothesis change as contamination is detected and subsequently corrected. This illustration specifically pertains to ground water evaluations for land disposal facilities operating under the Resource Conservation Recovery Act (RCRA), but the concept is similar for the soils contamination situation. Initially, the null hypothesis is that there is no contamination (A-C). Once a statistical demonstration can be made that the down gradient concentrations are first above background-level concentrations (B) and also above a relevant action limit or other standard (D), then the null hypothesis is that the site is contaminated. Most Superfund sites that require cleanup are in the situation described by D-E. The site must, at that point, be remediated (E,F) and proven to be clean (G) before the null hypothesis as described above can be rejected and the site declared clean.

If the null and alternative hypothesis described above were reversed, then a situation similar to C would designate a satisfactory cleanup. As can be seen by comparing C with G, the improper specification of the null and alternative hypothesis during a corrective action can result in very different levels of cleanup. (EPA, 1989h, p. 2-3)

A similar position was expressed by Ms. Chou who noted that when evaluating compliance with a risk-based standard, it was appropriate to utilize the null hypothesis specified by Ecology. She distinguished between this and a background-based standard. (Chou, p.1)

Ecology has reviewed the use of the one-tailed test when determining compliance with cleanup standards. The decision to utilize a one-tailed test was based on recommendations in EPA (1989h) and Exner, et al, (1989).

Issue #18: What is the appropriate way to evaluate the mean of soil data sets with non-detectable or non-quantifiable values?

It is generally recognized that trace levels (parts per billion or lower) may pose a risk to human health and the environment. Evaluating compliance with standards is frequently complicated by hazardous substance concentrations that are below detection limits established by analytical laboratories. To address this problem, Ecology proposed:

(d) For purposes of demonstrating compliance, measurements below the method detection limit shall generally be assigned a value equal to one half of the method detection limit. Measurements above the method detection limit but below the practical quantitation limit shall generally be assigned a value equal to the method detection limit. The department may approve alternate statistical procedures for handling non-detected volume or volumes below the practical quantitation limit. (WAC 173-340-740(7)(g))

One individual, Mr. Syrdal, recommended that this provision be modified as follows:

> "WAC 173-340-740(7)(g) Again, detectable levels below the practical quantification limit should generally be assigned a value equal to one-half the practical quantification limit." (Syrdal, p. 18)

Ecology's Response: Comment noted. See response to Issue #14 in Section XVII (Ground Water Cleanup Standards).

Issue #19: Is it appropriate to establish soil cleanup levels at concentrations which exceed dangerous waste designation levels?

One individual noted that the proposed rule is inconsistent with certain portions of the state Dangerous Waste Regulations (Chapter 173-303 WAC), and urged Ecology to clarify the relationship between the two regulations. Ms. Keeley stated:

> Ecology DW regs would designate ASARCO slag as DW for arsenic (assuming 100 ppm arsenic in slag). Ecology MTCA states that slag = soil, and provides soil cleanup levels of 20 ppm, 100 ppm, or 230 ppm arsenic. How will this discrepancy be addressed for slag which contains 100-230 ppm arsenic (permits? DW?) - it's DW but OK via MTCA?! Will slag w/>230 also be a DW? (Keeley, p. 1)

Ecology's Response: The Model Toxics Control Act provides the statutory authority to clean up contaminated sites. The Hazardous Waste Management Act (Chapter 70.105 RCW) provides the statutory authority for regulating current hazardous waste practices and Ecology has developed regulations which specify requirements for identifying/classifying hazardous wastes (under the state program, hazardous wastes are classified as either dangerous waste (DW) or extremely hazardous waste (EHW)), transporting, treating, storing, and disposing of such wastes (Chapter 173-303 WAC). In many cases, those regulations (or portions of the regulations) will be considered applicable state and federal laws for purposes of defining cleanup requirements under the MTCA.

Under the MTCA, the DW regulations could be considered legally applicable or relevant and appropriate:

> Legally Applicable: The DW regulations will be legally applicable if (1) the contaminated materials are a listed or characteristic dangerous waste/extremely hazardous waste (DW/EHW) under WAC 173-303-080 through 173-303-104 and (2) treatment, storage, or disposal occurred after the

effective date of the particular DW requirements. Ecology has historically considered that waste consolidation within the area of contamination or insitu treatment do not constitute waste generation or placement.

Relevant and Appropriate: Portions of the DW regulations may be considered relevant and appropriate in situations where the above requirements are not met. In particular, Ecology has historically considered that WAC 173-303-610(10) (which requires notices in deed to property) is a relevant and appropriate requirement for cleanup actions which result in residual levels of hazardous substances which exceed the DW levels.

Arsenic is classified as a human carcinogen by the International Agency for Research on Cancer and, consequently, wastes containing arsenic may be classified as carcinogenic dangerous wastes under WAC 173-303-103. This section specifies the following:

(2) Designation. Any person whose waste contains one or more IARC carcinogen(s) shall designate his waste if:

(a) The monthly or batch quantity exceeds 220 lbs.(100 kg); and either

(b)(i) The concentration of any one IARC positive (human or animal) carcinogen exceeds 1.0 percent of the waste quantity. Such waste shall be designated EHW, and such designation shall take precedence over any DW designation determined by (b)(ii) or (iii) of this subsection; or

(ii) The concentration of any one IARC positive (human or animal) carcinogen exceeds 0.01 percent of the waste quantity. Such waste shall be designated DW; or

(iii) The total concentration summed for all IARC positive and suspected (human and animal) carcinogens exceeds 1.0 percent of the waste quantity. Such waste shall be designated DW. (WAC 173-303-103(2)(a) and (b))

Under subsection (2)(b)(ii), soils containing arsenic levels greater than 100 ppm would exceed the DW designation levels. Consequently, portions of the DW regulations would generally be considered applicable state and federal laws.

Residential Soils: Under the proposed rule, Method A and B cleanup levels for soils in residential areas would be established at approximately 20 ppm arsenic. Method C cleanup levels could be established at concentrations up to 80 to 100 ppm. With respect to these residual levels, the DW regulations would not be considered an applicable state and federal law.

However, the cleanup action could involve the removal, treatment, or disposal of soils which exceed 100 ppm, thereby triggering some or all of the DW requirements. For example, if the cleanup action involves onsite containment of arsenic contaminated soils, WAC 173-303-610(10) would be considered relevant and appropriate.

Industrial Soils: Under the proposed rule, Method A and B cleanup levels for soils in industrial sites would be established at 200 and 230 ppm, respectively. WAC 173-303-610(10) would be a relevant and appropriate

since residual soil levels would exceed 100 ppm. In general, these requirements would be satisfied through the use of institutional controls (WAC 173-340-440).

In summary, the cleanup regulation provides the flexibility to perform cleanup actions which involve containment of soils with arsenic concentrations greater than 100 ppm without triggering the requirements of chapter 173-303 WAC. In those instances, however, institutional controls will be required.

Issue #20: Has Ecology adequately addressed potential exposures to windblown dust or soils?

Mr. Chartrand expressed his concerns that the proposed soil sections did not adequately address inhalation exposures that might occur as a result of windblown dust and soils. He noted that this was particularly a problem for those substances, such as cadmium and chromium, that are considered to be carcinogenic only when inhaled.

Ecology's Response: Comment noted. The final rule includes a new subsection which specifies that soil cleanup levels must be established at levels which prevents exceedances of cleanup levels for ambient air. Risks associated with inhalation of contaminated soils forms the basis for the Method A cleanup level for chromium.

XX. INDUSTRIAL SOIL CLEANUP STANDARDS (WAC 173-340-745)

A. The Public's Response

Soil cleanup levels are usually the subject of considerable discussion when developing cleanup requirements for individual sites. Consequently, it is not surprising that there was a considerable amount of public comment on the proposed soil cleanup standards for industrial sites. The principal issues raised during the rulemaking proceedings were the following:

Issue #1: **Is it appropriate for Ecology to distinguish between various land uses when establishing soil cleanup levels?**

Issue #2: **Can the industrial soil cleanup levels be applied to portions of individual sites?**

Issue #3: **Should industrial soil cleanup levels be established "as close as practicable" to residential soil cleanup levels?**

Issue #4: **What procedures were utilized to develop the cleanup levels in Table 3?**

Issue #5: **What procedures were utilized to establish the soil cleanup levels for lead?**

Issue #6: **What procedures were utilized to establish the soil cleanup levels for petroleum-related contaminants?**

Issue #7: **What procedures were utilized to establish soil cleanup levels for pentachlorophenol?**

Issue #8: **What procedures were utilized to establish soil cleanup levels for chromium?**

Issue #9: **What are appropriate procedures for establishing soil cleanup levels to protect ground water?**

Issue #10: **Should Ecology utilize soil leaching tests to establish soil cleanup levels that protect ground water?**

Issue #11: **What is an appropriate soil ingestion rate assumption for use in establishing soil cleanup levels for industrial sites?**

Issue #12: **What is an appropriate frequency of exposure for workers?**

Issue #13: **What is an appropriate point of compliance for soils which pose a direct contact threat?**

Issue #14: **What is an appropriate point of compliance for soils which pose a threat to ground water?**

Issue #15: **Is it appropriate to establish soil cleanup levels at concentrations which exceed dangerous waste designation levels?**

B. Ecology's Evaluation and Response

Issue #1: Is it appropriate for Ecology to distinguish between various land uses when establishing soil cleanup levels?

For purposes of establishing soil cleanup levels, Ecology proposed to distinguish between residential and industrial sites and included specific procedures for establishing soil cleanup levels that are protective of those uses. The proposed rule also provided the flexibility to establish site specific cleanup levels for uses such as agriculture, recreation, etc. This issue is discussed in Section XIX (Issue #1)

Issue #2: Can the industrial soil cleanup levels be applied to portions of individual sites?

Two individuals recommended that Ecology revise the rule to clarify that industrial cleanup levels could be applied to portions of a site. For example:

> The definition of a site in WAC 173-340-200 includes both onsite and offsite contamination. If an entire site must demonstrate industrial site use, then this could eliminate the use of industrial soil cleanup levels for an industrial site which has contaminated an offsite area which does not meet the industrial site definition. Industrial soil cleanup levels should be able to be used for that portion of a site which meets the definition, as long as cleaning up to those levels will not impact the cleanup on those portions of the site which are not industrial. The DOE-RL recommends adding language to WAC 173-340-745(1)(b) which says "To demonstrate industrial site use, the site, or portions thereof, shall...." (Izatt, p.6) [see also Syrdal, p. 18]

Ecology's Response: The final rule has been clarified to address the above concerns. WAC 173-340-745 states that industrial soil cleanup levels may be established for a portion of a site, while WAC 173-340-740 is used for non-industrial portions of the site (See WAC 173-340-745(1)(d).

