

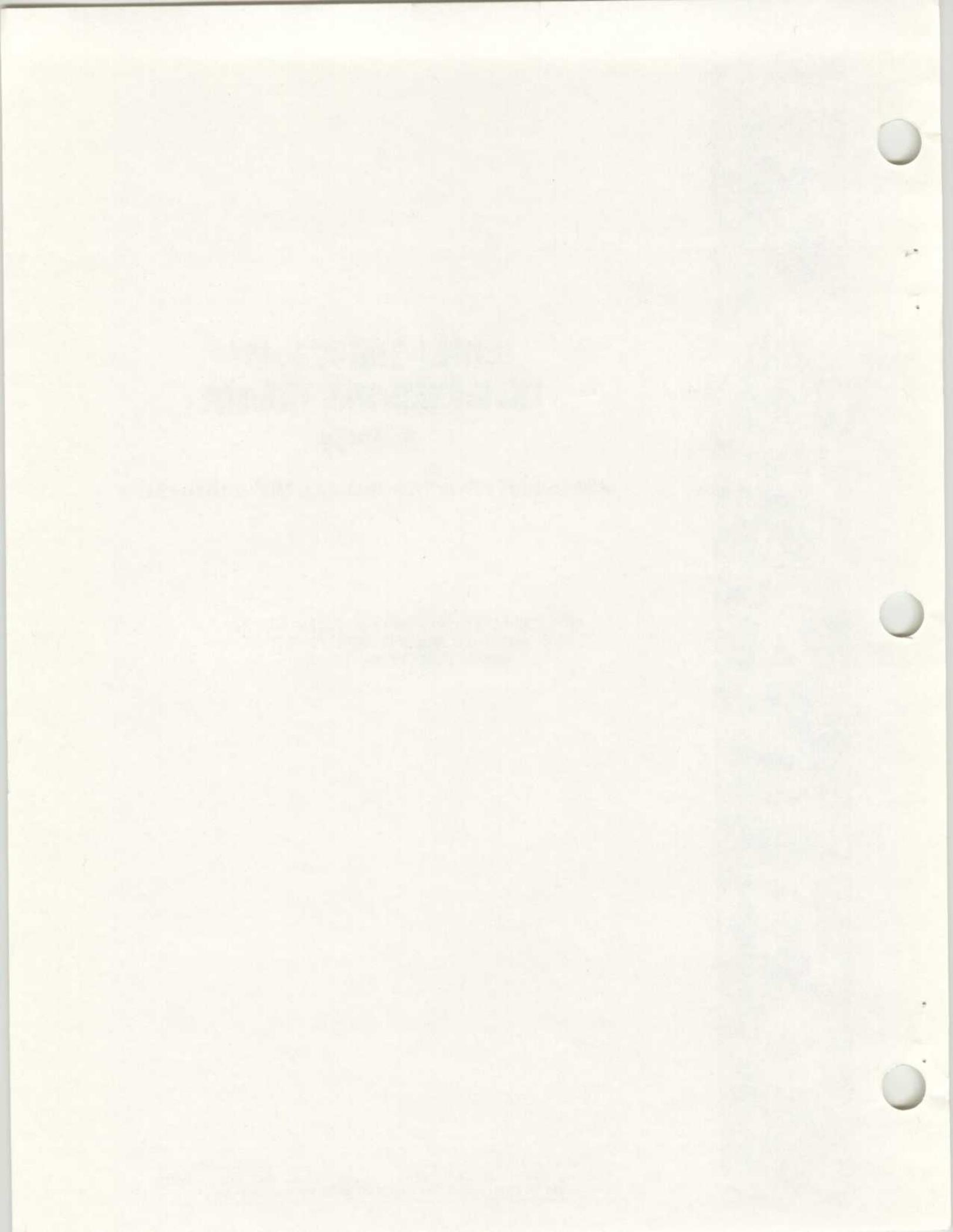


**UNITED STATES ARMY  
ENVIRONMENTAL HYGIENE  
AGENCY**

**ABERDEEN PROVING GROUND, MD 21010-5422**

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**WATER QUALITY INFORMATION PAPER NO. 32  
RISK ANALYSIS AND THE DEVELOPMENT OF  
WATER QUALITY CRITERIA**



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REPLY TO  
ATTENTION OF

DEPARTMENT OF THE ARMY  
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY  
ABERDEEN PROVING GROUND, MARYLAND 21010-5422



30 SEP 1988

HSHB-ME-WM

SUBJECT: Water Quality Information Paper No. 32

RISK ANALYSIS AND THE DEVELOPMENT OF WATER QUALITY CRITERIA

1. PURPOSE. To provide a rational framework for using decision risk analysis to develop standards for acceptable concentrations of military contaminants in water in the absence of health or biologically-based criteria.

2. BACKGROUND.

a. General.

(1) The Federal Water Pollution Control Act of 1972, as amended by the Clean Water Act of 1977, provides the authority for regulations governing the discharge of toxic pollutants in wastewaters. In 1976, the EPA was sued by several environmental groups because it was not meeting deadlines for establishing standards to control the discharge of pollutants in wastewaters. These standards were mandated by the Federal Water Pollution Control Act of 1972. As a result of a court-approved consent agreement arising from National Resource Defense Council vs EPA, a list of 65 toxic compounds was established for which EPA was to promulgate effluent limitations and standards for major industries. This list was expanded to include 126 elements and compounds which were considered to be potentially harmful to human health and the environment. This list is commonly referred to as the "priority pollutant list."

(2) The formulation of risk-based criteria for health were to be based on two methods depending on whether the prominent adverse affect to humans was cancer or other toxic manifestations. Similarly, criteria to protect aquatic life were also based on toxicological results and risk analysis.

(3) In cases where no criteria exist and where data on acute toxicity to humans or aquatic animals is not available, EPA has proposed guidelines for setting appropriate criteria. These include "Proposed Guidelines for Deriving Numerical Criteria for the Protection of Aquatic Organisms and Their Uses" (reference 24), as well as methods for risk assessment for carcinogens, mutagens, teratogens, chemical mixtures, and exposure assessment (references 17, 18, 19, 20, and 22). These guidelines should be considered when developing new or modifying existing methods for DOD applications.

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b. Army.

(1) The USAEHA is concerned with the problem of developing accurate methods of establishing acceptable concentrations of military contaminants where health and biologically-based criteria are nonexistent. The criteria developed should be based on the real or potential risks of such chemicals. Decision risk analysis is an appropriate method to address this problem.

(2) The USAEHA and USMBRD L have identified a requirement to develop a practical approach to risk assessment for DOD applications. A letter from USAEHA (Appendix A) was forwarded to OTSG (Appendix B) highlighting this problem and making some basic recommendations for developing a rational framework for decision risk analysis which meets military needs. Reference 14 outlined a method of hazard exposure and Rosenblatt et al. (reference 12) suggested a method for developing preliminary pollutant limit values.

(3) Crast (reference 6) has recently developed a set of guidelines to assess human health risks for hazardous chemical wastes. His approach incorporates aspects of EPA and OSHA guidance as well as the earlier work by Rosenblatt (reference 12). Although these guidelines were developed primarily for assessing human health risks involved in noncombat military missions at fixed sites, this approach represents a useful method which should be field tested and reviewed further. An outline of this approach is included as Appendix B. A uniform method of human health risk assessment, such as that proposed by Crast (reference 6), would provide a consistent method for evaluating risks and setting priorities on future research.

3. GENERAL.

a. Abbreviations and Definitions. A partial listing of definitions taken primarily from EPA reports and Rowe (reference 13) are included as Appendix C.

b. Components of Decision Risk Analysis.

(1) Decision risk analysis is composed of risk assessment and risk management. These terms are not used consistently in the literature. Risk assessment is a determination of risk and includes risk identification and risk characterization. Risk management is a systematic approach to determining how to evaluate risks (in terms of whether or not they have significant public health or ecological effects), and then deciding how to control them. The objectives of each component are outlined below:

Risk Assessment:

1. Hazard assessment
2. Exposure evaluation
3. Dose-adverse-effect evaluation
4. Risk characterization.

Risk Management:

1. Decision as to whether the risk has significant health impacts.
2. Determination of an acceptable level of risk.
3. Selection and implementation of a method for control.

