ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

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ACRONYMS AND ABBREVIATIONS

ORGANIZATIONS

USEPA	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
USFDA	UNITED STATES FOOD AND DRUG ADMINISTRATION
USDOD	UNITED STATES DEPARTMENT OF DEFENSE
USDOE	UNITED STATES DEPARTMENT OF ENERGY
NRC	NATIONAL RESEARCH COUNCIL
NJDEP	NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION

ABBREVIATIONS

CPF	CANCER POTENCY FACTOR
CSF	CANCER SLOPE FACTOR
DER	DECLARATION OF ENVIRONMENTAL RESTRICTIONS
ECRA	ENVIRONMENTAL CLEANUP RESPONSIBILITY ACT
FIFRA	FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT
HEAST	HEALTH EFFECTS ASSESSMENT SUMMARY TABLES
HI	HAZARD INDEX
HQ	HAZARD QUOTIENT
IRIS	INTEGRATED RISK INFORMATION SYSTEM
ISRA	INDUSTRIAL SITE RECOVERY ACT
Kd	DISTRIBUTION COEFFICIENT
Kg	KILOGRAM (2.2 POUNDS)
LMS	LINEARIZED MULTISTAGE MODEL

LOAEL	LOWEST OBSERVED ADVERSE EFFECT LEVEL
MF	MODIFYING FACTOR
mg	MILLIGRAMS (1/1,000,000 kg)
NFA	NO FURTHER ACTION
NOAEL	NO OBSERVED ADVERSE EFFECT LEVEL
PA	PRELIMINARY ASSESSMENT
pH	MEASURE OF ACID/BASE CONCENTRATION
RfD	REFERENCE DOSE
SI	SITE INVESTIGATION
TCLP	TOXICITY CHARACTERISTICS LEACHING PROCEDURE
TC	TOXICITY CHARACTERISTICS
UCL	UPPER CONFIDENCE LIMIT
UF	UNCERTAINTY FACTOR
UST	UNDERGROUND STORAGE TANKS

DRAFT REPORT OF THE

ENVIRONMENTAL RISK ASSESSMENT AND

RISK MANAGEMENT STUDY COMMISSION

I. EXECUTIVE SUMMARY

New Jersey has long been the national leader in industrial development, particularly in the chemical, petrochemical and pharmaceutical areas. However, this industrial activity has created a major environmental problem. New Jersey must now address the legacy of a past marked by widespread and often unregulated use of chemicals that has contaminated literally tens of thousands of sites. To address this problem the legislature passed and the Governor signed Senate Bill 1070 on June 16, 1993. Sections 1-22 of the Public Law - 1993 c.139 is also known as the Industrial Site Recovery Act (ISRA or the Act)[Appendix A].

As required by ISRA, the Environmental Risk Assessment and Risk Management Study Commission ("Commission") was established and given the charge... " to examine and assess the scientific basis for selecting the risk management standard of one in a million... and to examine and assess methodologies of risk assessment and their efficacy and applicability for the purpose of establishing remediation standards." The Commission held three public meetings and numerous deliberative and working sessions. The results of extensive assessment and evaluation led to several conclusions and

recommendations, as presented in Section X of this report.

The use of one in a million excess cancer risk (10^{-6}) is an issue of public policy, not of science. The application of the 10^{-6} guideline in risk management has been carried over into engineering, exposure assessment and regulatory decision making. However, the history of 10^{-6} does not reveal intent for use in any application other than food safety. It is grounded in the Delaney Amendment of the Food, Drug and Cosmetic Act, as amended, and was intended to limit exposure to carcinogens in the food supply. The Delaney Amendment was brought into USEPA with the transfer of the pesticide regulations(Federal Insecticide, Fungicide and Rodenticide Act, [FIFRA]) from the USFDA to the newly formed USEPA in 1970. Application of the 10^{-6} risk management standard to environmental chemicals other than pesticides in foods was a policy decision resulting in an extension of the FIFRA regulations.

In order to achieve remediation of affected sites, the Commission recommends that site remediation standards be flexible and reflect the future use of a site. Therefore, the Commission recommends that remediation goals be set as a function of anticipated use and that standards be adopted which consider non-cancer endpoints. The Commission further recommends that site remediation goals can be achieved by treatment and removal, or by exposure control technologies such as capping. However, when exposure control technologies are utilized, the standards are more strict and deed restrictions must be

applied. Further, the Commission recommends the severance of liability for the responsible party if remediation goals are met. There are requirements under which severance would be established. First, that a site be remediated to the permanent standards in effect at the time of the remediation. Second, that an escrow account be established by the State to collect and retain in exclusive perpetuity a surcharge for each remediated site. The escrow account will be used in the event that previously undetected contaminants with greater health impacts than those previously remediated are detected or if federal or State health standards for residual contaminants are decreased by at least a factor of ten. Third, the escrow account cannot be used in the event of fraud.

The Commission recommends adoption of a three-tiered approach to site remediation. Tier 1 is a restatement of the current NJDEP soil clean-up criteria using a risk management standard of 10^{-5}. Tier 2 combines site-specific physical characteristics and exposure information with the NJDEP default assumptions and is driven by the risk management standard presented in column III (Residual Risk of Permanent Remedy) Table 1. Tier 1 and Tier 2 are considered by the Commission as permanent remedies for all land uses and result in severance of future liability. Tier 3 builds on Tier 2 and provides alternative methods to derive site specific clean-up criteria. Tier 3 is driven by the risk management standards presented in column IV and V of Table 1. Severance of liability is not achieved using this option and a deed restriction is required.

The Commission recommends the establishment of a RISK ASSESSMENT AND RISK MANAGEMENT SCIENCE ADVISORY BOARD to advise the Commissioner of Environmental Protection and the Governor in human health related matters regarding site remediation, site reutilization and evaluation of future risk assessment policy.

The Commission recommends using the best available scientific information and judgement to predict hazard. The use of site specific data, rather than default assumptions is embraced by the Commission. Additionally, the Commission encourages the inclusion of scientifically defensible tools such as probabilistic analysis, physiologically based/pharmacokinetic modeling, mechanistic toxicology, bioavailability (particularly from soil and sediment materials), and environmental fate and transport modeling to more accurately predict environmental risk.

Table 1

RISK MANAGEMENT STANDARDS					
I USEPA Carcinogen Classification	II NJDEP Default Standards	III Residual Risk of Permanent Remedy[1]	IV Residual Risk of Exposure Control Remedy[2]	V Maximum Risk with Failure of Exposure Control Remedy[3]	VI Population Based (event/70 years)
A	10^{-5}	10^{-5}	10^{-6}	10^{-4}	1
B	10^{-5}	10^{-5}	10^{-6}	10^{-4}	1
C	10^{-5}	10^{-4}	10^{-5}	10^{-4}	1
Non Cancer Endpoints[4]	1	1	1	3	1

1) A "permanent remedy" for all land uses is defined as contaminant removal, destruction, irreversible transformation, or irreversible immobilization. Liability is severed.