Issue #3: Should industrial soil cleanup levels be established "as close as practicable" to residential soil cleanup levels?

In the proposed rule, Ecology specified that industrial soil cleanup levels shall be as close as practicable to soil cleanup levels established for residential areas. Several individuals recommended that this requirement should be eliminated:

> This paragraph should be deleted. This language essentially negates the industrial standards by requiring cleanup levels as close as practicable to nonindustrial compliance levels. Any site, regardless of whether cleanup levels are based on industrial site use or residential use, can only be cleaned to levels that are practicable. (Burgess and Dunster, p. 6)

****

"The DOE-RL feels that cleanup levels for industrial sites should be based on the reasonable maximum exposure and not set for residential exposure simply because it is technically practicable." (Izatt, p.7)

Ecology's Response: Ecology believes this provision is appropriate given the strong opposition to the industrial site classification expressed by environmental group representatives. (See Section XIX - Issue #1)

Issue #4: What procedures were utilized to develop the cleanup levels in Table 3?

The proposed rule included a list of Method A Compliance Cleanup Levels (Method A Cleanup Levels) for soils at industrial sites (Table #3). Several individuals requested clarification on how those values were derived.

Ecology's Response: In general, the procedures specified in the regulation were utilized to develop the soil cleanup levels in Table 3. Consequently, the values were derived from one of several sources. The following paragraphs provide a summary of the technical bases for the Method A values. Ecology is preparing guidance which provides greater detail on the underlying studies and factors that may be considered under Methods B and C:

Ground Water Protection: Method A Cleanup Levels for nine of the twenty-one hazardous substances have been established based on protection of ground water. These include the following hazardous substances: Benzene; Cadmium; DDT; Ethylene Dibromide; Mercury; Methylene Chloride; Tetrachloroethylene; 1,1,1 Trichloroethane and Trichloroethylene.

Direct Contact Potential: Method A Cleanup Levels for five of the twenty-one hazardous substances have been established on the basis of direct contact potential. Cleanup levels for four of those substances were based upon the direct contact formulae for carcinogens in WAC 173-340-745(4). These include the following hazardous substances: Arsenic; Lindane; PAHs (Carcinogenic); and PCB mixtures. The technical basis for the lead cleanup level is discussed under Issue #5 below.

Petroleum Contaminants: Method A Compliance Cleanup Levels for the six hazardous substances associated with petroleum releases were established at concentrations that protect ground water. These include the following substances: Ethylbenzene; Toluene, TPH (gasoline); TPH (Diesel); TPH (Other); and Xylenes. The technical basis for those levels is described in greater detail in Section XIX.

Inhalation Potential: The Method A cleanup level for chromium is based on preventing unacceptable risks associated with the inhalation of windblown dust.

Issue #5: What procedures were utilized to establish the soil cleanup levels for lead?

Several individuals expressed opinions on the proposed soil cleanup levels for lead. For example:

> The value presented for lead, 250 ppm, is unnecessarily conservative given the actual data by the Centers for Disease Control (CDC, 1985) on lead exposure in children and the guidance of both the CDC and the U.S. EPA (1989a) that lead levels of 500 to 1000 ppm do not result in measurable increases in children's blood lead levels. The U.S. EPA has set an interim cleanup level at Superfund sites of 500 to 1000 ppm (USEPA, 1989a). (Tsuji, p.7)

Ecology's Response: Evidence from human and animal studies indicate that exposure to elevated concentrations of lead compounds may result in a wide range of adverse effects (ATSDR, 1988a, 1990a). With respect to cleanup actions under the MTCA, the primary concerns are:

(1) Blood disorders resulting from lead's effects on heme synthesis;

(2) Central nervous system effects; and

(3) Carcinogenesis.

Several types of neurotoxic effects are associated with exposure to lead. Learning disabilities, encephalopathy, and irreversible brain damage can result from blood lead levels greater than 80 ug/dl and 100 ug/dl in children and sensitive adults, respectively. Children and fetuses with blood lead levels greater than 10 -20 ug/dl may also suffer neurotoxic effects resulting in decreased learning ability. Slowed nerve conduction has been observed in adults at 30-40 ug/dl (ATSDR, 1990)

Lead and inorganic lead compounds have been shown to cause cancer in animals and EPA has classified lead in Group B2 - probable human carcinogen (EPA, 1990). However, EPA has concluded that standard extrapolation methods would not adequately delineate the potential cancer risk (EPA, 1988). IARC has concluded that the evidence for carcinogenicity of lead is inadequate in humans and sufficient in animals and classified lead in IARC Group 2B- Possible Human Carcinogen.

The industrial soil cleanup level was based on correlation between soil lead levels and blood lead levels. It is consistent with the following guidelines:

> Correlation with Blood Lead Levels: The New Jersey Department of Environmental Protection has developed Interim Soil Action Levels for a number of contaminants including lead. The lead ISALs were based on observed correlations between ambient soil lead levels and blood lead levels (Madhaven, et al. 1989). The upper and lower range of values (1000 mg/kg and 250 mg/kg, respectively) are generally applied to industrial/commercial and residential properties, respectively.
>
> EPA Interim Soil Guidance: EPA (1989) has published interim soil cleanup levels for lead in residential areas (500 mg/kg) and industrial commercial areas (1000 mg/kg).

Issue #6: What procedures were utilized to establish the soil cleanup levels for petroleum-related contaminants?

The Method A soil cleanup levels for total petroleum hydrocarbons, ethylbenzene, toluene, and xylenes were based on preventing ground water contamination. See Section XIX - Issue #7.

Issue #7: What procedures were utilized to establish soil cleanup levels for pentachlorophenol?

The Method A soil cleanup level for pentachlorophenol has been deleted from Table #3 and will be reproposed (see discussion in Section XIX - Issue #6).

Issue #8: What procedures were utilized to establish soil cleanup levels for chromium?

The Method A soil cleanup levels for chromium were based on preventing excess cancer risks associated with the inhalation of wind blown dust. Chromium (VI) is classified by EPA in Group A - Human Carcinogen and a carcinogenic potency factor of 41 (mg/kg/day)-1 (unit risk of 1.2 x 10-2 ug/m3) has been calculated (EPA, 1990f and g). The following assumptions were utilized to calculate a soil cleanup level of 500 mg/kg: (1) concentrations in windblown dust are equal to soil concentrations; (2) average dust levels at the site(Total Suspended Particulates) are two times the average state levels (80 ug/m3) (Ecology, 1990); (3) duration of exposure is 20 years for a 70 kg worker; (4) a worker breathes 30 m3/day (5) twenty five percent of inhaled chromium is absorbed (EPA, 1984) and (6) one to hundred percent of the total chromium is chromium VI (ATSDR, 1989; EPA, 1984).

Issue #9: What are appropriate procedures for establishing soil cleanup levels to protect ground water?

Ecology proposed to establish soil cleanup levels at concentrations which will not result in ground water concentrations that exceed ground water cleanup levels. The rule specified that this determination would be made using the following procedure:

> For individual hazardous substances or mixtures, concentrations that are equal to or less than one hundred (100) times and ground water compliance cleanup level established in accordance with WAC 173-340-720 unless it can be demonstrated that a higher concentration is protective of ground water at the site. (WAC 173-340-740(3)(b)(i)(A))

A number of individuals states that the use of this approach was arbitrary and not scientifically sound. This is discussed in Section XIX (Issue #9).

Issue #10: Should Ecology utilize soil leaching tests to establish soil cleanup levels that protect ground water?

Several individuals recommended that Ecology consider basing the soil standard on the leachability of various hazardous substances. This issue is discussed in Section XIX (Issue #10).

Issue #11: What is an appropriate soil ingestion rate assumption for use in establishing soil cleanup levels for industrial sites?

Ecology proposed to utilize a soil ingestion rate of 100 mg/day when establishing soil cleanup levels for industrial sites. Several individuals expressed concerns that the use of this value would result in overestimates of actual exposures.

Ecology's Response: Ecology believes that the soil ingestion rates utilized to estimate soil cleanup levels in industrial areas are consistent with approaches used by other regulatory agencies and available scientific data. For example, EPA Region X utilizes an adult soil ingestion rate of 100 mg/day for both industrial and residential areas (EPA, 1990b).

Calabrese, et al, (1990) have completed a pilot study on adult soil ingestion rates. Using a mass balance approach, they estimated that median soil ingestion rates for adults ranged from 0.5 to 65 mg soil/day (means ranged from 5 to 77). They tentatively concluded that "both mean and median estimates for the three most reliable tracers (Al, Si, Y) are less than the EPA guidance figure of 100 mg/day and more closely approximate a value near 50 mg/day." Applying the children/adult ratios (based on the mean values) to the 95th percentile values for children reported in Calabrese et al. (1990a), one obtains upper bound values of 111, 6, and 65. Calabrese et al (1990b) cautioned that the reported values were based on five individuals and larger sample sizes would be necessary to confirm their preliminary findings.

Finally, several researchers have estimated potential ingestion rates which may apply to adults (Hawley, 1985; Lagoy, 1987; and Calabrese, et al, 1987). For example, Hawley estimated that an adult working outdoors for 8 hours per day would ingest the quantity of soil adhering to the inside surface of approximately 150 cm2 and an average soil adherence of 0.42 mg/cm2. Based on those values, he estimated a soil ingestion rate of 62 mg/day. Lagoy (1987) has reviewed these and other results and concluded values similar to Hawley's should be considered to represent an upper-bound rather than an average value.

Issue #12: What is an appropriate frequency of exposure for workers?

One commentor questioned the rationale for the proposed frequency of contact parameters used to calculate soil cleanup levels for workers:

> In calculating soil cleanup levels for workers, it is unclear why a different frequency of contact (1 or 100 percent) is used for

> assessing noncarcinogenic risks than for carcinogenic risks (0.3 or 30 percent). Although the chronic RfDs are not valid for short term exposures, U.S. EPA (1989a, b) allows evaluation of less than 100 percent frequency of contact by workers for assessing noncarcinogenic risks and uses the same exposure frequency as for carcinogenic risk calculations (0.36 or 36 percent). At worst case, for long term exposure (over much of a lifetime) workers would only be expected to be present a ta site for five out of seven days of the week. Some weeks they may work more days of the week, but also vacations and sick days would decrease the number of days worked over the years. The WDOE should also consider that the northern climate in Washington would decrease the amount of soil and dust ingested for much of the year. (Tsuji, p. 6)

Ecology's Response: Comment noted. Ecology has revised the rule to incorporate a duration of exposure of 0.4 for both carcinogens and noncarcinogens.