(2) Risk assessment thus determines the likelihood that exposed humans or ecosystems will be adversely affected and characterizes the nature of the effects they may experience. Risk management involves making decisions about the risks characterized during the assessment, setting standards, and selecting control options to reduce the probability of adverse effects to an "acceptable level." Risk management areas of concern include both the objective scientific criteria as well as the consideration of economic, social, and political factors.

(3) This report briefly reviews risk analysis and approaches which might be used in the decision making process. It identifies the scope of the current methods and some of the uncertainties involved in estimating risks. For the purpose of this report, risk assessment, the scientific estimate of risk, is clearly distinguished from risk management, the decision making process that balances the information on risk against the significance of regulation and control to the whole community.

c. Risk Assessment Overview. (reference 6; outlined in more detail in Appendix B).

(1) The first step in assessing the risk of a substance is the identification of the hazard. Hazard identification begins with the accumulation of site specific data on the potentially hazardous chemicals in order to gain an understanding of how the chemicals migrate from the site and the location of human exposure points. The potentially exposed human populations are also defined in general terms during this phase. Finally, the information gathered is used to make a decision regarding the need and extent of further risk analysis.

(2) Human Exposure Evaluation. Determining the nature and size of the population(s) exposed to various substances and the extent of their exposure involves the evaluation of hazardous chemical release and migration data, determining exposure pathways, and identifying exposure points.

(3) Dose-Adverse-Effect Evaluation. The description of the quantitative relationship between the amount of exposure to a substance and the extent of injury or disease is usually divided into two categories; carcinogens and noncarcinogens, based on the differences in the perceived biological mechanisms involved. In both cases, however, information on the effects is used to construct models to establish a range of low risk concentration values; doses for incremental risks for carcinogens or temporary acceptable daily intakes for noncarcinogens.

(4) Risk Characterization. This step involves the integration of the hazard identification, the human exposure assessment, and the dose-adverse-effect evaluation to determine the likelihood that humans will experience any of the various forms of toxicity associated with the hazardous materials. Comparisons are then made between projected intakes and acceptable intakes, and the risks from the total exposure dose are estimated. This information is then used by the decision maker in managing the risk by establishing desired maximum exposure limits and implementing controls to achieve those limits.

d. Models Used in Developing Dose-Response-Relationships. The risk assessment process includes the use number of models and statistical procedures which incorporate many assumptions and uncertainties. These models are developed to predict exposure, migration, fate, and dose-response relationships. In applying these models, it is important to understand the models, the assumptions, as well as the other uncertainties involved. These should be taken into consideration in the risk management process of determining acceptable risk.

(1) Dose-response relationships are used to predict the adverse health consequences of a given level of exposure to a specified chemical or compound. The dose-response curve is used to illustrate this relationship over a range of doses. It summarizes the relationship between dose and response which consists of a series of conditional probabilities indicating that if exposure A (dose) occurs, then outcome B (response) occurs. This relationship is used to estimate risks and determine acceptable levels of exposure.

(2) There are several alternative models used in extrapolating from high doses (used in experiments) to low doses (common environmental exposure levels) for developing continuous dose response functions. Since the extrapolated predictions of high dose animal studies are used to set limits on human exposure, selection of the model used is important. The assumptions that these models accurately predict the consequences of exposure at levels beyond that supported by experimental data is an area of uncertainty.

(3) There are basically three types of models used to dose-response relationships: the tolerance distribution model, models based on the "hit" theory, and models based on quantitative theories of carcinogenesis (reference 25). The threshold theory (tolerance distribution model) is based on the the assumption that individuals in an exposed population have their own "tolerance" for exposure to the toxic agent such that no response will occur if the level is below their tolerance and response will occur if the level is above their tolerance; individuals in the population have different tolerances. These models assume a deterministic process relating exposure to response, and that the dose response relationship is produced by the distribution of tolerances within the population. Large variation produces a shallow dose-response, and small variation leads to a steep dose-response. This class includes the logistic and probit models.

(4) Models based on the "hit" theory for the interaction of toxic molecules with susceptible biological targets. The one-hit model is based on the concept that the adverse response can be induced after a susceptible target has been exposed once to a single biologically effective unit of dose. Use of the model implies that any exposure can cause the effect in question. A version of this model, the "multihit" model implies that several hits are required for response. For small dose values, this model is similar to the linear model. These models are frequently used to express the dose-response function for carcinogens.

(5) Mechanistic models are also derived from quantitative theories of carcinogenesis. The multistage model is based on the theory that assumes that a single cell can generate a malignant tumor only after it has undergone a certain number of heritable changes. This model is also termed the Weibull model.

(6) One of the problems is that many of these models can appear quite similar to one another in the range of observable response rates (associated with high doses) but differ significantly at lower response rates which are the areas of prime interest. This is the most important limitation of dose-response relationship. An estimate of risk at a particularly low dose, or an estimate of the dose leading to a particular level of risk is highly dependent on the model selected. Differences of 3-4 orders of magnitude are quite common and this is a major source of uncertainty.

4. REGULATORY BACKGROUND. The following EPA documents provide guidance for developing risk assessment procedures:

a. Water Quality Criteria Documents, 1980; Announcement of 64 of 65 criteria for the original "priority pollutants." Includes methodology for derivation of biological and health based risks (reference 27).

b. Water Quality Standards Handbook, 1983; Reflects the revised methodology for derivation of risk-based water quality criteria. Includes response to public comments and critique by EPA Science Advisory Board (reference 16).

c. Guidelines for Carcinogenic Risk Assessment; 24 September 1986. Publishes EPA proposed guidelines for carcinogen risk assessments. The revised guidelines describe the salient principles for evaluating the nature and magnitude of cancer hazard from suspect carcinogens and general framework to be followed in developing analyses of carcinogenic risk.

d. Guidelines for Exposure Assessment; 24 September 1986. Provide a general approach and framework for carrying out human or nonhuman exposure assessments for specified pollutants. Identifies other technical guidance on developing statistical procedures and characterization of uncertainty in exposure assessment. Also identifies areas requiring further research.

e. Guidelines for Mutagenicity Risk Assessment; 24 September 1986. Describes procedures to be followed in assessing genetic risks associated with exposure of humans to chemical mutagens. These procedures incorporate a weight-of-evidence approach that considered the quality and adequacy of all available data on a chemical substance in order to make qualitative, and, where possible, quantitative evaluations of mutagenic potential.

f. Guidelines for the Health Assessment of Suspect Developmental Toxicants; 24 September 1986. Provide some of the scientific basis for these risk assessment Guidelines. Testing guidelines provide protocols designed to determine the potential of a test substance to induce structural and/or other abnormalities in the developing conceptus.

g. Guidelines for the Health Risk Assessment of Chemical Mixtures; 24 September 1986. Designed to provide a consistent approach for evaluating data on chronic and subchronic effects of chemical mixtures. Includes a consideration of assumptions inherent in predicting the magnitude and nature of toxicant interactions.

h. Permit Applicant's Guidance Manual for Exposure Information Under RCRA Section 3019. (FINAL). 1985. Promulgates guidance for exposure information requirements for toxicants under Section 3019, RCRA. Includes procedure for completing Exposure Information Reports (EIR).

i. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. 1985. Document provides a complete description of the method to be used in deriving the National Ambient Water Quality Criteria. Includes a discussion of the minimum data base, data evaluation, and calculations.

j. Superfund Health Assessment Manual. 1986. Submitted to EPA by ICF Inc. Describes the procedures for public health evaluation at Superfund sites as required by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 and the National Oil and Hazardous Substances Pollution Contingency Plan. Includes no-action alternatives.

5. ECOLOGICAL RISK ASSESSMENT. Ecological risk assessment refers to procedures which predict potential adverse effects to natural ecosystems as a result of pollution or habitat degradation. This analysis differs from the more traditional approach focused primarily on human health risks. Recently, this approach is being used more frequently by the EPA to support decisions concerning establishing priorities and developing standards or guidelines. A number of ecological risk assessment methods have been developed and, although most are quantitative, several are qualitative and can be applied to situations where little quantitative information is available. Although this subject is beyond the scope of this information paper, short review of existing methods is briefly described in Appendix D for general reference.

6. METHODOLOGY. Based on a review of available methods suitable for military applications, the recent set of guidelines presented by Crast (reference 6) was selected for further review and evaluation. These guidelines are outlined in Appendix B.

a. Limitations in the Scope of Risk Assessment Guidelines.