2) "Exposure controls" are defined as methods which prevent contact between contaminants of concern and the human population. Exposure controls include slurry walls, liners, fences, ventilation, polymer or clay lined landfill, hydraulic controls, and immobilization processes which may result in future contaminant release. Deed restrictions apply.

3) Minimum achieved by contaminant reduction (or removal), or the maximum risk resulting from failure of the exposure control remedy. Deed restrictions apply.

4) Hazard Quotient (HQ). The ratio of a single substance exposure level over a specified time period to a reference dose for that substance derived from a similar period. (Exposure Concentration/RfD).

II. INTRODUCTION

New Jersey has long been the national leader in industrial development, particularly in the chemical, petrochemical and pharmaceutical areas. However, this industrial activity has created a problem. New Jersey now has to deal with the legacy of a past marked by widespread and often unregulated use of chemicals that has contaminated literally tens of thousands of sites. This has led to New Jersey having the unenviable reputation of the largest number of sites on the federal Superfund list. But the Superfund legislation only covers 108 sites. Most of the remaining tens of thousands of known contaminated sites are relegated to the New Jersey ISRA law. It should be noted that additionally a large number of industrial sites in the State of New Jersey may also require remediation. These sites have not yet been identified in the current scheme because regulatory triggers have not been activated.

Based on information provided to the Commission by the NJDEP, approximately 17,000 sites of the New Jersey universe of 23,600 sites have been administratively delisted or actively remediated since 1984. Based on the data presented in Table 2, approximately 4,500 sites (ISRA sites and UST sites) have been fully remediated, 7,900 other sites have been administratively delisted and there have been 4,400 voluntary cleanups.

As reflected in the legislative debate on ISRA, the primary concern was that under the constraints of the Environmental Cleanup Responsibility Act (ECRA) few commercial properties satisfied the criteria for program completion during the period of 1984-1994. With the passage of ISRA some movement of property has occurred, however, many properties have been capped, sealed or otherwise delisted with a Declaration of Environmental Restriction in place. Since these capped sites have not been permanently remediated the underlying environmental quality has not markedly improved.

The universe of contaminated sites is a major liability to New Jersey. They represent lost opportunity for commercial activity and jobs, particularly in poorer areas of our State where they contribute substantially to issues of environmental inequality and injustice. The costs for these sites for both the public and the private sectors are substantial. Despite years of attention and investment of resources, the public perception is that little has changed and few sites have been remediated to the level of public use.

REMEDIATIONS IN NEW JERSEY

SITES ON THE COMPREHENSIVE SITE LIST (CSL)

Table 2A

No Further Action (NFA)	Assigned to Program[1] Cleanup Required[2]	Assigned to Program[1] Sites Under Review[3]	To Be Assessed	Total Sites as of 12/31/94
10,500	6,600	5,200	1,300	23,600

[1] Of the 11,800 sites listed, 2,000 have not been assigned to a specific remediation program (i.e. UST, Superfund, etc.)

[2] Of the 11,800 sites listed, 6,600 are known to be contaminated sites (i.e. on the Known Contaminated Sites in New Jersey (KCSNJ) Report).

[3] Sites in the NJDEP Site Remediation program undergoing investigation for the presence of contamination.

NO FURTHER ACTION DOCUMENTS (NFAs) ISSUED FOR SITES OR PORTIONS OF SITES[6]

Table 2B

	ISRA Cases and/or Areas of Concern from 1984	UST Cases and/or Areas of Concern from 1987	Superfund Sub-Sites[4] from 1981	Enforcement, Non-Superfund, Voluntary Cleanups & Others from 1981	Total NFAs[5]
NFAs-PA/SIs[7] only	5,100	2,800	NA	NA	7,900
NFAs-Cleanup Required	2,100	2,400	120	4,400	9,020
Total NFAs[5]	7,200	5,200	120	4,400	16,920

[4] Superfund data are as of 6/30/94. All other data are as of 12/31/94. The Superfund universe is 325 subsites within 108 overall Superfund sites as of 6/30/94.

[5] NFA documents are issued for sites or portions of sites.

[6] All areas in Table 2B are from the universe of sites in Table 2A.

[7] Preliminary Assessments/Site Investigations

Source: Site Remediation Program, New Jersey DEP, 1995.

STATUS OF BEECRA* CASES BY CALENDER YEAR
Table 2C

YEAR	CASES RECEIVED	ADMIN CLOSEOUT	CLEANUP CLOSEOUT	STILL ACTIVE
84	464	217	197	50
85	827	470	264	93
86	1245	855	266	124
87	1129	747	275	107
88	1286	801	304	181
89	1044	645	257	142
90	1074	708	228	138
91	816	541	186	89
92	763	531	112	120
93	720	541	38	141
94	740	513	13	214
95**	236	129	2	105
TOTAL	10,344	6698	2142	1504
		65%	21%	15%

* BUREAU OF ENVIRONMENTAL EVALUATION, CLEANUP & RESPONSE ASSESSMENT
**(1 JAN-30 JUNE)

STATUS OF BUREAU UST* CASES BY FISCAL YEAR
Table 2D

YEAR	CLOSED CASES	ENDING BALANCE
92**	822	3823
93	637	3045
94	721	3012
95	600	3056

* UNDERGROUND STORAGE TANKS
** STATISTICS NOT AVAILABLE PRIOR TO FY 92

On June 16, 1993, Senate Bill 1070 was signed into law. Sections 1-22 of Public Law-1993, c.139, is known as the Industrial Site Recovery Act (ISRA or "the Act") [Appendix A]. It requires the legislative and executive branches of the State government to establish the Environmental Risk Assessment and Risk Management Study Commission ("the Commission"). The charges to the Commission, as stated in the Act, are "(1) To examine and assess the scientific basis for selecting the risk management standard of one in a million...and (2) To examine and assess methodologies of risk assessment and their efficacy and applicability for the purpose of establishing remediation standards."

The legislature, in S-1070 declared "that it is policy of this State to protect the public health, safety and environment, to promote efficient and timely cleanups, and to eliminate any unnecessary financial burden of remediating contaminated sites."

The first principle of New Jersey environmental legislation continues to be protection of human health and the environment. The Commission's deliberations were guided by this fundamental principle.

The nine members of the Commission were appointed by the Governor, President of the Senate and Speaker of the General Assembly. In addition, the Commissioner of the NJDEP (or designee) serves as the tenth non-voting member of the Commission. Appointment procedures and a list of Commission members are provided in Appendix B.