Issue #13: What is an appropriate point of compliance for soils which pose a direct contact threat?

Ecology proposed that soil cleanup levels would generally have to be attained throughout the site. However, Ecology proposed to provide some flexibility to establish conditional points of compliance for soils that present a direct contact hazard. This issue is discussed in Section XIX (Issue #13).

Issue #14: What is an appropriate point of compliance for soils which pose a threat to ground water?

Ecology proposed that, "for soil cleanup levels based on the protection of ground water, the point of compliance shall be established in the soils throughout the site." (WAC 173-340-740(6)(b)) This issue is discussed in Section XIX (Issue #14).

Issue #15: Is it appropriate to establish soil cleanup levels at concentrations which exceed dangerous waste designation levels?

One individual noted that the proposed rule is inconsistent with certain portions of the state Dangerous Waste Regulations (Chapter 173-303 WAC), and urged Ecology to clarify the relationship between the two regulations. Ms. Keeley stated:

> Ecology DW regs would designate ASARCO slag as DW for arsenic (assuming 100 ppm arsenic in slag). Ecology MTCA states that slag = soil, and provides soil cleanup levels of 20 ppm, 100 ppm, or 230 ppm arsenic. How will this discrepancy be addressed for slag which contains 100-230 ppm arsenic (permits? DW?) - it's DW but OK via MTCA?! Will slag w/>230 also be a DW? (Keeley, p. 1)

This issue is discussed in Section XIX (Issue #19).

XXI. CLEANUP STANDARDS TO PROTECT AIR QUALITY (WAC 173-340-750)

A. The Public's Response

Several individuals provided comments on this section. The principal issues raised during the rulemaking process were the following:

Issue #1: **Is it appropriate that Ecology include cleanup standards to protect air quality in this regulation?**

Issue #2: **Under what circumstances should the air cleanup standards be applied?**

Issue #3: **When is it appropriate to require the use of "best available control technology" (BACT)?**

Issue #4: **Are there specific air regulations that should be defined as "applicable state and federal laws?"**

Issue #5: **Is it appropriate to utilize 10^{-5} or 10^{-6} risk levels to define cleanup requirements in areas where background risks are substantially higher?**

Issue #6: **Is it appropriate to utilize a child's weight and breathing rate to estimate ambient air concentrations that will result in no adverse health effects?**

Issue #7: **Does the proposed rule provide the flexibility to factor in available information on inhalation absorption rates?**

Issue #8: **What is an appropriate ventilation rate for use estimating daily exposures for adults and small children?**

Issue #9: **Does Ecology have the discretionary authority to establish ambient air concentrations more stringent than those in the proposed rule on a case-by-case basis?**

Issue #10: **When evaluating compliance with air cleanup levels, what averaging times should Ecology utilize?**

B. Ecology's Evaluation and Response

Issue #1: Is it appropriate that Ecology include cleanup standards to protect air quality in this regulation?

During the rulemaking process, several individuals questioned the need to develop requirements to protect air quality. For example, Mr. Fortier stated:

> Ecology has proposed a section on cleanup standards to protect air quality. We feel that this section is inappropriately placed in these amendments and should be deleted. Air is not a media that can have cleanup levels like soil and ground water. Air pollution is controlled at the source and environmental compliance is

appropriately monitored through compliance standards, not cleanup standards. (Fortier, p. 1)

Mr. Syrdal also questioned the need for this section and recommended:

> The most important flaw in Section 750 is that it ignores Ecology's proposed rules for toxic air pollutants. Ecology's air program has released draft air toxics rules for new sources, and is working on draft rules for existing sources. These rules will include "acceptable source impact levels" (ASILs) for a large universe of toxic air pollutants. The new source rules expressly apply to sites undergoing cleanup under the MTCA. See proposed WAC 173-460-030(1)(b)(iii). The air toxics rules are more comprehensive and detailed than Section 750. For instance, they deal with such critical issues as dispersion modeling protocols and fugitive emissions.
>
> Given this coverage, the worst thing Ecology could do would be to adopt a second set of rules covering the same subjects. This would violate the cleanup standard objective of preserving the integrity of existing programs. WAC 173-340-750 should contain nothing other than a statement that cleanup actions under this chapter must comply with the toxic air pollutant standards contained in WAC ch. 173-460. (Syrdal, p.19)

Ecology's Response: It is Ecology's intent to utilize the procedures in Chapter 173-460 WAC once those rules become effective and are determined to be applicable to particular sites or cleanup actions. However, sole reliance on those rules presents several problems. First, it is difficult to cross-reference a nonexistent rule. Second, Chapter 173-460 WAC will address only new sources of pollution; many of the MTCA concerns relate to existing sources. Finally, Mr. Syrdal's comment regarding the "comprehensive" coverage of "critical issues such as dispersion modeling and fugitive emissions" is somewhat misleading since the draft rule appears to include nonprocess fugitive emissions as one of several exempt sources.

Issue #2: Under what circumstances should the air cleanup standards be applied?

Mr. Izatt stated that "[t]here appears to be some confusion with regards to when the air quality standards apply." He recommended that this section be revised to provide a clear statement on applicability.

Mr. Belfiglio recommended that:

> It should be made clear that the air standards in Section 750 do not apply during cleanup. Otherwise common technologies such as air stripping may be curtailed even if emissions from them are acceptable to air pollution control authorities. (Belfiglio,)

Ecology's Response: The Department believes that the requirements in Section 750 are potentially applicable to those sites and/or cleanup actions which are releasing or have the potential to release hazardous substances into

the ambient air at levels which exceed cleanup standards established under that section or Chapter 173-460 WAC.

Issue #3: When is it appropriate to require the use of "best available control technology (BACT)?"

In the proposed rule, Ecology stated that a person must demonstrate that "best available control technology" had been utilized before the department would consider approving a conditional cleanup level. Mr. Syrdal expressed concerns with this provision and stated:

> Another problem with Section 750 is that the conditions for approval of a conditional cleanup level (CCL) gravely restrict Ecology's authority to approve a meaningful CCL. For instance, a party whose site is already cleaner than background should not have to employ "best available control technology" to obtain a CCL. (Syrdal, p. 20)

Ecology's Response: In the revised rule, Ecology has clarified the requirements for use of BACT (See WAC 173-340-710). In general, cleanup actions which result in the construction of new sources of air pollution (i.e., air stripping towers). This requirement is consistent with Chapter 173-403 WAC which requires BACT for new sources and must be satisfied independent of existing air quality. With respect to existing sources, Ecology will require the use of "reasonably available control technology" as required under WAC 173-400-040 (General Standards for Maximum Emissions). In both cases, additional controls measures may be required where residual emissions result in ambient air concentrations which exceed cleanup levels established under WAC 173-340-750.

Issue #4: Are there specific air regulations that should be defined as "applicable state and federal laws?"

Mr. Peterson recommended that the National Emission Standards for Hazardous Air Pollutants (NESHAPs) published under Section 112 of the Clean Air Act be identified as "applicable state and federal laws."

Ecology's Response: Ecology agrees that the NESHAP requirements may be applicable for some sites. However, due to the narrow focus of those standards (source and substance-specific), the Department has decided not to incorporate a reference to this regulation into the statute. This will not preclude a site-specific application of these or other air requirements.

Issue #5: Is it appropriate to utilize 10^{-5} or 10^{-6} risk levels to define cleanup requirements in areas where background risks are substantially higher?

Mr. Syrdal questioned the rationale for establishing cleanup requirements for air emissions on the basis of a 10^{-5} or 10^{-6} risk level. He stated:

> The continued use of the 10^{-5} and 10^{-6} risk levels for the air cleanup levels is even more problematic than the use of those levels for the other media. In most, if not all, of the urban areas of the state, for example, existing background risks exceed these levels. Expenditures to reduce air emission risks to these levels when the background is far greater than these levels would be wasteful at best, as would the necessary monitoring to establish the precise background level and sources of contamination surrounding an existing site. (Syrdal, p. 20)

Ecology's Response: Ecology recognizes that in many areas existing levels of hazardous substances result in cancer risks which exceed 10^{-5} and 10^{-6}. Indeed, Ecology has identified toxic air pollution as high priority for increased regulatory efforts. Consequently, from a human health and public policy perspective, Ecology would find it difficult to justify the use of risk levels already judged to be unacceptable to define "acceptable" levels for cleanup. Indeed, without tighter controls on individual sources such as cleanup sites, it is doubtful that Washington will see measurable improvements in air quality.

Issue #6: Is it appropriate to utilize a child's weight and breathing rate to estimate ambient air concentrations that will result in no adverse health effects?

Several participants expressed concerns that Ecology's proposal for developing cleanup levels for non-carcinogens was incorrect. For example, Mr. Syrdal stated:

> "[There is no] scientific basis to use a child's weight and breathing rate to derive an ambient concentration limit that will produce no adverse health effects after a lifetime of exposure." (Syrdal, p. 20)

Other individuals expressing similar concerns included the following individuals: Aldrich, p. 20; and Tsuji, p. 6.

Ecology's Response: The purpose of the equation for noncarcinogens is to derive an ambient concentration that will result in no adverse health effects following chronic exposure. The chronic reference dose is intended to be used where exposure durations range from seven years to a lifetime. It is not unreasonable to expect that young children will be exposed to a hazardous substance for seven years or more. It is also not unreasonable to assume that young children are potentially more susceptible to the effects of hazardous substances due to higher breathing rates relative to body weight. Consequently, Ecology believes that the use of the chronic reference dose in combination with a child's body weight and breathing rate is appropriate.

Issue #7: Does the proposed rule provide the flexibility to factor in available information on inhalation absorption rates?