(1) Most available methods (including reference 6) for risk assessment are generally limited in scope to fixed sites or situations such as those encountered at DOD industrial or installation restoration activities. Crast (reference 6) indicated that the problem areas associated with Army combat missions have not yet been fully identified for the application of risk assessment guidelines. The soldier-in-the-field depends primarily on the equipment and personnel immediately on hand to provide safe water for short-term operations. However, combat or combat training missions involve a variety of other inherent exposures to risk which should be considered when putting these risks in perspective. Exposure to chemical hazards, other than chemical agents has not yet been addressed fully.

(2) The approach outlined in "Risk Assessment Guidelines for Hazardous Chemical Waste," (reference 6), as well as those described in the Draft Superfund Health Assessment Manual (reference 9), are suited for industrial and fixed facilities. The Superfund Health Assessment Manual has been evaluated for Army applications (reference 10) and several recommendations for improvement have been made. Both these approaches should be reviewed further and incorporated into any standard methodology adopted for Army and DOD use in order to ensure that results of future evaluations are consistent and that decisions made concerning risk management will be based on comparable information.

b. Recommendations for Modification to Existing Guidelines.

(1) The guidelines should be staffed within the Agency for review and comments.

(2) The "Computerization of the Preliminary Pollutant Limit Value Concept" developed by CERL should be incorporated into the guidelines.

(3) The approach in the guidelines be broadened to include ecological risk assessment methods.

(4) The guidelines be augmented with approaches suitable to field applications (as opposed to fixed site/installations). This should consist of a systematic approach to determining acceptable level of risks where no other standards exist and time/location factors preclude full analysis.

(5) Where appropriate, potential benefits (health or safety) should be weighed against potential risks. This is relevant in tactical situations as well as for industrial and installation restoration missions. (For example, the use of a potentially hazardous defoliant should be weighed against the probable increase in casualties due to enemy action if the chemical were not used.)

c. Uncertainty in Human Health Risk Estimation.

(1) In addition to the uncertainty inherent in the assumptions related to the various exposure, pathway, and dose-effect models, the prediction of human risks based on high dose animal studies is also a source of uncertainty which must be considered in risk analysis. In order to be conservative and bias the results on the side of public safety, animal tests have been deliberately designed to yield positive outcomes (Havender, W.R.; "Of Mice and Men: The Benefits and Limitations of Animal Cancer Tests").

Two Basic areas of concern are:

(a) How well do animal cancer studies predict cancer incidence in humans?

(b) Do high dose studies actually project the risk of actual low dose exposures?

(2) The assumption involved in the first question is that "the basic biological processes" of mammalian species are very similar (man reacts in the same manner as rats or mice). This is questionable in many cases. A recent review of the National Cancer Institute/National Toxicity Program bioassay series (the largest in the country) which tests chemicals simultaneously in both rats and mice, indicates that about half the chemicals that are positive in one species are negative in the other. The extension from rodents to humans is not fully accepted.

(3) The second question concerning the use of high doses in animal tests assumes that such doses do not artifactually promote carcinogenic outcomes. Recent work suggests that many chemicals "causing" cancer in rodents at high doses work through toxicity induced cell proliferation and consequent promotion, a threshold process (absent incipient toxicity, there is no apparent carcinogenicity). Therefore some "positive" animal findings may merely be high dose artifacts having no relevance to low dose normal exposures.

(4) In both cases, species and dose variations add uncertainty to the risk estimates. This is combined with the uncertainty due to the extrapolation of nonlinear dose response relationships well beyond the range of the studies. Decision makers should keep these uncertainties in mind when selecting acceptable levels of risk and appropriate control measures.

(5) The results of high dose bioassay tests must be carefully reviewed before conclusions can be drawn. The resulting data should be considered together with the results of other tests prior to making any determination of dose response extrapolations and carcinogenic potency. In most instances, a single positive result from a carcinogen bioassay would not be considered sufficient for classifying or regulating a substance as carcinogen. Additional confirming evidence in other species as well as in vitro tests and pharmacokinetics data are required.

(6) Reference 6 lists some additional sources of uncertainty and assumptions involved in risk assessment (Appendix B). It is important in any risk estimate to state the assumptions in the models used, the safety factors included in each part of the estimate, and the statistical procedures applied.

## 7. ACCEPTABLE RISK CONCEPTS.

a. Acceptable risk is defined (reference 13) as "a level of risk for which a gamble is worth taking, or when the risk is imposed the parties affected are not, or are no longer, apprehensive about the risk." There is disagreement about what constitutes an acceptable level of risk. This varies among the various disciplines involved in risk analysis as well as among regulatory and special interest groups. In many cases, no consideration is given to the potential benefits of the hazard involved.

b. This lack of consensus is unlikely to change in the near future. It is, however, important that the Army (and/or DOD) develop a consistent approach to the concept of acceptable risk in the absence of outside regulatory guidance. This is vital since expenditures for control and remediation in risk management efforts are dependent on an assessment of the acceptable level of risk. In order to ensure that this funding is spent wisely, comparisons among alternative courses of action should be based on the same concept of acceptable risk. This will permit limited funds to be expended to achieve the greatest overall reduction in risk.

c. There are several methods for arriving at a level of acceptable risk. These include (Reference 13):

(1) Comparable Risks - evaluating the projected risk in comparison to other reference risks which are known and/or accepted elsewhere in society.

(2) Arbitrary Risk Numbers - deciding at what level (e.g.,  $10^{-5}$ ... $10^{-9}$ ) of health effects per year or lifetime should be used as benchmarks.

(3) A Set Value for Dollars to be Spent - this approach assumes a fixed dollar amount available for control, and these dollars are used to cost-effectively reduce risk up to the amount available. The object is to achieve the greatest amount of risk reduction for the dollars available and expended.

(4) A Set Value for Risk Reduction - this approach is based on risk reduced [as opposed to residual levels of risk as in (3)]. The approach often uses a percentage of risk reduction expressed in terms of percentage of health effects reduced or the reduction (decontamination) factors of controls which must be applied.

d. The suitability of each method depends on the specific situation. The effectiveness of these methods of setting risk levels is also dependent on the nature of the risk (chronic vs carcinogenic).

e. The comparison approach is similar to the method recommended in the 1981 USAEHA letter (Appendix A) and is a useful means of setting benchmarks for both chronic and carcinogenic risks for Army unique substances. With respect to cancer risks, it is probably more useful when compared to similar, better known, cancer risks rather than general risks. This method is not data intensive and can serve as a means of establishing preliminary risk levels in the absence of any specific regulatory guidance.

f. The use of arbitrary risk numbers is used to some extent by regulatory agencies to establish action levels (the level, generally above the margin of safety, where regulatory action will be legally defensible). It is appropriate for establishing de minimus levels for cancer risks but not for setting "acceptable levels." It is not considered a useful concept for chronic risks when thresholds exist.

g. The application of a "set value for dollars to be spent" method is useful if there is a source resource limitation or value limit to primary products, at least as a economic checkpoint. This approach is data intensive and requires economic value judgment. This approach is primarily economic, relating the amount spent on risk reduction directly to the productivity and cost consequences to the public. Placing a value on productivity and cost consequences is subjective and method dependent. This approach is not well suited to establishing preliminary risk levels for DOD applications.

h. The approach based on a "set value for risk reduction" is not applicable for the highly nonlinear or no effect level type of chronic risk but could be useful for cancer risks if based on control performance. This method could be useful in deciding between the adoption of BPI and BAT. It is essential in using this approach to refer to the residual risk level.

i. Recommending a standard approach to setting acceptable levels of risk is problematic due to a broad range of situations encountered in military operations. Normally, some initial analysis of the specific problem would be required. The following factors should be considered prior to deciding on the appropriate approach.

- (1) The magnitude and precision of health and environmental impacts.
- (2) The performance and cost of control systems.
- (3) The pathways and extent of exposure.
- (4) The direct and indirect benefits of the causative technology.