The general purposes of S-1070, including ISRA are to protect public health, safety and the environment, to incorporate new knowledge regarding the costs and complexities of remediation, to create a more efficient regulatory structure, to promote certainty in the regulatory process, and to promote efficient and timely remediation of known contaminated sites in New Jersey. Implicit in the debate surrounding ISRA, as

reflected in the name of the legislation, is the presumption that existing risk assessment-risk management policies may not be responsive to the needs of the people of the State of New Jersey. The Commission's mandate to evaluate the process and recommend procedures for improvement is the subject of this report. Ecological risk assessment was not the charge to this Commission.

The Commission held two administrative meetings and three public hearings (March 9-11, 1994) throughout New Jersey prior to commencement of its deliberations. The public meetings, were held at Camden County Community College (Blackwood), Cook College of Rutgers University (New Brunswick), and New Jersey Institute of Technology (Newark). Each witness was given five minutes for presentation and one minute for summation. In addition to offering oral testimony, each witness was strongly encouraged to present their written testimony and to send supporting material to the Office of Legislative Services. The Commission received approximately 40 written and oral comments from the general public, N.J. industry, the environmental community and academia. The locations and dates of the public meetings, the public comment process and a list of participants submitting written materials are presented in Appendix C. The written testimony, ranging from one page letters to multiple volume documents, was helpful to the deliberations of the Commission. The major tenor of the hearings was the deep concern that all witnesses had for the importance of the Commission's deliberations. However, some comments suggest that the purpose of the Commission may not have been clear to all participants in the hearings. Several individuals spoke only of the 108 *Superfund* sites rather than the broader issue of the approximately 24,000 potentially contaminated sites throughout New Jersey.

Transcripts of oral presentations offered at the March 9, 10, 11, 1994 public meetings, as well as written testimony received by the Commission, are provided in Appendix D. In addition, Appendix E contains a list of general reference

materials considered by the Commission.

III. THE SCIENTIFIC BASIS FOR SELECTING THE RISK MANAGEMENT STANDARD OF ONE IN A MILLION

The charge presented to the Commission in Section 47 of Public Law-1993, C.139 is "To examine and assess the scientific basis for selecting the risk management standard of one in a million..." The cancer risk management standard of one in a million (or $1x10^{-6}$; read "one times ten to the minus six") represents an increased lifetime chance of 0.000001 in 1 (or one chance in a million) of developing cancer due to exposure to a substance. By comparing this risk to our current risk of developing cancer from all causes, which is approximately 1 in 4 (American Cancer Society, 1994), a one in a million risk would increase an individual's risk of developing cancer by 0.00025% (2.5 ten-thousandths of one percent), i.e., from 250,000 in 1,000,000 to 250,001 in 1,000,000.

The use of the 1 in 1,000,000 excess cancer risk standard in public policy is grounded in the Delaney Amendment (September, 1958) to the Food, Drug and Cosmetic Act, as amended, and was intended to limit exposure to carcinogenic substances in the US food supply. One in a million was considered to be a maximal acceptable risk (known as de minimus). The basis for the de minimis risk for excess cancer of 10^{-6} is not supported by biological or medical science. The USFDA history of the 10^{-6} risk goal does not reveal intent for use in any application other than safety of indirect and direct food additives. The target population expected to be exposed to indirect or direct food additives was estimated in the tens of millions. This level of population exposure potential does not exist at the vast majority of the remedial sites. Other exposure patterns such as frequency and duration differ significantly for food additives and remedial sites. Therefore, the historical foundation supporting the one in a million risk standard should *not* be globally applied to all risk management situations.

The USEPA acquired the Delaney Amendment with the transfer of the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) to the newly formed environmental agency in 1970. Application to chemicals other than pesticides is an extension of the food residue policy. This policy was never intended to be used to regulate remediation of contaminated sites. Currently, the USEPA acceptable cancer risk standards range from 1×10^{-4} to 1×10^{-6} depending on the situation (USEPA, National Contingency Plan, 1990). Travis and Hattemer-Frey (1988) reported "every chemical with an individual risk above 4×10^{-3} ... was regulated." "Second, except for one FDA decision ..., no action was taken to reduce individual lifetime risk levels that were below 1×10^{-6}."

It is the opinion of the Commission that establishment of a single acceptable risk management standard (10^{-6}) for all site remediation structures has been an issue of public policy. Determination of risk level for a specific scenario should be based on the best available science and engineering. Review of the literature revealed no scientific basis for the selection of one in a million as the criterion for developing remediation standards for environmental pollutants (Kelly & Cardon, 1991). Indeed, the literature provides little or no scientific basis for any cancer risk standard. The nature of a policy statement of a single risk level standard (i.e. 10^{-6}) implies that remediation standards are based on science. In the opinion of the Commission, this is not the case. Since the risk level serves as a starting point in the technical evaluation of a large number of factors involved in developing remediation standards, the Commission believes that adopting a risk level from pre-existing food additive regulations is inappropriate. The Commission strongly suggests that remedial risk management policy options should be influenced by the characteristics of the site(s), the nature of the remediation and future land use. A discussion of the factors and default assumptions which should be considered, and a recommended risk management standard, are presented in subsequent sections of this report.

IV. FRAMEWORK FOR ESTABLISHING SITE REMEDIATION STRATEGIES

To achieve the goals of ISRA of protecting human health while promoting efficient, timely and cost effective remediation of contaminated sites, a strategy must be employed which considers a variety of factors, e.g., scientific, engineering, economic, societal, etc. Remediation standards which are developed based on these considerations should be viewed as a public policy decision which seeks to establish a balance among the relevant factors.

It should be appreciated that a unique set of factors applies in the case of contaminated sites. A number of contaminated sites currently exists with a population of individuals living or working near the sites that varies with time throughout the week. Similarly, limited numbers of individuals have access to some remediated sites; these numbers will be even smaller if a Declaration of Environmental Restrictions (DER) is appended to the deed for the site. Further, the imposition of a DER is a mechanism whereby the public can be informed regarding use of remediated sites. Therefore, risk management standards for contaminated sites should be developed differently than previous standards utilized for drinking water or food additives, where large numbers of individuals are exposed involuntarily.

Further, development of remediation standards should establish a basis for consistent decision-making that is supported by sound, peer reviewed toxicological and exposure data. Practical considerations, including limitations of analytical methodology, should also be considered in developing final remediation standards. If these practical considerations result in a level less stringent than the health-based criterion, the remediation standard may be modified by these considerations.

If "workable" standards cannot be developed, then the goal

of ISRA will not be achieved. Existing contaminated sites will remain unremediated and unavailable for reuse. Unremediated sites will remain a risk to nearby populations with potential for more individuals to be exposed, should the contamination spread.

V. RISK ASSESSMENT METHODOLOGIES

This section of the Commission report discusses the methods used to calculate a point estimate of risk. Subsequently, a discussion of the limitations of the currently applied methodology is presented.