Dr. Tsuji recommended that Ecology modify the equations in WAC 173-340-750 to incorporate an inhalation absorption parameter:

> An inhalation absorption parameter should be added to the equation for calculating cleanup levels protective of noncarcinogenic and carcinogenic effects of chemicals. For some chemicals such as arsenic, the toxicity criteria (e.g., cancer potency) is based on an absorbed dose. The U.S. EPA risk assessment procedures state that toxicity criteria based on an absorbed dose should be compared to an absorbed and not an administered dose (USEPA, 1989b). Therefore, for arsenic, an absorption parameter of 30% should be used as specified by the U.S. EPA (1984; 1989b). Using the equation as presented in the Proposed Amendments would be scientifically incorrect. (Tsuji, p. 6)

Ecology's Response: Comment noted. Ecology will revise the rule to provide such flexibility.

Issue #8: What is an appropriate ventilation rate for use estimating daily exposures for adults and small children?

Ecology proposed to develop cleanup levels for adults and children using breathing rates of 20 m^3/day and 10 m^3/day, respectively. Although, Ecology received no comments on this value, several individuals provided comments on an earlier proposal to base cleanup levels on a breathing rate of 1.3 m^3/hr. For example:

> Using a 1.3 m^3/hr as a normal breathing rate for 24 hours/day is simply too high. This would represent someone who is under moderate to heavy exertion for 24 hours. In the occupational environment, normal respiratory values used are 0.8 m^3/hr for average activity, and 1.0 -1.5 for heavy activity, and 1.0 -1.5 for heavy activity. It is not reasonable to assume that this high rate would occur for 24 hr/day for 30 years. (Eaton, comments on the October 16, 1989 draft)

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> "The breathing rate seems too high." (Lorenzana, comments on October 16, 1989 draft)

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> "There is little need to calculate exposures on an hourly basis. One can use the standard assumption for adults of 20 m^3/day which is for a 24 hour period. The assumption for ages 2-10 is 15 m^3/day and for ages 0-2 is 4 m^3/day." (Merritt, comments on October 16, 1989 draft)

Ecology's Response: The breathing rate used to calculate cleanup levels for carcinogens is 20 m^3/day. This value is based on data from the International Commission on Radiation Protection (ICRP, 1981) for a reference man. This assumes 16 hours of light activity and 8 hours of rest. Based on the above comments, the Department believes that this provides a reasonable basis for establishing cleanup levels that is similar to approaches used by other regulatory programs. For example:

- Ecology's Air Program - When establishing ASILs, Ecology utilizes inhalation reference doses and unit risk factors developed by EPA. These values are based on an breathing rate of 20 m3/day.

- EPA Incinerator Regulations - In May 1990, EPA proposed new emission control requirements for toxic substances released during the operation of hazardous waste incinerators. The approach used to develop reference air concentrations utilized a breathing rate of 20 m3/day (EPA, 1990h).

- EPA Risk Assessment Guidance for Superfund - EPA (1989a) specifies that "[f]or continuous exposure situations, or assessments in which specific activity patterns are not known, use 20 m^3 as the average adult daily inhalation rate and 30 m^3/day as the reasonable worst case." EPA (1989a) specifies inhalation rates ranging from 0.4 to 4.2 m3/hr for a 10 year old child.

Issue #9: Does Ecology have the discretionary authority to establish ambient air concentrations more stringent than those in the proposed rule on a case-by-case basis?

Several participants recommended that Ecology delete the phrase that would allow the department to establish cleanup levels at "any other concentrations that are necessary to protect human health and the environment." This issue along with Ecology's response is discussed in greater detail in Section III.

Issue #10: When evaluating compliance with air cleanup levels, what averaging times should Ecology utilize?

Ecology proposed the following requirements for monitoring compliance with air cleanup levels:

> Compliance monitoring. Compliance with ambient air cleanup levels for non-carcinogens shall be based on 24-hour time weighted averages. Compliance with ambient air cleanup levels for carcinogens shall be based on annual averages. (WAC 173-340-750(7))

Several participants stated that it was inappropriate to base compliance with chronic exposure limits using a 24-hour averaging interval. For example:

> Some sites may emit hazardous substances that pose a short term health risk. Acute exposure limits may be needed for these sites. But such limits must be based on acute health effects projections or data. One source of such limits may be OSHA permissible exposure limits for short term exposures to various hazardous chemicals. It is irresponsible to base 24-hour ambient concentration limits on a lifetime exposure reference dose. (Syrdal, p. 20)
>
> **********
>
> According to the Proposed Amendments, compliance with ambient air cleanup levels for noncarcinogens is to be based on 24-hour time weighted averages. This in effect compares acute exposure concentrations to cleanup levels developed using chronic (lifetime) reference doses. As noted by the U.S. EPA (1989b), however, chronic reference doses may be overly protective if used to evaluate the potential for adverse effects resulting from substantially less than lifetime exposures. Because of the way that chronic inhalation reference doses are derived, annual averages should be used instead to determine compliance. (Tsuji, p. 9)

Ecology's Response: The 24-hour averaging time was chosen to insure adequate protection of human health and maintain consistency with the approach being utilized under Chapter 173-460 WAC. In proposing this requirement, the Department attempted to balance the practical considerations of air monitoring with the underlying technical bases for individual cleanup levels.

Ecology believes the above comments have considerable merit and has reviewed approaches being used by other regulatory programs. These include:

> Ecology's Air Program - Ecology's approach for regulating toxic emissions for new sources is stated in the February, 1990 draft of Chapter 173-460 WAC (Controls for New Sources of Toxic Air Pollutants). The draft specifies that if an acceptable source impact level (ASIL) is based on an EPA inhalation reference dose, the averaging time specified by EPA shall be used. For other noncarcinogens, the draft rule specified that ASILs would be derived by dividing the TLV-TWA by 300 and compliance would be based on a twenty four hour averaging time.
>
> Other State Programs - Calabrese and Kenyon (1990) have reviewed and summarized approaches being used by seven other states to regulate air toxics. The found that averaging times for noncarcinogens varied from 8 hours to annual averages (See Table 1).
>
> EPA Superfund Program - EPA Region X specifies that "[f]or the concentration of particles (particulate concentration), the yearly average concentration is used for the average and upper bound case. Contaminant concentrations on particles are derived from soil average and upper bound concentrations. For the concentration of volatiles the yearly average is used for the average and upperbound cases." (EPA, 1990b)

On the basis of this review, Ecology concludes that when measuring compliance with air cleanup levels based on chronic reference doses or inhalation

reference concentrations it may be appropriate to utilize an averaging time other than 24 hours. The Department has revised the rule to provide the flexibility to utilize alternate averaging times.

XXII. SEDIMENT CLEANUP STANDARDS (WAC 173-340-WAC) [RESERVED]

A. The Public's Response

Several respondents were concerned with how the rules will apply in sediments.

> "Without seeing sediment standards, it is difficult to evaluate how this regulation will apply to multi-media contamination in estuary environments?" (Sacha, p. 2)

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> [T]he ports remain concerned about how this rule will be applied in aquatic cleanups. The proposed rule has reserved the section of the rule dealing with sediment standards and aquatic cleanups. While this section has been properly left to another forum to discuss, it is still somewhat unclear exactly how this rule will work in practice in aquatic environments where there are complex contribution and ownership patterns. (Johnson, p. 2)

B. Ecology's Evaluation and Response

Ecology intends to utilize the sediment management regulations to establish cleanup standards for sites involving sediment cleanup. For MTCA cleanup actions, the sediment cleanup standards will be applied within the overall regulatory framework established in the MTCA rule. Ecology recognizes there are continuing concerns regarding the relationship between the two regulations and has incorporated the following provision into WAC 173-340-710:

> Sediment management requirements. Sediment cleanup actions conducted under this chapter shall comply with the sediment cleanup standards in Chapter 173-204 WAC. In addition, a state remedial investigation/feasibility study conducted under WAC 173-340-350 shall also comply with the cleanup study plan requirements under Chapter 173-204 WAC. The process for selecting sediment cleanup actions under this chapter shall comply with the requirements in WAC 173-340-360.

XXIII. ANALYTICAL PROCEDURES (WAC 173-340-830 WAC)

Section VII discusses these issues.

XXIV. REFERENCES

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PART E

XXV. CONCISE EXPLANATORY STATEMENT

The following is the concise explanatory statement required by RCW 34.05.355 stating Ecology's reasons for adopting the rule and a description of any difference between the text of the proposed rule as published in the state register and the text of the rule as adopted, other than editing changes, and the reasons for the change.

Ecology is proposing to adopt amendments to the Model Toxics Control Act Cleanup Regulation, Chapter 173-340 WAC. The amendments define procedures for establishing cleanup standards, criteria for selecting cleanup actions to comply with those standards, and requirements for corrective actions at leaking underground storage tanks. The standards apply to sites where hazardous substances have been released into the environment at levels which present a threat to human health and the environment.

RCW 70.105D.030(2)(d) directs Ecology to adopt and enforce "minimum cleanup standards for remedial actions at least as stringent as the federal cleanup standards under Section 121 of the federal cleanup law, 42 U.S.C. 9621 and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law." RCW 70.105D.030 also establishes three basic requirements for remedial actions performed under the Model Toxics Control Act. Cleanup actions shall comply with cleanup standards, utilize permanent solutions to the maximum extent practicable and include adequate monitoring to ensure the effectiveness of the remedial action.

Within this statutory framework, the amendments define a two-step approach for establishing cleanup requirements for individual sites:

> Establishing Cleanup Standards: The standards provide a uniform, state-wide approach to cleanup that can be applied on a site-by-site basis. Establishing cleanup standards for individual sites requires specification of (1) hazardous substance concentrations that protect human health and the environment ("cleanup levels"); (2) the location on the site where cleanup levels must be attained ("points of compliance"); and (3) additional regulatory requirements that apply to a cleanup action because of the type of action and/or the location of the site.
>
> Selecting a Cleanup Action: This step involves evaluating methods that could be used to clean a site before deciding which of those methods would best achieve cleanup standards. Aside from meeting the standards, cleanup actions must also utilize permanent solutions to the maximum extent practicable, achieve cleanup in a reasonable timeframe, and include monitoring to ensure the long-term effectiveness of the cleanup action.

Cleanup levels established under this regulation are based on requirements under other applicable state and federal laws and health risk assessment. Using a health risk approach, cleanup levels for individual carcinogens are generally based upon an excess cancer risk of 1 in 1,000,000 (one-in-one million). The regulation provides the flexibility to utilize a cancer risk level of 1 in 100,000 in limited situations. In both cases, the total site risk cannot exceed 1 in 100,000. For noncarcinogens, cleanup levels are established at levels which are estimated to result in no acute or chronic toxic effects.