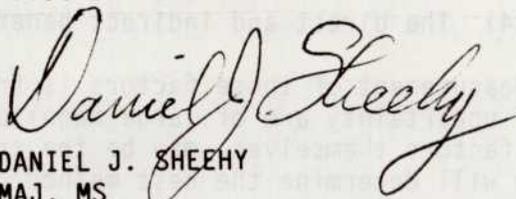
j. Measurement of these factors is frequently nonlinear, and if the ranges of uncertainty are of large magnitude, measurement problems, rather than the factors themselves, may be the critical parameter. The actual situation will determine the best method of setting a level of acceptable risk. However, since the Army and DOD are faced with the problem of setting acceptable concentrations of military contaminants in the absence of health and biologically-based criteria, the comparison method yielding relative risk may be the best preliminary approach prior to the availability of better information or regulatory guidance.

k. The comparison approach to interpreting analytic results (USAEHA letter "Interpretation of Water Sample Analysis") is a reasonable and quick first approach to putting risk estimates (particularly for carcinogens) in perspective. Although comparison to general risks (reference 1) is useful, a comparison to other cancer risks would be more appropriate for suspected carcinogens. Tables from references 7 and 8 would also be useful for indicating relative risks.

8. SUMMARY. Water quality standards for many military-unique chemicals have not been developed. This paper discusses the use of risk analysis to determine appropriate water quality criteria. Criteria are needed to support technological and financial decision making processes. Risk assessment and risk management comprise the components of risk analysis. The approach taken by Crast (reference 6 and Appendix B) incorporates EPA and OSHA guidance and can be adapted for DOD use in assessing human health risks for various chemicals. Risk assessment is comprised of four components: hazard assessment, exposure evaluation, dose-adverse-effect (dose-response) evaluation, and risk characterization. Several models and statistical procedures are available to develop dose-response relationships. However, it is important to understand the underlying assumptions of a given model and the uncertainties inherent in extrapolation from measurable high dose response rates to predicted low dose response. Another important uncertainty arises from extrapolating data derived from animal tests to generating dose-response relationships in humans. Standards development should also incorporate, or be supported with, findings from ecological risk assessments. Ecological risk assessment methods are summarized in Appendix D. Four of the major methods for arriving at a level of acceptable risk (risk management) are the comparable risk approach, the arbitrary risk numbers approach, the "set value for dollars to be spent" approach, and the "set value for risk reduction" approach. The comparable risk approach can be used for setting benchmarks for both chronic and carcinogenic risks for

Army unique substances (see Appendix A). The choice of approach will be site specific, however, and should include considerations of the magnitude and precision of health and environmental impacts, the performance and cost of control systems, the pathways and extent of exposure, and the direct and indirect benefits of the causative technology.

9. REFERENCES. See Appendix E for a list of references.



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SUBJECT: Interpretation of Water Sample Analyses

WQI (PAGE-32)  
WQI DC 20310

APPENDIX A

INTERPRETATION OF WATER SAMPLE ANALYSES  
(letter USAEHA enclosed)

HSE-OM

14 SEP 1981

SUBJECT: Interpretation of Water Sample Analyses

HQDA (DASG-PSP)  
WASH DC 20310

1. In the coming months this Agency will be collecting a large number of water samples from monitoring and drinking water wells located on installations throughout DA. The majority of these samples (400-600) will be from Resource Conservation and Recovery Act (RCRA) sites (i.e., solid and hazardous waste disposal sites) collected as part of a DA directed sampling program. In addition, samples will also be collected as part of programs aimed at responding to State regulatory requirements and requests from installations.
2. The water samples may need to be analyzed for a large number of organic and inorganic contaminants as a result of indications of contamination determined from baseline monitoring required by regulation. Many of these contaminants are suspected carcinogens. Most of them are not covered by National Interim Primary Drinking Water Regulations (NIPDWR) or applicable State regulations. Assessment of the health significance of concentrations of these contaminants in water will have to take into consideration water quality criteria developed for them by the US Environmental Protection Agency (EPA).
3. In recent months we have become aware of contamination of ground water by a number of suspected carcinogens at several DA installations. We feel this may well represent the tip of an iceberg since one MACOM (i.e., DARCOM) has informally estimated that as many as 36 of their installations potentially have ground water contamination. Therefore it seems that we may be presented with a large number of water samples containing detectable quantities of a variety of suspected carcinogens.
4. It is necessary that this Agency develop a method of interpreting these analytic results and placing them in proper perspective so that installation commanders can have a rational basis for making decisions as to actions to be taken in response to the results.
5. We have developed such a method as follows:
  - a. The concentration of a suspected carcinogen measured in a water sample will be compared to the estimated lifetime cancer risk levels for that substance published by the EPA in 45 Federal Register (FR) No. 231, 28 November 1980, pages 79318-79379. These risk levels are based on consumption, over a 70 year lifetime, of 2 liters of

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water and 6.5 grams (g) of fish and shellfish taken in that water daily. Since these samples will be ground water samples, the risk levels will be adjusted to reflect consumption of only 2 liters of water per day. The estimated lifetime cancer risk posed by ingestion of 2 liters of water containing the measured concentration will then be derived by dividing the measured concentration by the adjusted concentration representing an estimated risk of  $10^{-6}$ , and multiplying the result by  $10^{-6}$ .

b. Should there be more than one suspected carcinogen detected in a sample, the estimated risk posed by the concentration of each substance will be derived as described above. The risk estimates for all of the suspected carcinogens will then be arithmetically summed to arrive at an overall estimated lifetime cancer risk posed by consumption of that water.

c. Risk estimates for all samples from a particular installation found to contain detectable quantities of suspected carcinogens will be made and reported to the installation.

d. The risk estimates will then be placed in perspective in the reports to the installations. This will be done by using the method developed by Cohen and Lee<sup>1,2</sup> in which the risk estimate (assuming, conservatively, that all cancers will have a fatal outcome) is multiplied by the average loss of life expectancy in an individual afflicted with a fatal cancer (i.e., 20 years, a figure used by Cohen in his assessment of cancer risk from saccharin ingestion). The result is expressed in units of time (i.e., minutes, hours, days, etc.) of average lost life expectancy for the population at risk. Cohen and Lee have published such average loss of life expectancy figures for a wide variety of hazards encountered by the population in everyday activities (e.g., accidents in the home - 95 days, falls - 39 days, firearm accidents - 11 days, natural background radiation - 8 days, etc.). The result obtained as described above will be compared to these figures to put the risk in perspective. In addition, the conservative nature of the risk estimate itself will also be emphasized, i.e., the fact that evidence of carcinogenicity for many of the substances is in animals only, that the estimates are based on 2 liters daily consumption for a lifetime, an avowedly conservative model is used, etc.

e. For installations at which any sample shows concentrations of suspected carcinogens posing an estimated risk of more than  $10^{-3}$ , the reports will contain a recommendation that certain actions be taken. Depending on the nature and extent of contamination, these actions may include one or more of the following: performing a detailed ground water assessment program to further define the extent of contamination; clean-up of the aquifer; diversion of the plume (possibly indefinitely); additional water treatment; closing and capping waste disposal sites; obtaining alternate

1. Cohen, B.L., and Lee, I., A Catalog of Risks, Health Physics 36(6): 707-712, 1979.
2. Cohen, B.L., Relative Risk of Saccharin and Calorie Ingestion, Science 199: 983, 1978.

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SUBJECT: Interpretation of Water Sample Analyses

disposal sites or drinking water sources; performing long-term (possibly 30 years) quarterly monitoring. It will also be recommended that the applicable State authority (if the State has primacy), or the EPA, or in some circumstances both State and Federal authorities, be informed of the results and the actions to be taken. For those installations at which all water samples show concentrations of suspected carcinogens posing an estimated risk of less than  $10^{-3}$  the reports will usually not contain any recommendations for remedial action. However, the reports will contain a recommendation that the installation commander approach the applicable regulatory authority (State, Federal or both); present the water sample results and the assessment of risk to these authorities; and request their guidance on further actions to be taken in regard to the results. In the event that levels of contaminants in excess of NIPDWR or applicable State regulations are also found, guidance will also be offered by this Agency as to actions to be taken in response to these findings, based on the situation at hand.