Risk is the probability of an adverse effect such as cancer, liver disease or some other defect occurring in an individual or population. Risk from environmental agents is generally portrayed by the following relationship:

RISK = HAZARD x EXPOSURE

Hazard is that part of risk that encompasses the toxicity, internal dose, population sensitivity and physical state of the agent(s) in question. Exposure is that part of risk that encompasses potential dose, bioavailability from the environmental matrix, population density and time.

Control of any of the components in the formula can effectively reduce the risk. For example, use of engineering or institutional controls can reduce or eliminate the exposure term of the equation. Consequently, risk associated with the exposure will also be reduced or eliminated. Another example might be to modify the concentration of a contaminant through treatment or removal techniques, thereby effectively reducing the hazard. These are examples where management or treatment techniques can be employed to reduce risk to an individual or the overall risk to a population.

Quantitative health risk assessment is the process by which the probability of harm is estimated for environmental exposure to toxic chemicals. The National Research Council (NRC) in a 1984 report defined the overall terminology of quantitative risk assessment and the NRC report is still the most widely cited reference for a description of the methodology. The central idea in risk assessment is that there is some dose of a toxic chemical for which there are no or virtually no adverse health effects even with prolonged or lifetime exposure. This assumption is based upon observational (epidemiologic) or experimental (animal bioassay) data.

The NRC (1984) described four steps in the risk assessment process, hazard identification, dose:response assessment, exposure assessment and risk characterization.

Hazard identification is "the determination of whether a particular chemical is or is not causally linked to particular health effects." It is also the step of identifying which chemicals have been measured in various media at the site. Hazard identification further relates to the type of adverse health effect associated with the chemical(s) in question. Such effects could be: liver damage, birth defects, cancer, metabolic disruptions or one of any number of systemic toxicologic outcomes. A single chemical may cause multiple hazards depending on dose, and multiple chemicals may cause the same adverse effect.

Dose:Response assessment is the determination of the relationship between the magnitude of exposure and the probability of occurrence of the health effect in question. The dose:response assessment often requires extrapolation from high to low doses and from responses in laboratory animals to man.

Exposure assessment is the "process of measuring or estimating the intensity, frequency and duration of human exposure to an agent currently present in the environment or of

estimating hypothetical exposures that might arise from the release of new chemicals into the environment." It should be noted that the preferred method of evaluating exposure is actual measurement. Exposure assessment and its relationship to dose:response will be addressed more fully in the following section.

Risk characterization is the "process of estimating the incidence of a health effect occurring under the various conditions of human exposure." The current practice of risk characterization utilizes the data gathered in hazard identification, dose:response assessment, and exposure assessment to yield a single numerical value which is purported to represent an upper bound risk estimate for a given agent at a given site. Subsequent sections of this report describe more comprehensive approaches to define risk including the use of time considerations as a means of characterizing risk. In addition, this section discusses the conservative nature of many of the assumptions and factors which are utilized to calculate risk.

The USEPA (1989) employs a risk assessment paradigm similar to that proposed by the NRC, but uses slightly different headings for the four major steps in the risk assessment. The USEPA utilizes the more global term of "Data Collection and Evaluation" to represent "Hazard Identification", and "Toxicity Assessment" to represent "Dose:Response Assessment." In both instances the USEPA terminology is more inclusive. The Commission accepts the basic paradigm of the USEPA, but has reservations regarding broad based application of conservative assumptions to arrive at a single point estimate of risk.

In the application of dose:response data to risk assessment, the concept of threshold broadly states that smaller (lower) doses may result in lesser or no effects in a given percentage of the population of experimental animals or humans. Regulatory agencies (USEPA, NJDEP and many others worldwide) endorse this concept for non-carcinogenic chemicals. Regulatory decision

making for their class of chemicals is based on the reference dose (RfD). The RfD is established by determining the point at which the dose is so small as to cause no or negligible effects (no or lowest observed adverse effect level[NOAEL]or a NOAEL derived from a LOAEL (lowest observed adverse effect level) with appropriate uncertainty adjustments. Therefore, **RfD=NOAEL or LOAEL/UFXMF**. The RfD is expressed as mg of chemical/kg body wt./day. The uncertainty factors are applied to account for such factors are intraspecies and interspecies variability, intraindividual human variability, less than lifetime exposure, and estimation of NOAEL from a LOAEL. For carcinogenic substances, the threshold concept is not generally endorsed by regulatory authorities in the United States.

The USEPA Integrated Risk Information System (IRIS) and Health Effects Assessment Summary Tables (HEAST) databases contain RfD and cancer slope factor information for most of the chemicals for which soil standards have been contemplated by either the USEPA or the State of New Jersey. The State of New Jersey also uses toxicity factors developed by the Safe Drinking Water Quality Institute pursuant to the 1984 A-280 Amendment to the State Safe Drinking Water Act. ISRA suggests that the toxicity values used by the Safe Drinking Water Quality Institute, and others by the systems such as USEPA IRIS and HEAST be used to calculate risk. For some chemicals the primary toxicology literature must still be reviewed to develop RfDs. The primary consideration for utilization of any reference or toxicity data base is peer review to assure reviewed scientific validity.

VI. EXAMINATION AND ASSESSMENT OF RISK ASSESSMENT METHODOLOGIES

The primary components of a risk assessment include an evaluation of existing toxicology data, identification of appropriate exposure routes (inhalation, ingestion, etc),

identification of appropriate exposure pathways (air, water, soil) and utilization of a target risk management objective. In order to evaluate the efficacy of current practice, an understanding of the specific factors used to define each of the primary components is necessary. This section of the report discusses some, but certainly not all of the factors used to calculate risk. It is the desire and recommendation of the Commission that in the future, other factors be evaluated based upon the best available scientific information and these new factors be utilized by NJDEP to define risk.

One of the basic components of a risk assessment is the underlying evaluation of published, peer-reviewed toxicity data. If a substance has been shown to be or suspected to be carcinogenic, the toxicity evaluation will result in a "cancer potency factor" (CPF) or a "cancer slope factor" (CSF). For the purposes of these discussions, the CPF and CSF will be used interchangeably. If on the other hand a substance is noncarcinogenic, the toxicity evaluation will result in a "reference dose" or RfD.

> "Toxicity assessment for contaminants found at Superfund sites is generally accomplished in two steps: hazard identification and dose-response evaluation. The first step, hazard identification, is the process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans. Hazard identification involves characterizing the nature and strength of the evidence of causation. The second step, dose-response assessment, is the process of quantitatively evaluating the toxicity information and characterizing the relationship between the dose of the contaminant administered or received and the incidence of adverse health effects in the exposed population. From this quantitative dose-response

relationship, toxicity values (e.g., reference doses and slope factors) are derived that can be used to estimate the incidence or potential for adverse effects as a function of human exposure to the agent. These toxicity values are used in the risk characterization step to estimate the likelihood of adverse effects occurring in humans at different exposure levels (USEPA, 1993)."