Washington State's Underground Storage Tank Act, Chapter 90.76 RCW directs Ecology to establish an underground storage tank program which meets the federal requirements for program delegation. Ecology must adopt rules which are at least as stringent as the federal underground storage tank regulations (40 CFR Part 280 Subpart F).

Corrective action at petroleum and other hazardous waste sites in Washington State falls within the jurisdiction of the Model Toxics Control Act. Ecology is adopting Section 450 of Chapter 173-340 WAC to address the requirements of Chapter 70.105D RCW, Chapter 90.76 RCW and 40 CFR Part 280 regarding releases from underground storage tanks.

SUMMARY OF CHANGES

The following is a summary of the changes, other than editing, made in response to public concerns voiced through written and oral testimony. The changes are categorized according to the appropriate section in the regulation.

Section 120: Overview

(2)(a) was clarified by specifying that discovery of an historical release must be reported "within 90 days of discovery," and that most current releases must be reported "immediately." These additions provide potentially liable parties with clearer guidance.

(4)(b) contains additional guidance clarifying that "at some sites, restrictions on the use of the land and resources (institutional controls) will be required to insure continued protection of human health and the environment," and a notation of where additional overview discussion of these requirements is located. These additions provide potentially liable parties with clearer guidance.

Section 200: Definitions

"Applicable state and federal laws" was revised to clarify that the department will utilize the criteria in WAC 173-340-710(3) when evaluating whether a particular requirement is relevant and appropriate. This change was made in order to make the definition consistent with the provisions of WAC 173-340-710 and to reduce uncertainty during rule implementation.

"Carcinogenic potency factor" was revised to clarify that this value may be based on epidemiological data and may be expressed as a maximum likelihood estimate. This change was made in response to public comment urging Ecology to clarify this distinction.

"Cleanup action" was revised to clarify that cleanup actions shall comply with WAC 173-340-360. The specific requirements were substituted for the cross reference to improve rule readability.

"Cleanup level" was revised to "means the concentration of a hazardous substance in soil, water, air or sediment that is determined to be protective of human health and the environment under specified exposure conditions." This change was made to provide a clearer definition and relate the term to the statutory directive to protect human health and the environment.

"Cleanup standards" was expanded by clarifying that cleanup standards include cleanup levels, points of compliance, and additional regulatory requirements. This change was made in response comments requesting clarification on the relationship between cleanup levels, cleanup standards, and cleanup actions.

"Containment" was revised to incorporate the phrase "within a defined boundary." This change was in response to public comment requesting that Ecology clarify this portion of the definition.

"Direct contact" was added to clarify what is meant by the use of this term.

"Exposure" was expanded to incorporate the sentence "Exposure is quantified as the amount of the agent available at the exchange boundaries (e.g. skin, lungs, gut) and available for absorption." This change was made in response to public comment and is intended to provide a clearer definition by incorporating some of the concepts contained in federal guidance documents.

"Exposure pathway" was expanded to capture the concept of source, transport, human contact, and absorption. This change was made in response to public comment requesting that Ecology clarify this definition by incorporating some of the basic concepts found in federal guidance documents.

"Ground water" was revised by incorporating the phrase "below a surface". This change was made in order to clarify that the term "water" in the proposed amendments was referring to "surface water".

"Indicator hazardous substances" was expanded to indicate they can also be used during any phase of remedial action to characterize a site. This change was made to provide a clearer definition.

"Inhalation reference dose" was deleted in response to public comment that this term was covered under the term "reference dose".

"Institutional controls" was revised to ensure consistency with the revisions in WAC 173-340-440.

"Maximum contaminant level" or "MCL" was expanded to clarify that the Washington State Board of Health can also establish an MCL. This change was made to provide a clearer definition.

"Maximum contaminant level goal" was expanded to clarify that the Washington State Board of Health can also establish an MCLG. This change was made to provide a clearer definition.

"Null hypothesis" was expanded for rule clarification to explain that the null hypothesis "shall not apply to cleanup levels based on background concentrations." This change was made in response to public comments and in order to ensure consistency with federal guidance documents.

"Permanent solution" was revised by replacing the phrase "such as an off-site landfill" with "other than the approved disposal of any residue from preferred treatment technologies under subsections (4)(a)(i) through (iii) of this section". This change was made in response to public comment recommending that Ecology expand the definition to reflect current use of the term and in order to reduce confusion during rule implementation.

"Polychlorinated biphenyls" or "PCB mixtures" was revised by replacing the phrase "appropriate Test Methods for Evaluating Solid Wastes, U.S. EPA, SW-846 and any revisions of amendments thereto, or other test methods approved by the department" with the phrase "appropriate analytical methods as specified in WAC 173-340-830." This change was made in order to ensure consistency with WAC 173-340-830.

"Polycyclic aromatic hydrocarbons" or "PAH" was revised by replacing the phrase "appropriate Test Methods for Evaluating Solid Wastes, U.S. EPA, SW-846 and any revisions of amendments thereto, or other test methods approved by the department" with the phrase "appropriate analytical methods as specified in WAC 173-340-830." This change was made in order to ensure consistency with WAC 173-340-830.

"Radionuclide" was expanded to clarify that radionuclides are considered hazardous substances under this rule.

"State remedial investigation/feasibility study" was revised by replacing the word "plan" with the phrase "under WAC 173-340-360." This change was made to clarify that the RI/FS must address the factors in Section 360.

"Technically feasible" was changed to "technically possible" in response to public comment. This change was made to improve the readability of the rule by using words or phrases consistent with common usage.

"Technically practicable" was changed to "practicable". This change was made in order to improve the readability of the rule. In addition, the definition was expanded to define the role of cleanup costs in evaluating what is practicable. The definition was also expanded to clarify that an evaluation of "permanent to the maximum extent practicable" would be based on the factors in WAC 173-340-360(5).
"Total excess cancer risk" was added for clarification.

"Upper bound on the estimated cancer risk of one in 100,000" was added for clarification.

"Upper bound on the estimated cancer risk of one in 1,000,000" was added for clarification.

"Volatile organic compound" was revised for clarification.

Section 350: State Remedial Investigations and Feasibility Study

6(c)(iii) was revised from "aquifers" to "ground waters" in order to be consistent with other sections in the rule.

6(e) was revised to assure consistency with Section 360 by replacing (i) through (ix) with "be evaluated for compliance with the requirements in WAC 173-340-360 WAC."

Section 360: Selection of Cleanup Action

Subsection (1) was amended to incorporate the following sentence: "This section is intended to be used in conjunction with the cleanup standards defined in WAC 173-340-700 through WAC 173-340-760 and the administrative principles for the overall cleanup process (WAC 173-340-130)." This was added to clarify the relationships between these sections.

Subsection (1) was amended to incorporate the following sentence: "Because cleanup actions will often involve the use of several cleanup technologies or methods at a single site, the overall cleanup action shall meet the requirements of this section." This was added to emphasize that most cleanup actions will involve several technologies or methods.

Subsection (2) was retitled "Threshold Requirements". Paragraph (b) was moved to subsection (3). This change was made in response to public comment and is intended to provide a clearer separation between those requirements that relate to the level of protection and those related to the mix of technologies used at a site.

Subsection (3) of the proposed amendments was moved to WAC 173-340-700. Subsection (3) was retitled "Other Requirements" and paragraph (2)(b) of the proposed amendments incorporated into this subsection. In addition, the requirement that cleanup actions be technically practicable was deleted because it duplicates other requirements in this subsection and, consequently, would increase the potential for inconsistent interpreta-
tion and implementation of this section.

Subsections (4) and (5) of the proposed amendments were moved to other portions of the regulation in order to improve the readability of the rule.

Subsection (4) was retitled "Cleanup Technologies" and (6)(b) and (6)(c) of the proposed amendments incorporated into this subsection.

Subsection (5) was retitled "Permanent Solutions" and several parts of the proposed amendments were incorporated into this subsection. The following provides a summary of the modifications made to this subsection:

(5)(a) was added to provide an overall focus for this subsection.

The language in (5)(b) was in (6)(a) of the proposed amendments. The phrase "such as an off-site landfill" was replaced with "other than the approved disposal of any residue from preferred treatment technologies under subsections (4)(a)(i) through (iii) of this section". This change was made in response to public comment recommending that Ecology expand the definition to reflect current use of the term and in order to reduce the potential for inconsistent rule interpretation.

(5)(c) was added to clarify what types of technologies result in permanent solutions. This change was made in order to reduce uncertainty in rule implementation.

(5)(d) is a combination of (6)(d), (7)(c), and WAC 173-340-350(6)(e) of the proposed amendments. This change was made to clarify that the list of factors considered during the remedial investigation/feasibility study were the same factors used to determine whether a cleanup action represents a permanent solution to the maximum extent practicable. In addition, the phrase "the degree the cleanup action may perform to a higher level than specific standards in WAC 173-340-700 through 173-340-760, and improvement of the overall environmental quality" was added to (5)(d)(i). This change was made in response to a public comment and is intended to clarify that a number of factors are considered when evaluating the overall protectiveness of human health and the environment.

The following language was incorporated into (5)(e): "A cleanup action or a portion of the cleanup action shall not be selected unless it can be demonstrated that representative higher preference technologies were considered and found to be impracticable based upon the factors in subsection (d)." This was based on language in (9)(a)(vi) of the proposed amendments and was added here to emphasize the need to consider higher preference technologies during the remedial investigation/feasibility study. The word "representative" was added to clarify that a person was not required to identify and evaluate every technology in a particular technology category.

The language in (5)(f) was in (6)(e) of the proposed amendments.

Subsection (6) was retitled "Restoration Time Frame" and the provisions from subsection (8) of the proposed amendments were incorporated into this subsection. In addition, (ix) was revised to state "Natural processes which reduce concentrations of hazardous substances and have been documented to occur at the site or under similar site conditions." This change was made to clarify that several natural processes may result in a reduction in the levels of hazardous substances. This change was also made to clarify that such processes and resulting reductions must be documented to occur. Such documentation may include site-specific data or information gathered under similar site conditions.

The provisions of proposed subsection (7) were incorporated into subsection (5). Subsection (7) was retitled "Ground Water Restoration" and the language relating to ground water remediation included in (4)(b)(ii) of the proposed amendments was incorporated into this subsection. The reference to RCW 90.48.010 and RCW 90.54.020 was deleted because those provisions generally apply to preventative actions.