6. The above described method relies on making a risk estimate using the conservative EPA model, putting that risk in perspective, and, at risk levels below  $10^{-3}$ , allowing the applicable State or Federal authority to make a decision as to actions to be taken by deliberately informing them of the situation. We feel this course is warranted because of the failure of any regulatory or consensus body to define an acceptable risk of cancer. As described above, for risk estimates in excess of  $10^{-3}$ , we propose to advise the installation commander to take certain actions, depending on the circumstances. This is because we feel that most authorities would consider a risk greater than  $10^{-3}$  to be unacceptable, and that in the absence of a consensus in the regulatory or scientific communities, it would be prudent for DA to consider such a risk unacceptable as well. However, we do not know how far below  $10^{-3}$  authorities would consider the risk unacceptable. Therefore, we feel it is advisable to recommend that DA installations be committed to possibly time consuming, expensive and/or disruptive actions when the cancer risk is estimated to be greater than  $10^{-3}$ . However, when risk estimates are below  $10^{-3}$ , DA installations should not be committed to these actions unless required to do so by applicable authority. In this way we will permit the applicable regulatory authority to make a decision as to acceptable risk in these situations as, it may not be necessary or appropriate for DA to make a unilateral decision on this important and controversial issue.

7. Request that your office, and whatever other HQDA elements you deem necessary, review the above described method and authorize this Agency to proceed in this manner. Should authorization not be forthcoming, further request we be provided with an alternate approach.

8. Questions concerning these comments may be directed to MAJ(P) J. Thomasino, MC, Occupational and Environmental Medicine Division, AUTOVON 584-2714/3030.

FOR THE COMMANDER:

ORIGINAL SIGNED

ARTHUR R. MORTON  
COL, MC  
Director, Occupational and  
Environmental Health

CF:  
Cdr, HSC (HSPA-P)

DEPARTMENT OF THE ARMY  
HEADQUARTERS, UNITED STATES ARMY HEALTH SERVICES COMMAND  
Fort Sam Houston, Texas 78234

28 SEP 81

HSPA-P

SUBJECT: Interpretation of Results of Water Analyses

HQDA (DASG-PSP)  
WASH DC 20310

ORIGINAL	<i>hap</i>
ACTION	_____
INFO	<i>WDE</i>
	<i>please forward</i>

*DOE Action*  
*OEMD (act)*

1. Reference letter, HSE-OM, USAEHA, 14 September 1981, subject: Interpretation of Water Sample Analyses. (I)

*copy*  
*WDE*

2. In the referenced letter, USAEHA proposed a procedure to interpret the results of water analyses when suspected carcinogens are found. We agree that such a procedure is needed, but we disagree with several points of the procedure.

a. Paragraph 5a. The assumptions that people will drink two liters of the water for 70 years is unrealistic if applied to people living and working on an Army installation. On the other hand, if the water is used or provided to communities off the installations, the assumptions could apply. Assumptions like these need to be applied carefully and may need to be adjusted on a case by case basis.

b. Paragraph 5c. The risk assessment should be sent to the MACOM Surgeon and not to the installation.

c. Paragraph 5e. The Army should not go to any regulatory authorities asking them what corrective actions to take. Instead, the Army should first decide what to do, and then, if required, tell the regulatory authorities what is planned and the reasons why.

3. The proposed procedure should be discussed with the Navy and Air Force. If all the services can agree on the procedure, a DOD position could be established which would be stronger than one solely implemented by the Army.

FOR THE COMMANDER:

Original signed  
M. M. WOODEN  
1LT, AGC  
Asst AG

CF:  
✓ Cdr. USAEHA

VEN AG  
JLT ABC  
W. W. HODGINS

10/11/52

FOR THE COMMANDER:

3. The proposed procedure should be discussed with the Navy and Air Force. It will be suggested that one jointly implemented by the Navy and Air Force should be discussed with the Navy and Air Force. It will be suggested that one jointly implemented by the Navy and Air Force should be discussed with the Navy and Air Force.

4. The proposed procedure should be discussed with the Navy and Air Force. It will be suggested that one jointly implemented by the Navy and Air Force should be discussed with the Navy and Air Force.

5. In the referenced letter, USNEM suggested a procedure to investigate the possibility of water analysis with suspected infections are from the water. The proposed procedure is to be discussed with the Navy and Air Force. It will be suggested that one jointly implemented by the Navy and Air Force should be discussed with the Navy and Air Force.

6. Reference is made to the letter of 14 September 1952, subject: "Water Analysis". The proposed procedure is to be discussed with the Navy and Air Force. It will be suggested that one jointly implemented by the Navy and Air Force should be discussed with the Navy and Air Force.

VEN AG  
JLT ABC  
W. W. HODGINS

Handwritten notes and stamps in a box, including the word "ACTION" and a signature.

SUBJECT: Investigation of results of water analysis

10/11/52

10/11/52

1. A review of the available literature concerning risk assessment suggested that the recent guidelines put together by the Crast Group (1986) were the best available comprehensive approach for the identification of industrial, municipal, and agricultural sites. These guidelines were developed in 1986 for the purpose of identifying sites which may be hazardous to public health and the environment. The guidelines are contained in the Crast Group's "Risk Assessment Guidelines for Hazardous Waste Sites" (Crast, 1986).

2. Crast subdivided the process of risk assessment at a specific site into four phases: hazard identification, human exposure assessment, dose-response-effect evaluation, and risk characterization.

3. HAZARD IDENTIFICATION involves gathering and evaluating site specific data on potentially hazardous chemicals. It determines if it is correct to infer that toxic effects observed in one setting will occur in other settings.

### APPENDIX B

## AN OUTLINE OF "RISK ASSESSMENT GUIDELINES FOR HAZARDOUS CHEMICAL WASTES" (Crast, 1986)

- (1) GATHER AND EVALUATE EXISTING DATA ON THE SITE. Include climate, air, ground water, surface water, soil, and other site data.
- (2) IDENTIFY SOURCES AND PATHWAYS OF POTENTIALLY HAZARDOUS WASTES. Inspect for local hazardous waste sources and identify pathways.
- (3) ESTABLISH THE BASELINE CHEMICAL DATA OF POTENTIALLY HAZARDOUS WASTES. Obtain and describe their physical, chemical, and biological properties.
- (4) COMPARE PERTINENT STANDARDS OR CRITERIA TO DETERMINE WHO SETS STANDARDS (MCLs, MACDs) and which are applicable at this site.
- (5) EVALUATE BASELINE TOXICOLOGICAL DATA. Investigate toxicologic and toxicodynamic responses; identify treatment data and the studies.
- (6) IDENTIFY POTENTIAL TARGET POPULATIONS. Demographics on exposed populations (air-borne, surface water, ground water, and soil). Include occupational exposures and direct ingestion use.
- (7) SUMMARIZE SITE SPECIFIC DATA TO PREPARE A SUCCESSION ANALYSIS OF SOURCE AND MIGRATION PATHWAYS. This should answer four questions:

To what chemicals are the populations exposed?  
What is size and distribution of exposed populations?  
Is there a hazard?

How do exposures occur?

The answers to these questions will be used to determine if a complete risk assessment is needed.

1. A review of the available literature concerning risk assessment suggested that the recent guidelines put together by LTC Crast (Crast, 1986) were the best available comprehensive approach for fixed installation or industrial mission activities. These guidelines were developed from earlier studies at USMBRDL to be compatible with other Federal Agencies while recognizing the Army's unique hazardous chemical waste problems. The following is an outline of Crast's Guidelines taken, for the most part, directly from his publication.

2. Crast subdivided the process of risk assessment at a specific site into four phases: hazard identification, human exposure assessment, dose-adverse-effect evaluation, and risk characterization.

a. HAZARD IDENTIFICATION involves gathering and evaluating site specific data on potentially hazardous chemicals. It determines if it is correct to infer that toxic effects observed in one setting will occur in other settings.

(1) GATHER AND EVALUATE EXISTING DATA on the site: include climate, air, ground water, ground-water use, surface water, surface water use, soil, and biota, etc. Describe the history.

(2) IDENTIFY SOURCES AND MIGRATION PATTERNS of preliminary onsite inspection to locate hazardous material sources and migratory patterns.

(3) ESTABLISH THE BASELINE CHEMICAL DATA of significant chemicals and describe their physical, chemical and biological properties.

(4) COMPARE PERTINENT STANDARDS OR CRITERIA to determine who sets standards (MCL's, NAAQS) and which are applicable at this site.

(5) EVALUATE BASELINE TOXICOLOGICAL DATA: investigate toxicokinetic and toxicodynamic responses; identify insufficient data and lab studies.

(6) IDENTIFY POTENTIAL TARGET POPULATIONS(S): demographics on exposed populations (air plume, surface water, ground water, and soil). Include occupational exposures and direct inadvertent use.

(7) SUMMARIZE SITE SPECIFIC DATA to prepare a succinct analysis of source and migration pathways. This should answer four questions;

To what chemicals are the populations exposed?