The USEPA definitions for CSF and RfD are shown below:

Cancer Slope Factor (CSF): A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive groups) that is likely to be without appreciable risk of deleterious effects during a lifetime.

There are many acceptable numerical estimates of common exposure related variables, such as soil ingestion rate, length of residence in a home, body surface area and weight. These have been quantified and described in USEPA guidance documents (see USEPA references). These are point estimates i.e., they do not describe the statistical distribution of the exposure variables. However, for some variables such as ingestion of drinking water, reasonable distribution data are available. These exposure distributions will be described more fully in the "Uncertainty Analysis and Conservatism" section of this report.

For soil standards, many avenues or pathways of exposure have been considered. For example, some chemicals may

volatilize from soil and be inhaled. Other chemicals may leach out of soil into groundwater and become part of a drinking water supply. Chemical fate and transport modeling results in an estimated concentration of contaminant in an environmental medium such as air, water or food. Further, each site is associated with a unique constellation of physical and chemical properties and activity patterns which result in a probability of human exposure which may be different from other sites.

It has been suggested that the greatest source of uncertainty in the risk assessment equation is the estimation of the CSF and RfD (Wilson, 1991). In order to understand this uncertainty, the following limited analysis of the methodology for collection of toxicology data and utilizing risk management assumptions is provided.

There are two quantitative approaches generally utilized for risk assessment. For carcinogens, a low dose extrapolation model is used to describe the dose:response relationship at environmental levels of exposure. As indicated previously, environmental exposure concentrations are often as much as three orders of magnitude (i.e. 1000 X) lower than those used to define the dose:response relationship (for carcinogens) in experimental animals. Indeed, testing animals is carried out on the assumption that high doses (maximum tolerated dose, etc.) will overcome or compensate for the loss of statistical power in observing a low frequency of tumor production. However, the biological basis of this hypothesis has yet to be proven. The cancer responses are assumed to be linear with no threshold. Historically, according to the USEPA National Contingency Plan (1990) the de minimis site risk level for carcinogenic substances has varied from 1×10^{-4} to 1×10^{-6}. As discussed previously, this risk level was established by the USFDA for food additives and adopted by USEPA and NJDEP for certain other uses.

Regulatory and health agencies throughout the world accept the hypothesis that humans are the most sensitive species when

extrapolating from laboratory animal toxicity data. This argument can be joined from both sides. However, the Commission supports the premise of comparative human sensitivity for public health protection in the absence of peer-reviewed data to the contrary.

While head of the Carcinogen Assessment Group (CAG)of USEPA, Anderson (1984) evaluated the conservative nature of the assumptions used in the estimation of cancer slope factors (CSFs) generally derived from animal experimentation. The over estimation for an individual assumption could be 1 to 12 fold. It was concluded that when all factors were considered, the over estimate of risk could be 15 to 10,800 fold. However, in the absence of other methodologies the USEPA derived CSFs (potency factors) are recommended by the Commission for use by the NJDEP. The derivation of the CSFs defines a "plausible upper bound" of potency. Generally the linearized multistage (LMS) model for carcinogenic agents produces the most conservative estimate of risk of the models tested. This conservatism has led USEPA to state that risk estimates based on the upper bound of the LMS are high and the true risks, which are unknown, may be as low as zero.

Allen et al.(1988) described the uncertainty associated with CSF for 23 chemicals which have been shown to be carcinogenic in humans. The ratio for the 90% upper confidence limit (UCL) and the best estimate of the LMS vary by 5 to 1000 fold. For the carcinogenic substance acrylonitrile, Crouch (1992) calculated the probability distributions of unit risk. The USEPA (1986) defines unit risk as the excess lifetime risk due to a continuous constant lifetime exposure, under an assumption of low-dose linearity, of one unit of carcinogen concentration. The USEPA unit risk value for acrylonitriles using the LMS was 45 times larger than Crouch's best estimate of risk.

Like CSFs, chemical specific RfDs are developed based upon a known set of toxicologic data and the application of the data to

basic risk management paradigms. The RfD is expressed in terms of body weight (for example, in units of mg/kg/day). For non-carcinogens there is an assumed threshold for adverse effects and an acceptable Hazard Quotient (H.Q.)of 1.0.

> Hazard Quotient (H.Q.). The ratio of a single substance exposure level over a specified time period to a reference dose for that substance derived from a similar exposure period.

> Hazard Index (H.I.). The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-duration exposures.

H.Q. values greater than 1.0 indicate that the environmental exposures are greater than the RfD and hence unacceptable. Those H.Q. values less than 1.0 indicate environmental exposures are less than the RfD.

The process of developing an RfD requires that scientific judgement be applied to a weight of evidence evaluation of the literature, to decisions as to the appropriate choices of toxicological endpoints, and to the uncertainty factors to be used. An RfD for a particular chemical may change when additional health effects data become available.

UNCERTAINTY ANALYSIS and CONSERVATISM

Probabilistic analysis is a mathematical technique that can be used to characterize the distribution of doses in exposed populations and the uncertainty in estimates of dose for individuals. The technique was developed in the 1940s by Federal researchers and has been used by the DOD, DOE, and EPA in

numerous applications. To date, no formal guidance for the use of probabilistic analysis of risk has been issued by the USEPA.

Monte Carlo, Latin Hypercube or similar methods of probablistic analysis are computational techniques which permit arithmetic or algebraic operations to be performed on equations whose inputs are probability distributions rather than single values. This is accomplished through iterative random sampling of the individual distributions and combination of samples of each iteration according to the mathematical form of the overall equation. The outcome of this procedure is itself a distribution reflecting the probability of any numerical solution to the equation. The practical implication of the use of uncertainty analysis estimated by Monte Carlo, Latin Hypercubes or similar techniques for risk assessment is that risks can be calculated using the entire distributional range for inputs which have significant variability in the population. Currently, USEPA endorses the use of Monte Carlo analysis as a way of characterizing exposures to high-end individuals (USEPA, 1992). Guidance on the use of Monte Carlo analysis has been issued by USEPA Region III(USEPA, 1994). The Agency is currently organizing workshops for the training of personnel in evaluating Monte Carlo based exposure and risk analyses (personal communication, Dr. William Wood, 1995).

The current methodology for estimating risk requires that inputs the possible values of which are, in fact, normally distributed in the population be represented by a single numerical value (*point estimate*). Regardless of whether the point estimate is selected as the mean, an upper percentile estimate, or some other estimate of the distribution, no single value can adequately represent an entire distribution. Possible examples of such inputs include daily inhalation volume, soil and/or water ingestion rate, time spent inside and outside a residence, years lived in a given residence, body weight and food consumption rate.