Subsection (8) was retitled "Containment Actions." and language from 6(e)(iv) and (v) of the proposed amendments incorporated into this section. These changes were made in order to consolidate requirements pertaining to containment actions into one subsection. In addition, the following language was incorporated into this section: "If the proposed cleanup action involves onsite containment, the draft cleanup action plan shall specify the types, levels, and amounts of hazardous substances remaining onsite and the measures that will be utilized to prevent migration and contact with those substances." This language was added to address concerns that nearby residents might be unaware that hazardous substances remain on-site.

Subsection (9) was retitled "Expectations" and new language added which provides guidance on Ecology's expectations with respect to the use of various cleanup technologies. This change was made in response to public comment and is similar to provisions in the federal cleanup regulations.

Subsections (9) through (12) in the proposed amendments were renumbered. Subsection (10), Draft Cleanup Action Plan, was amended to incorporate the following item: (ix) Where the cleanup action involves on-site containment, specifications of the types, levels, and amounts of hazardous substances remaining on site and the measures that will be utilized to prevent migration and contact with those substances." This language was added to ensure that the list of items enumerated in this subsection include all of the items listed elsewhere in Section 360.

Subsection (12) was revised to clarify that Ecology will provide public notice when cleanup levels specified in the cleanup action plan cannot be achieved. This provision was added in order to ensure compliance with federal requirements.
Subsection (13) was amended to incorporate "or order or decree" after "record of decision" and to delete the reference to record of decision in (a) and (b). This change was made to address situations where federal cleanup actions are performed as a result of an order or consent decree and do not involve preparation of a record of decision.

Section 420 - Periodic Review

Subsection (2) was added to clarify which factors will be considered during the periodic review. This section consolidates factors specified elsewhere in the rule.

Subsection (3) clarifies where the periodic review will be published, and subsection (4) clarifies when additional public review and comment on a cleanup action plan will be required. This subsection was added to address concerns that interested citizens would not be aware of ongoing reviews and/or changes in the cleanup action plan.

Section 440 - Institutional Controls

Subsection (1) was amended to include the sentence "Institutional controls are measures undertaken to limit or prohibit activities that may interfere with the integrity of an interim action or cleanup action or result in exposure to hazardous substances at a site." This sentence was added in order to clarify that institutional controls include a wide range of measures.

Subsection (3) was added to clarify that the term "institutional controls" refers to both the physical actions undertaken to restrict the use of a site and the legal and administrative mechanisms used to ensure that those restrictions are maintained over time.

4(a) was amended to clarify restrictive covenants were required for properties owned by the potentially liable parties. 4(b) was added to provide the flexibility to utilize measures other than restrictive covenants in areas of the site that are outside the property where the release of hazardous substances occurred. This change was made in recognition of the practical difficulties associated implementing and overseeing restrictive covenants for properties owned by persons not considered potentially liable persons under this chapter.

5(a) contains additional language providing a clearer statement that site activities that assure the integrity of a cleanup action must also continue to protect human health and the environment.

Subsection (6) has been amended to incorporate the sentence "It is the department's expectation that such assurances will be required whenever the cleanup action includes containment and in other appropriate situations." This language was added to address public concerns that the potentially liable party might not have sufficient financial resources to perform operation and maintenance measures associated with the containment of hazardous substances.

Subsection (7) was revised to reflect the change in use of the terms "method A and B cleanup levels" instead of "compliance levels established under WAC 173-340-700 through 760."

Section 450 - Releases from Underground Storage Tanks

2(b) has been amended to clarify that during an initial response, the UST owner or UST operator is required to remove as much of the hazardous substance as is possible from an underground storage tank.
Subsection 8(b) has been expanded to clarify that additional requirements imposed by Ecology will be directed towards assuring adequate protection of human health and the environment.

Section 700 - Overview of Cleanup Standards

This section has been reorganized in order to provide a more concise overview of the cleanup standards portions of the rule. This change was made in response to public comment and is intended to improve the readability of the rule. The original language is now located in Sections 700, 704, 705, 706, 707, and 708. This section now provides a more concise summary of the procedures and requirements for establishing cleanup standards and describes the relationship between cleanup standards and selection of cleanup actions.

The phrase "the goal is to establish cleanup levels as close as possible to natural background levels" has been deleted from the final rule. This change was made in response to concerns that it reflected an approach that is different than one based upon protecting human health and the environment and, consequently, would complicate interpretation and implementation of this rule.

Subsection (1) has been modified to reflect the purpose of this section and clarifies the relationship between this section and referenced sections. The second sentence was originally located in 700(6)(c) and 8(c) of the proposed amendments.

Subsection (2) was retitled to "Cleanup standards versus selection of cleanup actions" and includes language which explains that establishing cleanup standards requires establishing cleanup levels, points of compliance, and additional regulatory requirements that apply to a cleanup action because of the type of action and/or the location of the site. This subsection also summarizes the procedures for evaluating and selecting cleanup actions. This subsection was included to provide clearer guidance on the relationship between cleanup levels, cleanup standards, and cleanup actions.

Subsection (3) describes the three basic methods for establishing cleanup levels. This represents a summary of provisions contained in sections 700(5)

through 700(9) of the proposed amendments. The three methods have been renamed Method A, Method B, and Method C. This change was made in response to public comment and is designed to improve the readability of the rule.

Subsection (4) summarizes additional requirements for setting cleanup levels. These provisions are located elsewhere in the regulation and have been reiterated here for clarity.

Subsection (5) summarizes the linkages between cleanup standards and cleanup actions.

Subsection (6) introduces the basic concepts associated with establishing points of compliance, restoration time frame, and compliance monitoring. These provisions are located elsewhere in the regulation and have been reiterated here for clarity.

Subsection (7) has been added in order to identify some of the principles underlying cleanup standards. The following additions were made:

The language in (7)(a) was added to clarify the relationship between this subsection and other portions of the rule.

The following language was added to (7)(b): "Establishing cleanup standards and selecting an appropriate cleanup action involves both technical and public policy decisions. This chapter is intended to constrain the range of decisions needed to be made on individual sites to promote expeditious cleanups." This language was added to highlight the dual nature of many of the decisions under this chapter.

The language in (7)(c) was added in order to describe Ecology's interpretation of the statutory policy that "each person has a fundamental and inalienable right to a healthful environment". This was added to clarify the public policy underlying the technical procedures in the rule.

The language in (7)(d) was added to restate a provision already included in WAC 173-340-720 through WAC 173-340-750. This change was made in order to facilitate consistent rule interpretation and implementation.

The language in (7)(e) was originally located in WAC 173-340-360 of the proposed rule. It was moved into this section to improve rule readability and facilitate consistent rule interpretation and implementation.

The language in (7)(f) was added to clarify when it is appropriate to consider cleanup costs under this chapter. It summarizes requirements in other portions of the rule.

The language in (7)(g) was added to restate several provisions from WAC 173-340-360. This change was made to improve rule readability and facilitate consistent rule interpretation and implementation.

The language in (7)(h) was added to restate provisions already included in WAC 173-340-720 through WAC 173-340-750. This change was made in order to facilitate consistent rule interpretation and implementation.

The language in (7)(i) was added to restate provisions already included in WAC 173-340-360, WAC 173-340-740, and WAC 173-340-745. This change was made in order to facilitate consistent rule interpretation and implementation.

Section 702 - General Policies

The language in this section was originally located in WAC 173-340-705(1) through 173-430-705(6) of the proposed amendments.

Section 704 - Use of Method A

Subsection (1) contains language originally located in WAC 173-340-700(5)(b) of the proposed amendments.

Subsection (2) contains language originally located in WAC 173-340-700(6) of the proposed amendments. The phrase "For individual hazardous substances not addressed under (a) and (b) of this subsection, concentrations that do not exceed natural background levels or the practical quantification limit for the substance in question. This change was made in order to increase the number of sites where Method A could be used.

Subsection (3) contains language originally located in WAC 173-340-700(6)(a)(iii) of the proposed amendments. This subsection was revised to clarify that a decision by Ecology to require more stringent cleanup levels than those required under subsection (2) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

The following language was added to subsection (4): Caution on misusing method A tables. Method A tables have been developed for specific purposes. They are intended to provide conservative cleanup levels for sites undergoing routine cleanup actions or those sites with relatively few hazardous substances. The tables may not be appropriate for defining cleanup levels at other sites. For these reasons, the values in these tables should not automatically be used to define cleanup levels that must be met for financial, real estate, insurance coverage or placement, or similar transactions or purposes. Exceedances of the values in these tables do not necessarily trigger requirements for cleanup action under this chapter." This addition was made in response to public comment. It was made in order to provide a concise summary of the purpose for the tables and a cautionary note on their use for other purposes.

Subsection (5) contains language originally located in WAC 173-340-700(6)(b) of the proposed amendments.

Section 705 - Use of Method B

Subsection (1) contains language originally located in WAC 173-340-700(5)(c) of the proposed amendments.

Subsection (2) contains language originally located in WAC 173-340-700(7)(a)(i) through (iii) of the proposed amendments. The following changes were made:

In (2)(c), the phrase "sufficiently protective" has been added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In subsection (2)(c)(ii), the phrase "excess cancer risk" has been replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.
Subsection (3) contains language originally located in WAC 173-340-700(7)(a)(iv) of the proposed amendments. This subsection was revised to clarify that a decision by Ecology to require Method B cleanup levels more stringent than those required under subsection (2) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (4) contains language originally located in WAC 173-340-700(7)(b) of the proposed amendments. The phrase "including cleanup levels based on applicable state and federal laws" was added to this subsection in order to clarify that when evaluating the hazard index and total excess cancer risk, cleanup levels based on applicable state and federal laws would also be reviewed.
Subsection (5) contains language originally located in WAC 173-340-700(7)(c) of the proposed amendments.

Section 706. Use of Method C

Subsection (1) contains language originally located in WAC 173-340-700(5)(d) of the proposed amendments. Items (iv) and (v) were deleted. This change was made in response to public comment that it was inappropriate to consider the cost of cleanup when establishing cleanup levels. In addition, the following language was added to this subsection "The site is defined as an industrial site and meets the criteria for establishing soil cleanup levels under WAC 173-340-745." This was added to clarify the relationship between Method C cleanup levels and cleanup levels established under WAC 173-340-745.