What is size and distribution of exposed populations?

Is there a hazard?

How do exposures occur?

The answers to these questions will be used to determine if a complete risk assessment is needed.

(8) DETERMINE THE NEED AND EXTENT OF FURTHER RISK ANALYSIS.

b. HUMAN EXPOSURE EVALUATION involves describing the nature and size of the population exposed to a substance and the magnitude and duration of their exposure.

(1) EVALUATE RELEASE AND MIGRATION to consider both the real (measured) and potential releases and migration. Monitoring results or models can be used.

(2) ESTIMATE OR MEASURE EXPOSURE PATHWAYS to identify principle pathways of exposure in landfill--soil migration--ground water--well water (drinking).

(3) DETERMINE THE INTERMEDIA TRANSFER COEFFICIENTS to determine the partition coefficients (K) of the specific chemicals. Partition coefficient (K) = the concentration of the Ctm divided by the concentration of Csm.

(4) IDENTIFY AND EVALUATE EXPOSURE POINTS to determine which populations are likely to be exposed through contact with contaminated media (air, soil, water, or biota-ingestion). Modeling may be used to predict exposure point concentrations after fate analysis.

(5) EVALUATE POPULATION GROUPS AT EXPOSURE POINTS and enumerate exposed populations, describe human intake parameters, calculate route specific exposure dose for all methods of contact, and calculate total exposure dose. Sum the total of inhalation, oral, dermal doses. Includes average (CDI), peak, and background.

(6) SUMMARIZE SITE SPECIFIC EXPOSURE EVALUATION to provide reliable data and/or estimates for coupling with dose-adverse-effects.

c. DOSE-ADVERSE-EFFECT-EVALUATION describes the quantitative relationship between the amount of exposure to a substance and the extent of injury or disease (or degradation of the environment).

Current theory classifies carcinogens as nonthreshold dose-adverse-effect (the one hit response), and many noncarcinogens as threshold dose-adverse-effect.

(1) CARCINOGENS:

(a) IDENTIFY INFORMATION SOURCES FOR CARCINOGENESIS - should check for current classification!

(b) CLASSIFY WEIGHT OR EVIDENCE FOR EACH CHEMICAL - evidence is based on long-term bioassays, short-term tests (genetic alteration or transformation in vitro), and epidemiological studies. Chemicals classed by EPA category based on evidence.

(c) SELECT AN EXTRAPOLATION MODEL FOR CARCINOGENS - the linear nonthreshold model has been adopted as the primary basis for risk assessment. The modified linear multistage model is used at low doses.

(d) SELECT BEST AVAILABLE DATA FOR CALCULATIONS - carefully analyzing each study using the criteria:

Strength of association - relative risk of exposed vs nonexposed  
Dose response relationship - positive correlation  
Consistency of association - between studies, methods, circumstances  
Temporarily correct association - consider multifactorial nature  
Biological plausability - causal interpretation is biologically possible  
Route of Exposure - source with assessment i.e., oral-oral

(e) ESTIMATE THE POTENCY FACTOR FROM THE LINEAR MULTISPACE LOW DOSE EXTRAPOLATION MODEL use EPA carcinogenic potency factors expressed as the lifetime cancer risk per mg/kg weight/day.

(f) ESTABLISH RANGE OF LOW RISKS some states have zero level limits which mean undetectable with present technology; this means a risk from  $10^{-4}$  to  $10^{-7}$  with most values  $10^{-6}$  to  $10^{-5}$ .

(g) CALCULATE DOSES FOR INCREMENTAL RISKS given the range of risk (R) to be  $1 \times 10^{-7}$  to  $1 \times 10^{-4}$  then:

$$d = 1 \times 10^{-7} / q^* = \text{dose at } 1 \times 10^{-7} \text{ risk etc}$$

The dose at any desired risk level can be calculated if the carcinogen potency factor ( $q^*$ ) is known. These calculations provide 95-percent confidence that the risk of cancer will not be underestimated if exposed to that daily dose (d) for a lifetime.

## (2) NONCARCINOGENS

(a) IDENTIFY INFORMATION SOURCES - lists sources of both general population and occupational exposures.

(b) DEFINE ACCEPTABLE DAILY INTAKE VALUES - values must be developed for chemicals identified as potentially hazardous but do not have legal or relevant standards. The ADI-C chronic and ADI-S subchronic are total intake levels with system toxicity from each media specific route. The NRC has established guidelines for developing EEGL's which are the maximum acceptable levels permitted in a day. The EEGL values are not generally appropriate for situations involving general population exposures. The EEGL's are recommended as guidelines for military personnel operating under emergency conditions and whose circumstances are peculiar to military operations.

(c) IDENTIFY EXISTING ACCEPTABLE DAILY INTAKES - from the draft EPA ADI's and published WHO ADI's and other literature.

(d) IDENTIFY CRITERIA, ADVISORIES, AND GUIDELINES - when there are no appropriate ADI's, the next step is to ID Federal or State media specific criteria. Care must be used in selecting criteria.

(e) CONVERT OTHER CRITERIA TO ACCEPTABLE DAILY INTAKES - from the concentration in the given media (i.e., surface or drinking water) to ADI.

(f) ESTABLISH NEW ACCEPTABLE DAILY INTAKE FROM LITERATURE - involves identifying NOAEL in animal studies, establishing relevant uncertainly factors, and calculating new ADI's.

(g) ESTABLISH TEMPORARY ACCEPTABLE DAILY INTAKES - as required, only when there is no other available data and then the most conservative values must be used.

(3) SUMMARIZE DOSE-ADVERSE-EFFECT EVALUATION - to provide the necessary data to allow a comparison to the exposure value.

d. RISK CHARACTERIZATION is the final step which determines the likelihood that humans will experience any of the various forms of toxicity associated with the hazardous chemical. Here the comparison is made between calculated risks and target risks for carcinogens AND between projected intakes and acceptable intakes for noncarcinogens.

Social, economic, and political considerations are not included

(1) Carcinogens

dose (a) Estimate the carcinogenic risk from the total exposure

(b) Describe risks exceeding 1 out of a million

(c) Estimate attributable and/or relative risk

(d) Analyze population groups exposed to excessive risk

(2) Noncarcinogens: estimate hazard index for multiple chemicals

(3) Establish media specific target concentrations

coefficients (a) Identify principle exposure pathways and partition

(b) Calculate the media-specific estimated safe levels in terms of the PPLV - (Rosenblatt, 1980). This is the level of the chemical in the media that would not present risk to the population at the expected points assuming the exposure pathways do not change.

e. SOURCES OF UNCERTAINTY IN RISK ASSESSMENT. The assumptions and uncertainties of the risk assessment process must be determined in order to properly interpret the findings of the study. Following, is a list of the uncertainties outlined by Crast.

- (1) Incomplete site history and characterization data.
- (2) The extrapolation of the results from animal studies to humans.
- (3) The extrapolations of results from high dose studies to the much lower site exposures.
- (4) Toxic studies normally on a single genetic strain; extrapolation to dissimilar human populations increases the uncertainty of results.
- (5) There are no threshold doses for carcinogens.
- (6) Exposure modeling is based on many simplifying assumptions.
- (7) Assuming that the average doses used when conducting research will give a reasonable measure of correlation when the actual doses vary over time.
- (8) Adding toxicants and doses of the same toxicant from different sources.
- (9) The effective target dose is assumed proportional to intake dose in the absence of toxicokinetic data.

APPENDIX C

ABBREVIATIONS AND DEFINITIONS

AIC	Acceptable Intake for Chronic Exposure – The highest human intake of a chemical, expressed as mg/kg/day, that does not cause adverse effects when exposure is long-term (lifetime). The AIC is usually based on chronic animal studies.
AIS	Acceptable Intake for Subchronic Exposure – The highest human intake of a chemical, expressed in mg/kg/day, that does not cause adverse effects when exposure is short-term (but not acute). The AIS is usually based on subchronic animal studies.
Acceptable Risk	A level of risk for which a gamble is worth taking, or when risk is imposed the parties affected are not, or are no longer, apprehensive about the risk.
Acceptance Standard	A standard set at a level where socio-economic factors are balanced against risk. It may be based on either performance or design.
Acute Effects	Generally refers to the toxic effects of a substance which become manifest after only a short period of exposure of a duration measured in minutes, hours, or days.
ADI	Acceptable Daily Intake
Ambient Level Goals	Levels of contaminants in air, water or land which will not adversely affect human health or the ecology, continuous exposure assumed.
Background Concentration Level	The normally occurring concentration level of a substance in a given environment and medium.
Benefit-Cost Ratio	The ratio of total social benefit to total social costs related to a specific activity.
Bio-accumulative	A toxicant having a biological half life of greater than 30 days, thus tending to allow accumulation, especially within a functioning life systems.
Biological Modeling	Models of the fate and effects of toxic pollutants in biological systems, involving ecological and metabolic systems.
Carcinogenic	Capable of producing cancer in a tissue upon exposure.