The USEPA has recognized the strengths and weaknesses of Monte Carlo analysis as evidenced by the publication entitled "A Monte Carlo Approach to Simulating Residential Occupancy Periods and Its Application to the General U.S. Population" (USEPA 450/3-92-011 [Aug.,1992]), and by the memo of February 26, 1992, from the Deputy Administrator Habicht to Assistant Administrators and Regional Administrators entitled "Guidance on Risk Characterization for Risk Managers and Risk Assessors."

Whereas Monte Carlo analysis holds promise for generating more realistic estimates of risk and risk-based standards, it is important to realize that this approach is dependent upon the quality of input information. Therefore, incomplete or inaccurate distributional input data can result in faulty and misleading risk estimates. The Commission recognizes the benefits and pitfalls of the application of probabilistic techniques. However, the Commission strongly recommends the development and validation of standard probabilistic approaches that can eventually be used to better define risk.

ENVIRONMENTAL FATE AND TRANSPORT CONSIDERATIONS IN RISK ASSESSMENT

In order to determine appropriate exposure concentrations, site-specific environmental fate and transport analysis are necessary. No single set of fate and transport equations exist which can, with great confidence, predict the precise movement of a chemical in soil through multiple media such as air, water and vegetation, and ultimately to a human internal dose. The physicochemical and thermodynamic properties of a chemical result in interactions with soil which retard or enhance its ability to move in the environment. Most chemical fate models consider one medium at a time. For example, most air models do not address interaction with soil or water. They usually predict air concentration at some distance from a source, such as a stack under specific meteorologic conditions. Multiphase models are being used by regulatory agencies to predict site-specific

transport characteristics. Chemicals may, however, move from soil to air and be inhaled or be absorbed by a plant which is then consumed.

It is recognized that total soil contaminant concentrations are frequently much greater than the amount of the contaminant which may be released over prolonged exposure scenarios. Bioavailability varies by soil matrices, chemicals at the site and time. Testing and evaluation protocols which are predictive of actual release potential under varied management scenarios need to be developed and implemented. For example, the current USEPA Toxicity Characteristic Leaching Procedure (TCLP) and Toxicity Characterization (TC) testing and evaluation protocols do not provide accurate contaminant release estimates under many conditions.

The results of many fate and transport models are purported to be quantitative but have uncertainties. For example, many models do not include contaminant reduction by natural attenuation processes such as biodegradation. Therefore, these models may over estimate contaminant transport from the initial point of release. The strengths of the models are that they provide time dependent estimates of contaminant concentrations at receptor interfaces. The concentrations are then used to estimate internal dose(s) and ultimately human risk.

Application of appropriate (validated) environmental fate and transport models should improve the overall risk assessment process.

VII. REMEDY SELECTION and the MITIGATION of RISK

Risk management seeks to control or mitigate risks and reduce the probability of exposure. The selection of the appropriate remedial action is, in effect, a risk management decision. Remediation is achieved through either removal or

treatment of contaminants, or by the use of engineering or institutional controls. Factors such as community acceptance, cost reasonableness, technical feasibility, land use and other regulatory constraints need to be evaluated by the risk manager.

RECOMMENDED SITE REMEDIATION STANDARDS

Numerous factors must be considered when establishing site remediation standards. These include: (1) chemical classification with regard to carcinogenicity or other toxicant endpoints; (2) exposure scenarios based on land usage and total population impacted; and (3) permanent versus exposure control remedies.

In addition, remediation standards and approaches which sever responsible party long-term liability provide incentives to remediate contaminated sites. A recommendation for severing long-term liability is presented in Section VIII.

Chemical classification of carcinogenic compounds has been codified by several organizations including the USEPA, the National Toxicology Program and the International Agency for Research on Cancer.

It is assumed that there is some risk of cancer following exposure to any dose of a carcinogen, whereas for non-carcinogenic chemicals a dose which produces no adverse physiological effects can be established. Chemicals are presently classified as carcinogens by USEPA based on weight of scientific evidence according to the following scheme from the 1989 Risk Assessment guidance for Superfund:

Class A*	Carcinogenic to humans
Class B*	Probably carcinogenic to humans
Class C	Possibly carcinogenic to humans

* Likely or known carcinogens as described in "Draft

Revisions to Guidelines for Carcinogen Risk Assessment." USEPA/600/BP-92/003, August, 1994.

An "acceptable" or "de minimis" level of cancer risk of 1 x 10^{-6} has been selected for carcinogens by the USEPA. This is a policy decision which is fundamentally a consideration of the minimum risk which has been deemed worthy of society's attention. For non-carcinogenic effects, "acceptable" levels of exposure are determined based on a Hazard Index (USEPA, 1989) using an established reference dose (RfD).

Historically, many states have adopted the 10^{-6} concept to deal with water pollution, air pollution, fish and game consumption and soil contamination. There are exceptions to the 10^{-6} risk level for fish consumption and water quality criteria in some states. Recently, several states (California, Michigan, Texas, as well as New Jersey) have adopted a 10^{-5} risk management standard for selected environmental exposures, e.g., limited exposures to small populations. In addition, New Jersey incorporated the 10^{-6} cancer risk standard into its site transfer and reclamation acts such as the Environmental Cleanup and Recovery Act (which was superseded by ISRA), and 10^{-5} risk management standard for air pollution. The actual risk goals are encoded in NJSA 58:10B as of June, 1993.

Exposure assessment and evaluation is the key element in risk assessment because it leads to a dose or consumption estimate upon which the overall management decision will be based. Two factors to be considered when establishing soil and groundwater remediation standards are: 1) exposure scenarios based on land usage, e.g. residential, commercial, or industrial and 2) total population size affected. The exposure scenarios influence the cleanup standard required to achieve acceptable risk levels because of different modes and extent of human contact with potentially contaminated materials. For example, a site specific risk assessment could yield different soil and

groundwater contaminant level cleanup requirements (for the same acceptable risk level, e.g. 10^{-6}) for different land usages, i.e., residential versus industrial.

The size of the total affected population, in addition to the individual risk level, is important from a public health perspective. A risk level of 10^{-6} is of greater concern when it results in an additional 10 cancers in 70 years (for a large exposed population) than when it produces 0.1 cancers in 70 years (for a smaller exposed population). Hence, risk level alone is not sufficient to establish a cleanup standard.

Site remediation can be accomplished using several approaches including *permanent* (complete clean-up) *and/or exposure control remedies*. Permanent remedies are the most desirable. However, to apply the same risk level remediation requirements to both permanent and exposure control remedies provides little incentive to achieve a permanent, typically more costly remedy. For example, the economic differential between an exposure control remedy (i.e., capping) and a permanent remedy (i.e., removal by thermal desorption) may be so large that capping becomes the remedy of choice.