Subsection (2) contains language originally located in WAC 173-340-700(8) of the proposed amendments. The following changes have been made:

In subsection (2)(c), the phrase "sufficiently protective" has been added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In subsection (2)(c)(ii), the phrase "excess cancer risk" has been replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.
Subsection (3) contains language originally located in WAC 173-340-700(8)(a)(iv) of the proposed amendments. This subsection was revised to clarify that a decision by Ecology to require more stringent cleanup levels than those required under subsection (2) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (4) contains language originally located in WAC 173-340-700(8)(b) of the proposed amendments. The phrase "including cleanup levels based on applicable state and federal laws" was added to this subsection in order to clarify that when evaluating the hazard index and total excess cancer risk, cleanup levels based on applicable state and federal laws would also be reviewed.
Subsection (5) contains language originally located in WAC 173-340-700(8)(c) of the proposed amendments.

Section 707. Analytical Considerations

The language in this section was included in WAC 173-340-705(12) of the proposed amendments and was reordered as a separate section to help make the final rule easier to read.

Section 708. Human Health Risk Assessment Procedures

Subsections (2), (3), (5), (6), (7), (8), (9), (10), and (11) were included in WAC 173-340-700 or WAC 173-340-705 of the proposed amendments and were incorporate into a single section to help make the rule easier to read.

In (11)(c)(ii), the word "lower" was substituted for "upper" in order to minimize the number of false positives.

In (11)(d), the sentence "The number of samples for other media shall be sufficient to provide a representative measure of background concentrations and shall be determined on a case-by-case basis." was added in order to clarify that minimum sample size requirements only apply to soil sampling.

The following language was added to this section: "(12), "Significant figures. Risk assessment results shall be presented using one significant figure." This was added in response to public comments that the degree of detail in risk assessment results should be commensurate to the precision of available methods.
Section 710. Applicable State and Federal Laws

(1)(a) was revised to incorporate the phrase "those requirements that the department determines, based on consideration of the criteria in subsection (3) of this section". This was added to clarify that site-specific flexibility exists with respect to a determination that a requirement is relevant and appropriate.

A new sentence, "WAC 173-340-710 through WAC 173-340-760 identifies several requirements the department shall consider relevant and appropriate for establishing cleanup standards.", was added to subsection (3). This sentence will clarify that certain specified requirements which are considered relevant and appropriate on a statewide basis are identified in the regulation.

Subsection (6) was added to this section in order to provide clearer guidance to potentially liable parties. This subsection includes a list of selected applications of applicable state and federal laws formerly located in WAC 173-340-360 of the proposed amendments.

(6)(b) was revised to clarify that Best Available Control Technology will be required for releases of hazardous substances into the air resulting from cleanup actions. This revision was made to ensure that cleanup actions will be performed in a manner that minimizes air impacts.

(6)(c) was revised to clarify that the solid waste closure requirements in Chapter 173-304 WAC are minimum requirements for cleanup actions at solid waste landfills conducted under this chapter. This change was made to address the concerns associated with the long-term leaching of hazardous substances and to reduce regulatory uncertainty as to whether cleanup actions must comply with these requirements.

(6)(d) was added to clarify the relationship between the sediment management rules (Chapter 173-204 WAC) and this chapter. This subsection was prepared in response to public comment and specifies the following: "Sediment cleanup actions conducted under this chapter shall comply with sediment cleanup standards in Chapter 173-204 WAC. In addition, a state remedial investigation/feasibility study conducted under WAC 173-340-350 shall also comply with the cleanup study plan requirements under Chapter 173-204 WAC. The process for selecting sediment cleanup actions under this chapter shall comply with the requirements in WAC 173-340-360".

A new subsection (7) has been added to clarify that interim actions must comply with applicable requirements and that the department may determine that other requirements are relevant and appropriate. This change was made to in response to public comment and is intended to reduce regulatory uncertainty.

Section 720. Ground Water Cleanup Standards

In (1)(a)(ii)(C), the term "technically infeasible" was replaced with the term "technically impossible" in order to clarify that cost is not a factor in making this determination.

(1)(c) was added to clarify the approach Ecology will utilize where there is an extremely low probability that ground water classified as a potential future source of drinking will actually be used for that purpose. The new language was made in response to public comment and provides the flexibility to establish ground water cleanup levels based on protecting adjacent surface waters.

Subsection (2) has been retitled "Method A cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

(2)(b) has been revised to clarify that a decision to establish more stringent Method A cleanup levels than those specified under (2)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

The Method A cleanup level for ethylbenzene was revised to 30 ug/liter in order to correct a typographical error.

The Method A cleanup level for pentachlorophenol was deleted from Table 1 because of recent toxicological information received after the proposed amendments were issued that indicated a lower level may be more appropriate than the proposed value. Ecology is evaluating that information and intends to amend Table 1 at a later date.

The rule was revised to incorporate footnotes to Table 1 which provide a short rationale for individual cleanup levels and incorporate the cautionary footnote found in WAC 173-340-704. This revision was made in response to public

comment. It was made in order to provide a concise summary of the purpose for the tables and a cautionary note on their use for other purposes. The information contained in the footnotes will also facilitate site investigations and evaluations of cleanup action alternatives.

(2)(b) was revised to clarify that a decision by Ecology to require Method A cleanup levels more stringent than those required under subsection (2)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (3) has been retitled "Method B cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (3)(a)(ii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In (3)(a)(ii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

In (3)(a)(ii)(B), the assumption for average lifetime was changed to 75 years in order to maintain consistency with current federal procedures.
(3)(b) was revised to clarify that a decision by Ecology to require Method B cleanup levels more stringent than those required under subsection (3)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (4) has been retitled "Method C cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (4)(b)(ii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In (4)(b)(ii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

(4)(c) was revised to clarify that a decision by Ecology to require Method C cleanup levels more stringent than those required under subsection (4)(b) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

(5)(a) has been revised to clarify that adjustments to take into account multiple hazardous substances and multiple pathways of exposures are

"downward". This subsection has also been expanded to clarify that in making these adjustments the hazard index shall not exceed one (1) and the total excess cancer risk shall not exceed 1 in 100,000. This change was made to assure protection of human health and the environment, to provide a more explicit statement on Ecology's intent, and to improve the readability of the regulation by restating cross-referenced language.

(5)(b) has been added to clarify that the limits on the hazard index and total excess cancer risk also apply to those sites where there is exposure to only one hazardous substance by one pathway of exposure, including cleanup levels based on applicable state and federal laws.

(6)(d) has been added to state that where the affected ground water flows into nearby surface water, the cleanup level may be based on protection of the surface water. The new subsection specifies that in these situations, the department may approve a conditional point of compliance that is located within the surface water as close as technically possible to the point or points where ground water flows into the surface water and includes criteria for making this determination. This change was made in response to public comment and is intended to provide greater consistency with other Ecology programs.
(7)(c) was added to clarify that where separate toxicity values are available for inhalation and ingestion, health risks associated with the inhalation of volatilized hazardous substances should be evaluated separately from the risks associated with ingestion of drinking water. This change was made in response in public comment and will allow the differences in toxicity to be taken into account when establishing cleanup levels.

(8)(a) was expanded to provide criteria for evaluating when it is appropriate to base compliance with ground water cleanup levels on filtered samples. This change was made to clarify that there are situations where filtering is appropriate.

In (8)(d)(ii), the phrase "parametric test for percentiles based on tolerance intervals" was added in order to provide a better description of this alternate statistical method.

In (8)(f), the evaluation criteria were modified in order to reduce the potential for false positive results.

(8)(g) was amended to provide more detail on alternate statistical methods for handling non-detected values or values below the practical quantitation limit. This change was made in response to public comment urging Ecology to identify alternate methods in the rule.

Section 730. Surface Water Cleanup Standards

(1)(b) has been revised to clarify that Ecology does not expect that cleanup standards will be applied to stormwater runoff that is in the process of being conveyed to a treatment system. This change was made to clarify what types of surface water the standards would apply to. It also was intended to address concerns that Ecology would impose regulatory requirements that were unnecessarily burdensome at cleanup sites.

(1)(c) has been amended to include the phrase "applicable state and federal laws". This additional language reflects the fact that applicable state and federal laws may include requirements related to location, use, or actions.

Subsection (2) has been retitled "Method A cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

(2)(b) has been revised to clarify that a decision to establish more stringent Method A cleanup levels than those specified under (2)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (3) has been retitled "Method B cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

(3)(a)(i) has been amended to provide the flexibility for a person to demonstrate that water quality criteria established under section 304 of the clean water act are not relevant and appropriate for a specific water body or hazardous substance. This change was made in order to provide the flexibility to consider site-specific factors and/or new scientific information and maintain consistency with federal guidance.

In (3)(a)(iii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In (3)(a)(iii)(A) and (B), the fish consumption rate has been changed to 54 grams/day. This change was made in order to maintain consistency with federal guidance.

In (3)(a)(iii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

In (3)(a)(iii)(B), the assumption for average lifetime has been changed to 75 years in order to maintain consistency with current federal procedures.

(3)(b) was revised to clarify that a decision by Ecology to require Method B cleanup levels more stringent than those required under subsection (3)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (4) has been retitled "Method C cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (4)(b)(iii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

(4)(c) was revised to clarify that a decision by Ecology to require Method B cleanup levels more stringent than those required under subsection (4)(b) would be based upon a site-specific evaluation. This change was made in response to

public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

(5)(a) has been revised to clarify that adjustments to take into account multiple hazardous substances and multiple pathways of exposures are downward and that in making these adjustments the hazard index shall not exceed one (1) and the total excess cancer risk shall not exceed 1 in 100,000. This change was made to assure protection of human health and the environment, to provide a more explicit statement on Ecology's intent, and to improve the readability of the regulation by restating cross-referenced language.

(5)(b) has been added to clarify that the limits on the hazard index and total excess cancer risk also apply to those sites where there is exposure to only one hazardous substances by one pathway of exposure, including cleanup levels based on applicable state and federal laws.

(7)(a) and (7)(b) have been added to the regulation in order to clarify that compliance monitoring procedures must be specified in a compliance monitoring plan prepared in accordance with the requirements in WAC 173-340-410. This change was made to avoid inconsistencies within the rule.