CERL	Construction Engineering Research Laboratory
Co-carcinogen	An agent, not itself a carcinogen, which enhances the action of a given carcinogen when present in an administered mixture with that substance.
CDI	Chronic Daily Intake - The projected human intake of a chemical averaged over 70 years, expressed as mg/kg/day. The CDI is calculated by multiplying LTC by human intake and body weight factors and is used for chronic risk characterization.
Csm	Chemical in source media
Ctm	Chemical in target media
Chronic Effects	Generally refers to toxic effects of a substance which become manifest after prolonged or repeated exposures of a duration of weeks, months, or years.
Conservatism	When referring to risk analyses, the tendency to inject a certain bias into an analysis, e.g., a weighting toward protection of human health.
Continuous Exposure	Exposure lasting for 90 days (occasionally shorter times are specified).
CEGL	Continuous Exposure Guidance Level - Formerly Continuous Exposure Level (CEL); a ceiling concentration designed to avoid adverse health effects, either immediate or delayed, and to avoid degradation in crew performance that might endanger the objectives of a particular mission after exposure of up to 90 days (promulgated by COT).
De Minimus	Legally set level of a pollutant below which one need not be concerned
Delayed Acute Effects	Delayed death or injury as a result of massive exposure to a toxic agent in a specific event or set of events.
DOD	Department of Defense
Dose-Response Curves	Functional relationship between amount of substance and lethality/morbidity.
Dose-Effect-Response	Empirical relationship between amount of substance and health impact.

Water Quality Information Paper No. 32

Environmental Fate	The disposition of a substance in various environmental media; air, water, soil, etc.
Environmental Impact	Impact on biota and abiotic components of the environment.
Emergency	An unforeseen and unpredicted event requiring immediate response to preserve lives, vital equipment, or critical missions.
EEGL	Emergency Exposure Guidance Levels - Formerly Emergency Exposure Limit (EEL); acceptable concentration for unpredicted single, short-term emergency exposure of a defined occupational group (promulgated by COT).
EPA	U.S. Environmental Protection Agency
Expected Risk	Multiplicative function of probability and consequences estimates of a given event.
Exposure (to risk)	The condition of being vulnerable to a particular outcome of an activity, if that outcome occurs.
Exposure Pathways	Means by which risks are transmitted. The route by which a given population is exposed to a toxic substance, ie. via drinking water, air, dermal contact, food, etc.
Hazard	Danger, peril, threat, which does not necessarily imply potential for occurrence.
Hazardous Substance	A substance whose effect on man or animals is potentially large but undefined since the exposure pathway may or may not exist. It leads to risk only if an exposure pathway exists.
LC50	The calculated concentration of a substance in either air or water (as separate figures) which will cause the death of 50 percent of an experimental animal population under controlled conditions and time exposure, most often 96 hours for aquatic species. (The 50 may or may not be subscripted.)

LD50	The lethal dose to 50 percent of a population; the calculated dose of a chemical substance which is expected to cause the death of 50 percent of an entire population of an experimental animal species as determined from exposure to the substance by any route other than inhalation. (The 50 may or may not be subscripted.)
Logistic Curve	An "S" shaped curve which, if plotting dose-effect responses, is linear at low doses, of higher degree at higher doses, and finally saturates at very high doses where the effect in question always occurs.
Logistic Model	A model which assumes dose response follows a logistic curve.
LTC	Long-term Concentration - The projected chemical concentration at exposure point averaged over human lifetime, assumed to be 70 years. The LTC for the 70 year period beginning with the date of RI/FS is used for chronic risk characterization. Unless otherwise stated, the LTC refers to the best estimate concentration value, not the upper bound estimate.
MAC	Maximal allowable or acceptable concentration - Sometimes a ceiling concentration, applicable to airborne exposure in the workplace (promulgated by several countries).
MCL	Maximum contaminant level
Mitigation Strategies	Control strategies to reduce risk after exposure or possible exposure. For environmental concerns also includes compensation.
MEG	Multimedia Environmental Goals - Levels of significant contaminants or degradants in ambient air, water, or land or in emissions of effluents conveyed to the ambient media) that are judged to be (1) appropriate for preventing certain negative effects in the surrounding populations or ecosystems, or (2) representative of the control limits achievable through technology.
Multistage Models	Dose response models which assume there are a given number of biological stages through which the ingested material must pass, e.g., metabolism, covalent binding, deoxyribonucleic acid (DNA) repair, etc., without being deactivated before manifestation of the effect in question is possible.

Water Quality Information Paper No. 32

Mutagenic	Resulting in permanent change in hereditary material involving a physical change in chromosome relations, a fundamental change in the arrangement of genes, or an alteration in the makeup of DNA.
NAAQS	National Ambient Air Quality Standards
NOAEL	No-observed-adverse-effect-level
Nonpersistent Toxicant	A pollutant with a biological half-life of less than 4 days.
NRC	Nuclear Regulatory Commission
One-hit Model	A dose response model which assumes response is elicited after a susceptible target has been hit once by a biologically effective unit of dose.
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit - Acceptable concentration of airborne toxicants in the workplace for 8h/d, 40 h/wk (promulgated by OSHA).
PPLV	Preliminary Pollutant Level Value
Public Emergency Limit	Acceptable concentration for exposure of the public (previously, but no longer, promulgated by COT).
RCRA	Resource Conservation and Recovery Act
Relative Risk	An estimate of the likelihood of an event in terms of the likelihood of other events of a similar magnitude or the comparison of event magnitudes for events of the same likelihood.
Risk	The potential realization of unwanted, negative consequences of an event. Downside of a gamble.
Risk Acceptance	Willingness of an individual, group, or society to accept a specific level of risk in order to obtain some gain or benefit.
Risk Aversion	The act of reducing risk.
Safety Factor	Element that allows uncertainty in interpretation of experimental data in establishing standards, tolerances, and limits.

SAR	Structure activity relationship
Sensitivity Analysis	A method used to examine the operation of a system by measuring the deviation of its normal behavior due to perturbations in the performance of its components from their nominal values.
STC	Short-term Concentration - The projected chemical concentration in the exposure medium averaged over short time period (10 to 90 days). The peak STC (i.e., highest one projected over the entire evaluation period, usually 70 years) is used for subchronic risk characterization. Unless otherwise stated, the STC refers to the best estimate concentration value, not the upper bound estimate.
Short-term Effects	Acute health effects lasting minutes to hours.
Short-term Exposure	Single exposure, usually 1 hour or less; not more than 24 hours.
SPEGL	Short-Term Public Emergency Guidance Level - Formerly Short-Term Emergency Limit (STPL); acceptable concentration for unpredicted, single, short-term, emergency exposure of the general public (promulgated by COT)
STPL	Short-Term Public Limit - Acceptable concentration for predicted single, short-term, exposure of the general public (promulgated by COT).
SDI	Subchronic Daily Intake - The projected human intake of a chemical averaged over a short time period, expressed as mg/kg/day. The SDI is calculated by multiplying peak STC by human intake and body weight factors and is used for subchronic risk characterization
Synergism	Production of an effect by two or more agents acting together which is greater in magnitude than the sum of the effects which would be produced individually.
Teratogenic	Inducing structural and/or functional deviation in an embryo during its development, resulting in congenital birth defects.
Threshold Level	The level of exposure concentration or dosage of a toxicant below which no effects are expected to occur.