The proposed remediation criteria (Table 1) require an order-of-magnitude more stringent standard when exposure controls are employed. This concept has been incorporated in recognition of the fact that these controls may deteriorate and permanent remedies are most desirable. In addition, a maximum residual contaminant level must be achieved when exposure controls are employed. This is to ensure that in the event of a total failure of all exposure controls a minimum level of environmental and public health protection is maintained. This "safety-net" imposes a more stringent requirement than current regulations.

In order to assure that the risk values recommended by the Commission do not lead to an undesirable public health effect from an inadequate remediation, the Commission suggests that an

additional test that is based on the size of the population at risk for the specific site may be beneficial. The Commission suggests that this could be done by characterizing risk based upon the duration of time during which one adverse event might be expected to occur in the total population at risk. This characterization provides population-based, as well as individually-based risk goals. For this purpose, we suggest that any remedy that still results in one or more adverse events every 70 years, not withstanding the success in achieving the individual risk based standards, would not be acceptable. Hence, to achieve an acceptable remediation, more stringent individual risk based standards may be required.

It must be recognized that these risk levels are exposure scenario dependent. As a hypothetical example, a site with a resulting residual contamination in soil, eg., 40 mg contaminant/kg soil, may satisfy the risk management criteria (Acceptable Risk Levels: Table 1) for commercial/industrial property, but not satisfy the criteria for residential use.

VIII. LONG-TERM LIABILITY

While establishing cleanup standards for the remediation of industrial sites, the Commission also wishes to make known an existing substantial impediment to the cleanup of contaminated sites, namely liability into the indeterminate future. In the general case, State and Federal regulations require the responsible party to retain liability essentially in perpetuity. Even after the transfer of property, once or many times, the responsible party remains liable for any subsequent discovery of pollution or regulatory actions revising the cleanup standards. The new Industrial Site Recovery Act through PL 1993, C. 139 indicates that long-term liability is severed unless an order of magnitude decrease in remedial standards occurs and the original

remedy is no longer protective. Changing remedial targets and ongoing liability exposure provide disincentives for timely remediation.

In the opinion of the Commission, providing for the severing of liability is important in order to promote remediation and redevelopment of contaminated sites in New Jersey. The Commission has provided risk level incentives to drive the remediation process to a permanent remedy, as opposed to remedies that limit exposure. The Commission recommends that a further incentive to provide permanent remedies is to sever the liability of the responsible party if a cleanup is performed in accordance with the standards in effect at the time of the remediation.

Therefore, it is the recommendation of the Commission that if a site is permanently remediated and a surcharge is paid on that remediation (discussed below), future liability is completely and permanently severed. The severing of liability recommendation does not apply to exposure control remediation alternatives or if fraud or other illegal acts are committed in association with the investigation, remediation or severance of liability at that site.

The Commission goal is to recommend a flexible approach to site remediation and the severance of liability. In the opinion of the Commission, a site once remediated is not immune from further action if standards change. However, the Commission opines that retaining liability for remediation on the part of the initial responsible party in perpetuity is poor public policy and has contributed to the slow pace of environmental remediation in New Jersey. Once the property is permanently remediated, including payment of a surcharge, severance of liability should occur. Financing for potential subsequent remediation(s) would be provided by placing an appropriate surcharge (perhaps 1-5%) on all cleanups as they occur. All funds collected as a result of this surcharge can only be utilized to provide follow-up remedial

services for previously closed sites within the state.

IX. RECOMMENDED RISK ASSESSMENT APPROACHES

A three-tiered approach for development of soil remediation standards is necessary to provide adequate flexibility and to provide incentives to stimulate remediation. A three-tiered approach is presented that defines the approach to be used to develop soil specific site clean up criteria.

Tier 1, which is applicable for residential and non-residential land use is a restatement of the current NJDEP soil clean-up criteria using a risk management standard of 10^{-5}. Remediations conducted under these criteria are considered permanent and result in severed liability. In a general case a responsible party could screen the site against Tier 1 criteria, determine if remediation is necessary, and broadly evaluate remedial options. If greater precision or site specificity is desired the responsible party may wish to evaluate the site using Tier 2 criteria presented in Column III, Table 1. In Tier 2, site specificity in terms of physical characteristics and exposure scenarios are used to develop remediation criteria. Administrative delistings or remediations conducted under these criteria are considered permanent and result in severed liability. Site specific analysis minimizes the application of NJDEP default assumptions and reduces the uncertainty of the assessment. Sites remediated under Tiers 1 and 2 are eligible for surcharge reimbursement for the land use category under which they were remediated. However, these sites may require listing in the proposed central repository and/or a Declaration of Environmental Restriction (DER) if they are not remediated to residential criteria. Tier 3 builds on Tier 2 and provides alternative methods to derive site specific information. Development of Tier 2 and Tier 3 remediation criteria is supported by the use of site specific exposure data, physical

characterization of the site, environmental fate and transport data, bioavailability, uncertainty analyses and other scientifically defensible methodologies. If permanent remediation is not practical, exposure control remedies such as those described in Column IV and V of Table 1 may be evaluated. However, the following criteria must be satisfied prior to the application of Tier 3:(1) Costs for permanent remediation (Tiers 1 or 2) must exceed 110% of the costs for the Tier 3 option; (2) it can reasonably be demonstrated that under the projected exposure scenarios off-site receptors will not likely be impacted by on-site contaminants such that resultant risks exceed the values presented in Column IV, Table 1. In addition, Tier 3 remediations are not permanent and do not result in severance of liability. These sites must be listed in the proposed central repository and will require a DER. Tier 3 clean-ups may result in sites that are utilizable for non-residential, as well as selected residential, usage such that exposure to soils can be controlled. However, Tier 3 clean-ups, since they are not permanent, are not eligible for surcharge reimbursements.

GENERIC STANDARDS

Generic remediation standards are problematic for the soil-to-groundwater pathway. The reason for this is that this pathway is highly site-specific because transport of the contaminants to the aquifer is involved. The appropriate remediation standard should account for physical site dimensions, such as the location of contamination, rate and potential extent of contaminant release, distance to the water table, and the location of point-of-compliance for the receiving groundwater. These parameters are not needed for other exposure pathways where little or no transport is involved. It should also be pointed out that treatment pathways that involve transport are substantially more complicated to analyze than those that do not. In addition to utilizing traditional concepts of risk assessment, substantial

knowledge of site geology, environmental chemistry and contaminant transport is required.