Section 740. Soil Cleanup Standards

(1)(c) was to provide additional flexibility to establish soil cleanup levels for commercial sites and industrial sites not meeting the criteria in WAC 173-340-745. This change was made in conjunction with the decision to limit the use of WAC 173-340-745 to industrial sites. This new subsection states that soil cleanup levels will be established based on residential site use unless specified conditions are met. For those sites meeting those conditions, soil cleanup levels will be established as close as practicable to method B soil cleanup levels and at least as stringent as Method C soil cleanup levels. The new subsection also states that the overall limits on the hazard index and total excess cancer risk apply to these sites. This addition is designed to improve rule readability and reduce regulatory uncertainty during rule implementation. It is also intended to provide additional flexibility to address potential differences in exposure arising from differences in site use.

(1)(e) has been amended to include the phrase "applicable state and federal laws". This additional language reflects the fact that applicable state and federal laws may include requirements related to location, use, or actions.

Subsection (2) has been retitled "Method A cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

The Method A cleanup level for pentachlorophenol was deleted from Table 2 because of recent toxicological information received after the proposed amendments were issued that indicates a lower level may be more appropriate than the proposed value. Ecology is evaluating that information and intends to amend Table 1 at a later date.

The rule was revised to incorporate footnotes to Table 1 which provide a short rationale for individual cleanup levels and incorporate the cautionary footnote found in WAC 173-340-704. This revision was made in response to public comment. It was made in order to provide a concise summary of the purpose for the tables and a cautionary note on their use for other purposes. The information contained in the footnotes will also facilitate site investigations and evaluations of cleanup action alternatives.

(2)(b) has been revised to clarify that a decision to establish more stringent Method A cleanup levels than those specified under (2)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (3) has been retitled "Method B cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (3)(a)(iii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In (3)(a)(iii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

In (3)(a)(iii)(B), the assumption for average lifetime was changed to 75 years in order to maintain consistency with current federal procedures.
A new subsection (3)(a)(iv) was added to the rule. This specifies that Method B soil cleanup levels shall be set at concentrations which prevent violations of Method B ambient air cleanup levels established under WAC 173-340-750. This change was made in response to public comments which expressed concerns that the regulation did not address potential risks associated with windblown soils or vapors.

(3)(b) was revised to clarify that a decision by Ecology to require Method B cleanup levels more stringent than those required under subsection (3)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (4) has been retitled "Method C cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (4)(b)(iii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In (4)(b)(iii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

A new subsection (4)(b)(iv) was added to the rule. This specifies that Method C soil cleanup levels shall be set at concentrations which prevent violations of Method C ambient air cleanup levels established under WAC 173-340-750. This

change was made in response to public comments which expressed concerns that the regulation did not address potential risks associated with windblown soils or vapors.

(4)(c) was revised to clarify that a decision by Ecology to require Method C cleanup levels more stringent than those required under subsection (4)(b) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

(5)(a) has been revised to clarify that adjustments to take into account multiple hazardous substances and multiple pathways of exposures are "downward". This subsection has also been expanded to clarify that in making these adjustments the hazard index shall not exceed one (1) and the total excess cancer risk shall not exceed 1 in 100,000. This change was made to assure protection of human health and the environment, to provide a more explicit statement on Ecology's intent, and to improve the readability of the regulation by restating cross-referenced language.

(5)(b) has been added to clarify that the limits on the hazard index and total excess cancer risk also apply to those sites where there is exposure to only one hazardous substance by one pathway of exposure, including cleanup levels based on applicable state and federal laws.

Subsection (6) was modified. Modifications include the deletion of (6)e) of the proposed amendments and the addition of a new (6)(d) which clarifies that containment of contaminated soils may represent an acceptable cleanup action under WAC 173-340-360. This change was made in response to public comment and is intended to improve rule interpretation.

(7)(a) has been amended to state that the department may approve the use of alternate procedures for stabilized soils. This addition was made in response addresses the concern that the use of routine testing procedures would discourage the use of stabilization technologies.

In (7)(d)(ii), the phrase "parametric test for percentiles based on tolerance intervals" was added in order to provide a better description of this alternate statistical method.

In (7)(f), the evaluation criteria were modified in order to reduce the potential for false positive results.

(7)(g) was amended to provide more detail on alternate statistical methods for handling non-detected values or values below the practical quantitation limit. This change was made in response to public comment urging Ecology to identify alternate methods in the rule.

Section 745. Soil Cleanup Standards for Industrial Sites

(1)(b) was revised to provide more specific criteria for judging whether a site qualifies as an industrial site. These changes were made in response to public concerns that the industrial site use category was too broad under the proposed amendments.

(1)(b) was revised to clarify that this section does not apply to commercial sites. This change addresses public concerns that many commercial sites were

located near or within residential areas and should not be handled in a manner similar to industrial sites.

A new subsection (1)(c) was added to clarify that the department's expectation that only sites within a limited number of large industrial areas will qualify for industrial soil cleanup levels. This was added to address public concerns that the industrial site use category was too broad under the proposed amendments.

Subsection (2) has been retitled "Method A cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

The rule was revised to incorporate footnotes to Table 1 which provide a short rationale for individual cleanup levels and incorporate the cautionary footnote found in WAC 173-340-704. This revision was made in response to public comment. It was made in order to provide a concise summary of the purpose for the tables and a cautionary note on their use for other purposes. The information contained in the footnotes will also facilitate site investigations and evaluations of cleanup action alternatives.

The Method A cleanup level for pentachlorophenol was deleted from Table 3 because of recent toxicological information received after the proposed amendments were issued that indicates a lower level may be more appropriate than the proposed value. Ecology is evaluating that information and intends to amend Table 1 at a later date.

(2)(b) has been revised to clarify that a decision to establish more stringent Method A cleanup levels than those specified under (2)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

A new subsection (3), "Method B cleanup levels", has been added to this section. This subsection specifies that the rule does not provide procedures for establishing Method B soil cleanup levels at industrial sites. This clarification is designed to reduce regulatory uncertainty during rule implementation.

Subsection (4) has been retitled "Method C cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (4)(a)(iii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In (4)(a)(iii)(A) and (B), the frequency of contact has been revised to 0.4. This change was made in response to public comment which recommended that the proposed values be modified in order to maintain consistency with current federal guidance.

In (4)(a)(iii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to

clarify that current risk assessment procedures provide upper bound estimates.

In (4)(a)(iii)(B), the assumption for average lifetime was changed to 75 years in order to maintain consistency with current federal procedures.
(4)(b) was revised to clarify that a decision by Ecology to require Method C cleanup levels more stringent than those required under subsection (4)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

(5)(a) has been revised to clarify that adjustments to take into account multiple hazardous substances and multiple pathways of exposures are "downward". This subsection has also been expanded to clarify that in making these adjustments the hazard index shall not exceed one (1) and the total excess cancer risk shall not exceed 1 in 100,000. This change was made to assure protection of human health and the environment, to provide a more explicit statement on Ecology's intent, and to improve the readability of the regulation by restating cross-referenced language.

(5)(b) has been added to clarify that the limits on the hazard index and total excess cancer risk also apply to those sites where there is exposure to only one hazardous substances by one pathway of exposure, including cleanup levels based on applicable state and federal laws.

In subsection (6), a cross reference to WAC 173-340-740 was substituted for existing language in order to minimize duplication of provisions.

Section 750. Cleanup Standards to Protect Air Quality

(1)(b) was revised to clarify that the overall limits on the hazard index and total excess cancer risk apply to nonresidential site uses. This revision was made to clarify Ecology's intent and maintain consistency with other sections of the rule.

(1)(c) was revised to clarify that ambient air cleanup levels shall be set at levels which do not directly or indirectly cause violations of standards established under other applicable laws, as well as those established under this chapter. This change was made to ensure consistency with other Ecology programs.

Subsection (2) has been retitled "Method A cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

(2)(b) has been revised to clarify that a decision to establish more stringent Method A cleanup levels than those specified under (2)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (3) has been retitled "Method B cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (3)(a)(ii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in

estimated risks greater than the acceptable risk levels specified in the rule.

In (3)(a)(ii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

In (3)(a)(ii)(B), the assumption for average lifetime was changed to 75 years in order to maintain consistency with current federal procedures.
(3)(b) was revised to clarify that a decision by Ecology to require Method B cleanup levels more stringent than those required under subsection (3)(a) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

Subsection (4) has been retitled "Method C cleanup levels" consistent with changes in WAC 173-340-700 to improve rule readability.

In (4)(b)(ii), the phrase "sufficiently protective" was added to address concerns that Ecology would utilize applicable state and federal laws to establish cleanup levels when those requirements, while applicable, were not based on protecting human health and the environment or would result in estimated risks greater than the acceptable risk levels specified in the rule.

In (4)(b)(ii)(B), the phrase "excess cancer risk" was replaced with the phrase "the upper bound on the estimated excess cancer risk". This change was made in response to public comment and the amended language is intended to clarify that current risk assessment procedures provide upper bound estimates.

(4)(c) was revised to clarify that a decision by Ecology to require Method C cleanup levels more stringent than those required under subsection (4)(b) would be based upon a site-specific evaluation. This change was made in response to public concerns that the proposed language was too broad and may result in cleanup levels unrelated to site-specific conditions.

(5)(a) has been revised to clarify that adjustments to take into account multiple hazardous substances and multiple pathways of exposures are "downward". This subsection has also been expanded to clarify that in making these adjustments the hazard index shall not exceed one (1) and the total excess cancer risk shall not exceed 1 in 100,000. This change was made to assure protection of human health and the environment, to provide a more explicit statement on Ecology's intent, and to improve the readability of the regulation by restating cross-referenced language.

(5)(b) was added to clarify that the limits on the hazard index and total excess cancer risk also apply to those sites where there is exposure to only one hazardous substances by one pathway of exposure, including cleanup levels based on applicable state and federal laws.

(7)(a) and (7)(b) were added to the regulation in order to clarify that compliance monitoring procedures must be specified in a compliance monitoring plan prepared in accordance with the requirements in WAC 173-340-410. This change was made to ensure consistency with other sections of the rule.

Subsection (7) was revised to state that averaging times in applicable state and federal laws shall be used to demonstrate compliance with those requirements. This change was made to ensure the integrity of existing programs and minimize inter-program inconsistencies in rule implementation.

Subsection (7) was revised to provide the flexibility to use alternate averaging times for noncarcinogens when the cleanup level is based on an inhalation reference dose which specifies an averaging time other than a 24-hour averaging time. This change was made in response to public comment and ensures that compliance monitoring procedures are consistent with the toxicological bases for individual reference doses.

XXVI. PUBLIC NOTICE DOCUMENTS