Water Quality Information Paper No. 32

TLV	Threshold Limit Value - Acceptable concentration of airborne toxicants for 8 hours per day, 40 hours per week exposure of human in industry (promulgated by American Conference of Governmental Industrial Hygienists).
Toxic Substance	A substance for which exposure to man or animals results in deleterious effects.
Unpredicted Exposure	Exposure that is unplanned; time of occurrence is not predicted, and eventual occurrence is not certain.
USAEHA	U.S. Army Environmental Hygiene Agency
USAMBRDL	U.S. Army Medical Research and Development Laboratory
Water Quality Criteria	The levels of pollutants that affect use of water for drinking, swimming, aquaculture, farming and industrial use.
Water Quality Standard	A management plan that considers (1) what the water will be used for, (2) setting levels to protect those uses, (3) implementing and enforcing the water treatment plans, and (4) protecting existing high quality waters.
Zero Threshold Pollutant	A term used to denote those compounds for which a threshold has not been established; especially referring to genotoxins.

**TLV**  
Threshold Limit Value - Acceptable concentration of airborne toxicants for 8 hours per day, 40 hours per week exposure of human in industry (established by American Conference of Governmental Industrial Hygienists).

**Toxic substance**  
A substance for which exposure to man or animals results in deleterious effects.

**Unpredicted Exposure**  
Exposure that is unannounced; time of occurrence is not predicted, and eventual occurrence is not certain.

**USEPA**  
U.S. Army Environmental Hygiene Agency

**USAMRIID**  
U.S. Army Medical Research and Development Laboratory

**Water Quality Criteria**  
The levels of pollutants that affect use of water for drinking, swimming, agriculture, farming and industrial use.

**Water Quality Standard**  
A management plan that consists (1) what the water will be used for, (2) setting levels to protect those uses, (3) implementing and enforcing the water treatment plan, and (4) protecting existing high quality water.

**Zero Threshold Pollutant**  
A term used to denote those compounds for which a threshold has not been established; especially referring to genotoxins.

APPENDIX D

ECOLOGICAL RISK ASSESSMENT

1. INTRODUCTION.

a. Determining the effect of anthropogenic stresses on ecosystems is difficult due to the variable effects of nutrient cycling, productivity, diversity, oceanographic/limnologic and/or climatic changes, species interactions, and other processes. The results of standard laboratory toxicity studies (bioassays, MICROTOX®, etc.) do not directly indicate effects upon natural populations because of interactions with the physical/chemical environment which can reduce or increase effects in other populations. It is clear that an ecosystem rather than species or population level perspective is required for consideration of these effects.

b. No single set of risk assessment methods are universally applicable to all ecological risk assessment problems. The variation in types of stresses, receptors of concern, ecological conditions, and available data will require a flexible set of risk assessment methods which can be adapted and tailored to specific situations. This Appendix briefly identifies the general types of ecological risk assessment methods currently available for ecological risk assessments.

2. APPLICABLE ECOLOGICAL RISK ASSESSMENT METHODS. Several basic categories of methods used in the traditional 4-step risk assessment process (hazard identification, exposure assessment, dose-response assessment, and risk characterization) are relevant to ecological risk assessment. These include toxicology, modeling, microcosm and mesocosms, and ecosystem level testing (Levin, et al, 1984).

a. Toxicology.

(1) Toxicology tests will probably continue to be useful and necessary for screening stress sources in order to identify and rank them in terms of their potential hazard. Although widely used laboratory exposure tests do provide valuable information on toxic impacts on individuals, tissues, and/or target receptors, these results can not be readily extrapolated to the community or ecosystem level due to problems in selecting measurable endpoints, interspecific differences, and changes in the nature of the stress due to environmental interactions. Both fate and food chain modeling can assist in extrapolations, but these models are expensive to validate under a variety of conditions.

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© MICROTOX is a registered tradename of Beckman Instruments, Inc., Carlsbad, California. Use of trademarked name does not imply endorsement by the U.S. Army, but is intended only to assist in identification of a specific product.

(2) The use of integrated field and laboratory toxicological studies may be useful in providing a more appropriate measure of ecosystem level impacts of adverse stresses. For example, wildlife toxicology (Kendall, 1982) combined with modeling methods would help identify effects due to multiple exposures and also provide information on nonlethal impacts such as reproductive impairment or reproductive compensation (Jensen and Marshall, 1983).

b. Modeling.

(1) Because ecosystem level data is generally incomplete in terms of the fate, transport, and effects of toxic substances or other stresses, both analytic and simulation models will be of increasing utility in ecological risk assessments. Models will provide methods of evaluating processes and predicting impacts of various stresses. When adequately validated, models can aid in extrapolating from laboratory and micro/mesocosm results to communities and ecosystems.

(2) Fate and transport models help to identify the transformation and distribution of potential stress agents within the ecosystem. These models can be categorized into partitioning models, physical transport models, and integrative fate and transport models. Partitioning models such as SAR's (Lipnick, 1985) have considerable potential for application in accounting for the transport metabolism and receptor interaction of a series of toxicants. Physical models, such as those used to predict circulation and simulate trajectory for oil spills (Spaulding et al, 1986), are becoming more sophisticated and useful in determining the zone of potential adverse effects. Integrative fate and transport models are used to simulate the transport and accumulation of toxic substances in specific aquatic systems. These compartment models may be particularly useful in the regulatory process.

(3) Effects models have been developed at the individual, population, and community/ecosystem level. The SAR's have been used to estimate effects of toxic substances on biota and are useful as screening tests to rank stresses. Models of population dynamics are frequently used to predict population effects of important species adversely impacted by chemical and physical stresses as well as harvesting effort. Some of these models have now been extended to multispecies stock assessments. Although multispecies, community, and ecosystem models are complex, they can aid in helping to explain the theoretical framework needed to understand the key components and processes, focus monitoring efforts, and reduce uncertainty in the models.

c. Micro/Mesocosms.

(1) In an attempt to overcome the limitations of laboratory bioassays in predicting ecosystem effects, microcosms and mesocosms have been developed and applied. These systems are more complex than bioassay studies but less complex than field studies at the ecosystem level. They offer considerable potential as an intermediate method which can emulate the basic ecosystem components and still allow enough control to permit experimental manipulation. The merits of this approach have been described by Kimball and Levin (1985). Recent applications for mesocosms (Oviatt et al, 1987) and microcosms (Kelly, et al, 1987) have demonstrated their utility in the aquatic environment.

(2) Some of the appropriate applications suggested for microcosm studies include the effects of perturbants (stresses) on biochemical cycles and small organisms (relative to the size of the microcosm); studies on the fundamental mechanisms of toxicity; fate and pathway of toxins; and the validation of other procedures such as bioassays and models. When combined with field studies, results from micro/mesocosm experiments can help determine the stimulation of nuisance organisms, the effects on fish production, and other quantities of societal concern (Levin et al, 1984).

d. Ecosystem Level Testing.

(1) Field experimentation may be the only way to actually determine the effects of a particular stress agent on the ecosystem of concern. Field methods will continue to serve as a means of validating the results of toxicological, microcosm, and modeling methods and reducing some of the uncertainty in risk assessments. Although the establishment of experimental ecological reserves for such studies has been suggested (Levin, et al, 1984), this approach may be limited in nearcoastal ecosystems with the possible exception of wetland areas.

(2) The use of case studies of existing impacts can provide useful information especially where existing baseline or long term data exists. Contingency plans which would facilitate rapid mobilization of research efforts on preselected targets of opportunity could provide useful information on both impacts and recovery mechanisms. Multiattribute decision making methods could be used to select sites which would be most useful in providing information needed to confirm predictions from other methods.

(3) Long-term monitoring programs are necessary for establishing the data bases for assessing changes in environmental quality. This approach is particularly vital for evaluating cumulative impacts from multiple stress agents. Obtaining this type of information is expensive and requires long-term funding commitments. For fixed facility situations such as any Army industrial or base area ecosystems, existing data bases from related monitoring programs should be considered as potential sources for retrospective studies.

(4) Biomonitoring methods will also contribute to long-term validation of risk assessments and associated models. Methods such as the monitoring of selected indicator organisms, programs similar to the mussel watch and herring gull efforts, and long-term fouling plate or artificial habitat studies are useful for assessing excessive levels of contamination. Some species can act as sentinels (Clark et al, 1987) and be effective in identifying hot spots, cumulative impacts, and bioconcentration. When combined with modeling approaches and less frequent water quality analysis, biomonitoring of selected species, life stages, or tissues, can be a cost-effective method of confirming multimedia environmental model predictions. Here again, for fixed facility Army operations, field biomonitoring studies can serve as cost-effective methods of evaluating change.

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APPENDIX E

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