SITE-SPECIFIC STANDARDS

In many cases, generic remediation standards may have a greater degree of uncertainty and be more stringent than necessary to protect groundwater quality. Therefore, the calculation of site-specific cleanup standards should be encouraged. When this is done, it must be carried out according to a decision tree that would be developed by the NJDEP with guidance from an advisory committee. Site-specific calculations may be limited to using only those parameters which have already been measured during the site assessment (extent of contamination, distance to groundwater, etc.) or may involve a more detailed assessment in which additional site parameters are determined. Key site parameters which are relevant for this pathway include soil pH, soil organic carbon, soil texture, soil moisture, dry bulk density, porosity, grain size analysis, soil permeability, direct measurements of the actual absorption of the contaminant to the soil, elevation of the water table, and the groundwater flow velocity.

It is not appropriate to treat all classes of chemicals (volatiles, semi-volatiles, ionizable organics, metals, base neutrals, etc.) in the same manner when the soil-to-groundwater pathway is considered, due to the wide range of mobilities exhibited by the contaminants in the soil. The mobility of a chemical can be approximated from its distribution coefficient (Kd). Mobile chemicals (low Kd) must be treated differently from immobile chemicals (high Kd) as discussed below. Certain chemicals will have mobilities that vary with pH.

It is important to recognize that the mobility of different classes of contaminants (e.g., volatiles, semi-volatiles, metals, etc.) in soils may differ by several orders of magnitude. This

variability will impact site specific standards when the transport to groundwater or vapor intrusion into buildings contribute significantly to the overall risk. Site specific factors that will impact transport in addition to contaminant class include contaminant leaching rates, soil characteristics (e.g., organic carbon content, moisture content, pH, particle size distribution) and infiltration (the physical and hydrogeologic dimensions of the contaminated site and its location relative to potential receptors media).

In addition to currently accepted EPA or other peer-reviewed methods, it is recommended that acceptable methods for gathering site specific data, transport models, estimation of transport parameters, and leaching rates be developed and validated by the NJDEP. These methods should be revised at regular intervals to incorporate the most accurate scientific data and measurement techniques as such information becomes available.

For protection of ground water, if a responsible party can demonstrate that (1) source material, i.e. free phase product, has been remediated, (2)chemicals of interest will degrade *in situ* to a concentration equal to or less than the current ground water quality standards within a reasonable period of time, perhaps 30 years, (3) will not adversely impact surface water receptors and (4) can demonstrate that ground water is not currently, or likely to be used as a source of potable water in the foreseeable future, it is suggested that active or proposed ground water remediation may be suspended and a formal ground water monitoring program initiated.

X. RECOMMENDATIONS

New Jersey has long been the national leader in industrial development, particularly in the chemical, petrochemical and pharmaceutical areas. However, New Jersey has a challenge. We now have to deal with the legacy of a past marked by widespread and often

unregulated use of chemicals that has contaminated literally tens of thousands of sites. This has led to New Jersey having the unenviable reputation of the largest number of sites on the federal Superfund list. But the Superfund legislation only covers 108 New Jersey sites. Most of the remaining thousands of known contaminated sites are relegated to the New Jersey ISRA law. It should be noted that a large number of industrial sites in the State of New Jersey may also require remediation. These sites have not yet been identified in the current scheme because regulatory triggers have not been activated.

This universe of sites is a major liability to New Jersey. It represents lost opportunity for commercial activity and jobs, particularly in economically disadvantaged areas of our State where the sites contribute substantially to issues of environmental inequality and injustice. The transaction costs for these sites for both the private sector and for government are substantial. Yet, despite years of attention and investment of public and private resources, the public perception is that little has changed and few sites have been remediated to the level of public use.

There are several impediments to remediation. In the opinion of the Commission the major impediments include:

1. The inability to achieve permanence and sever liability in a timely and cost effective manner.

2. The broad-based application of redundant conservative default assumptions.

3. Lack of performance-based regulatory objectives.

In order to overcome these impediments and to provide momentum and incentives for remediation of contaminated sites to full economic activity while at the same time maintaining public health and environmental goals, the Commission makes the following recommendations:

1) The Commission recommends using the best available scientific information and judgement to predict human health risk. The use of site specific data, rather than default assumptions is embraced by the Commission. Additionally, the Commission encourages the inclusion of scientifically defensible tools such as probablistic analysis, physiologically based/pharmacokinetic modeling, mechanistic toxicology, bioavailability (particularly from soil and sediment materials), and environmental fate and transport modeling to more accurately predict environmental risk.

2) The Commission recommends adoption of the principles put forth in Table 1. These principles provide incentives for permanent remediation and in the opinion of the Commission are protective of public health.

3) The Commission recommends adoption of a three-tiered approach to site remediation. Tier 1 is a restatement of the current NJDEP soil clean-up criteria using a risk management standard of 10^{-5}. Tier 2 combines site-specific physical characteristics and exposure information with the NJDEP default assumptions and is driven by

the risk management standard presented in column III (Residual Risk of Permanent Remedy) Table 1. Tier 1 and Tier 2 are considered by the Commission as permanent remedies for all land uses and result in severance of future liability. Tier 3 builds on Tier 2 and provides alternative methods to derive site specific clean-up criteria. Tier 3 is driven by the risk management standards presented in columns IV and V of Table 1. Severance of liability is not achieved using this option and a deed restriction is required.

4) The Commission strongly supports a risk management standard of 1 x 10^{-5} for Class A&B carcinogens for calculation of soil remediation standards. Cumulative risk for using specific pathway should not exceed 10^{-5}. Previous discussions have demonstrated that USEPA endorses and utilizes a flexible risk management structure. This flexible approach is supported by the National Oil and Hazardous Substances Pollution Contingency Plan (USEPA, 1990) risk management guidance values of 1 x 10^{-4} to 1 x 10^{-6}.

5) The Commission endorses the NJDEP policy of differential remediation criteria for residential and non-residential sites, consistent with Table 1.

6) The Commission recommends that if a site is permanently remediated and a surcharge paid on that remediation, future liability is completely and permanently severed. This recommendation should stimulate cleanup, insure complete and comprehensive remediation, and

provide a mechanism to protect human health and the environment.

7) The Commission recommends a surcharge of approximately one to five percent be assessed on all remediations both permanent and exposure control remedies initiated after the adoption of this report. The Commission recognizes that complete severance of long term liability may result in a small percentage of sites requiring re-remediation. The fees generated as a result of this surcharge shall be allocated to the Site Remediation Program within NJDEP for the sole purpose of readdressing previously remediated and closed sites.

8) The Commission recommends the development and validation of standard probabilistic approaches that can be used to better define risk.

9) The Commission recommends the establishment of a central repository of all known contaminated sites. The Commission further recommends that NJDEP establish and maintain a repository of Declarations of Environmental Restrictions (DER) for all sites not remediated to the residential clean-up criteria.

10) The Commission recommends the establishment of a Risk Assessment and Risk Management Science Advisory Board. This Board will advise the Commissioner of NJDEP in the efficient implementation of these recommendations and, if appropriate, evaluation of future risk assessment policy.

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